FDA Glossary
Compiled by: Yawtsong Lee
Last updated: September 16, 2016
[Top] [Laws & Regulations] [FDA Organization] [SFDA 国食药监]
食品和药物管理局局长 Robert M. Califf, MD

2-(4-hydroxyphenyl) acetamide	2 -（ 4 -羟 qiǎng 苯基）乙酰胺
AAA = abdominal aortic aneurysm	腹主动脉瘤
ABCs = airways，breathing，circulation	气道、呼吸、循环
ABI/ACS = Automated Broker Interface of the Automated Commercial System	自动商业系统下的自动经纪人界面(CBP 的自动商业系统)
ABMS = American Board of Medical Specialities	美国医学专业委员会
absorbable collagen sponge	吸收性胶原海绵
absorption rate constant/absorption rate coefficient Ka	吸收速率常数/吸收速率系数
abstinence symptoms	戒断症状
ACA = Patient Protection and Affordable Care Act; Obamacare	患者保护与平价医疗法案；奥巴马医改
Accelerated Approval regulation[1]	加速批准
access to medicine (ATM)	有药品可使用
ACCF = American College of Cardiology Foundation	美国心脏病学会基金会
accredited school	备案，立案学校
accuracy	准确度
Accutane, a brand of isotretinoin	异维(生素) A 酸;异维甲酸；保肤灵
ACE inhibitors = angiotensin converting enzyme inhibitors = ACEI	血管紧张素转化酶抑制剂
acetaminophen	扑热息痛；醋氨酚;对乙酰(xian)氨基酚
acid reflux	胃酸逆流
acidified food	酸化食品
ACO[2]: Accountable Care Organization	责任制医疗组织
ACR-20 improvement criteria (American College of Rheumatology)	美国风湿病学会类风湿关节炎改善的基本定义要求触痛关节数减少≥20% 肿胀关节数减少≥20% 加上以下五条中三条好转≥20%
acrylamide	丙烯酰胺
ACS[3] = Automated Commercial System	自动商业系统
ACTH = adrenocorticotropic hormone	促肾上腺皮质激素
Actimmune (Interferon gamma-1 b)[4]	干扰素微克— 1b
action letter	决定通知
active comparator	活性对照药物；活性药物对照组
active control = AC	阳性对照，活性对照；阳性药
active ingredient	有效成分
Active Substance Master File (ASMF)	欧洲药物主文件
Actos (pioglitazone)	艾可拓(匹格列酮)（日本武田制药公司 Takeda 的糖尿病药物）
acute myocardial infarction	急性心肌梗死
acute tibial fractures	急性胫骨骨折
Adalat XL[5] (Nifedipine Extended Release Tablets) by Bayer	硝苯地平缓释片；拜新同，心痛定、艾克地平
adalimumab (Humira)[6]	阿达木单抗

adaptive design	自适应设计
adaptive randomization	自适应随机
ADC[7] Antibody Drug Conjugates	抗体-药物偶联剂
ADE = adverse drug event	药物不良事件
adenosine	腺苷
adenoviral vectors	腺病毒载体
adequate and well-controlled studies	充分严格的对照研究
ADHD = Attention-deficit hyperactivity disorder	注意力缺陷多动障碍；注意力不足过动症；多动症
adhesion barrier product	防黏著产品
adjuvant	助剂；佐剂 auxiliary;
adjuvant therapy	佐药疗法，辅助疗法
ADL = activities of daily living	日常生活活动能力
ADME = absorption, distribution, metabolism, and excretion	药物的吸收、分布、代谢和排泄
administrative detention	行政扣留权
ADP Adenosine diphosphate[8]	腺嘌呤核甘二磷酸
ADR = adverse drug reaction	药物不良反应
adrenal cortex	肾上腺皮质
adrenal cortical hormone	肾上腺皮质激素
adrenal gland	肾上腺
adrenaline	肾上腺素
adrenoceptor	肾上腺受体
adrenocortical steroids	肾上腺皮质类固醇 me
adulterant	掺杂物
adulterated devices	掺假器械
AdvaMed = Advanced Medical Technology Association, medical technology (medical devices) trade association	先进医疗技术协会
adventitious infectious agents[9]	外来感染物
adverse drug reaction = ADR	药物不良反应
adverse effect	副作用
adverse event = AE	不良事件
adverse medical events	不良医学事件
adverse reaction (adverse event) [10]	药物不良反应
advisory	提醒
Advisory Committee on Medical Uses of Isotopes ACMUI	（美国）同位素医用咨询委员会
advocacy and support groups[11]	倡导和支持团体
AE = adverse event [12]	不良事件
AERS = Adverse Event Reporting System; now FDA Adverse Event Reporting System (FAERS)	不良事件报告系统;
aflatoxin	黄曲霉素；黄曲霉毒素
Aflibercept[13]	阿柏西普
african sleeping sickness	非洲昏睡病；非洲锥虫病
AFSSAPS = Agence Française de Sécurité Sanitaire des Produits de Santé	法国卫生安全和健康产品委员会；法国医疗产品安全局
after effect	后遗效应

agency	审理部门（指 FDA）
agonist	兴奋剂，激动剂，刺激物；竞争剂；拮抗剂
agonist, partial	部分激动药
AHA = American Heart Association	美国心脏病协会
AI = aromatase inhibitor	芳香酶抑制药
AIP = Application Integrity Policy[14] also Fraud Policy	防伪政策
air embolism	气体栓塞
air handling	空气处理
air lock	阻隔室
alanine aminotransferase = ALT[15]	丙氨酸氨基转移酶
ALARP region (as low as reasonably practicable)	尽合理可行程度的低
Alb = albumin	白蛋白
Alcohol and Tobacco Tax and Trade Bureau TTB	烟酒税务和贸易局
ALD = Approximate Lethal Dose	近似致死剂量
ALF = acute liver failure	急性肝功能衰竭
alkaline phosphatase[16] = ALP	碱性磷酸酶
alkylating agent	烷化剂
allele[17]	等位基因
allergenicity	致敏性
allergic shock	过敏性休克
allogeneic hematopoietic stem cell	异基因造血干细胞
allograft[18] transplantation	同种异体移植
allosteric AKT inhibitor	变构 Akt 抑制剂
ALOP = Appropriate Level of Protection	适当的保护水平
ALP = Alkaline phosphatase	碱性磷酸酶
alpha spending function	消耗函数
ALS = amyotrophic lateral sclerosis; Lou Gehrig's Disease	肌萎缩性脊髓侧索硬化；渐冻症
ALT = alanine aminotransferase	丙氨酸氨基转换酶
Alzheimer's Disease	老年痴呆症;阿尔茨海默氏病
Ambien (Zolpidem)	唑吡坦，赛诺菲研制安眠药
amino acid sequence	氨基酸序列
aminoglycoside antibiotics	氨基糖苷类抗生素
amphetamines	安菲他明；苯丙胺
amyotrophic lateral sclerosis = ALS	肌萎缩侧索硬化
ANA[19] = antinuclear antibodies	抗核抗体
analysis of covariance (ANCOVA)[20]	协变量分析
analysis sets	统计分析的数据集
analyte	待测物；分析物
Analyte specific reagents ASRs	分析物特异性试剂
anaphylaxis	过敏性反应；过敏休克
ANDA = abbreviated new drug application	简化新药申请
angina pectoris	心绞痛
angioplasty	血管成形术
angioplasty balloons	血管修复气囊
animal trial	动物试验
Annual Product Reviews (APR)	年度产品审查

anotia	无耳;又称“无耳畸形”
antibiotic prophylaxis	预防性抗生素使用
antibiotic resistance	抗生素抗性
antihistamine	抗组胺剂
Anti-Infective	抗感染药物
anti-inflammatory agents	抗炎药
anti-metabolites	抗代谢物；干扰代谢药物
antimicrobial resistance	耐药性
anti-neoplastic agent	抗肿瘤药
anti-nutrients	抗营养素
antipyretic，analgesics and anti-inflammatory drugs	解热镇痛抗炎药
anti-TNF agent; TNF blocker drugs	抗肿瘤坏死因子抑制剂
anti-TNF therapy	抗 TNF-α 治疗
AORN = Association of Perioperative Registered Nurses	美国围手术注册护士协会
aortic disease	主动脉疾病
aortic dissection	主动脉夹层
aortic stenosis	主动脉瓣狭窄
APEC	亚太经济合作组织
APHIS = Animal and Plant Health Inspection Service	动植物卫生检验局
APIC = Association of Professionals of Infection Control and Epidemiology	美国感染控制和流行病专业协会
APIs = active pharmaceutical ingredients / Drug Substance (bulk drug substances)	原料药 / 活性药用成分
aplastic anemia = pancytopenia	再生障碍性贫血
apoptotic	细胞凋亡的
Appropriate Level of Protection (ALOP)	适当的保护水平
approval	批准
approved drugs	已批准药物
approximate lethal dose = ALD	近似致死剂量
aprotinin	抑肽酶
AQSIQ = China's General Administration for Quality Supervision, Inspection and Quarantine	国家质量监督检验检疫总局；质检总局
arachidonic acid	花生四烯酸
Arava = leflunomide	爱若华（来氟米特）
archival copy	存档用副本
Area Under the Curve = AUC; area under the plasma concentration-time curve	药时曲线下面积/血药浓度-时间曲线下面积
ARGNB = antibiotic-resistant gram-negative bacilli	耐药革兰阴性杆菌
ARM[21]	组
arrhythmia	心律不齐
arsenicals = arsenic compounds	砷化合物
artery infusion	动脉滴注
artificial discs	人造脊椎
artificial heart valve	人工心脏瓣膜
artificial pancreas	人工胰脏
AS = ankylosing spondylitis	强直性脊柱炎

ASCO = American Society of Clinical Oncology	美国临床肿瘤学会
ASD = atrial septal defect	房间隔缺损
aseptic packaging	无菌包装
Asian Harmonization Working Party = AHWP	医疗器械法规亚洲协调会
aspartate aminotransferase = AST[22]	天门冬氨酸氨基转移酶
aspergillin	曲霉菌素
aspergillus flavus	黄曲霉
aspergillus ochraceus	赫曲霉
ASR = alternative summary reports	
assay	化验
assay constancy CA	检验恒定性
assay sensitiviy AS	检验灵敏度
assistant investigator = AI	助理研究者
assurance[23]	临床试验许可
AST = antimicrobial susceptibility test	药敏试验 = 抗菌药物敏感性试验
AST = aspartate aminotransferase	天门冬酸氨基转换酶
ASTM International (ASTM), originally known as the American Society for Testing and Materials	美国材料与试验协会
AstraZeneca	阿斯利康
as-treated analysis[24]	接受治疗分析
atopic dermatitis = AD	异位性皮炎
atorvastatin	阿托伐他汀非诺贝特片 cholesterol-lowering drug
ATP adenosine triphosphate	腺嘌呤核甘三磷酸
ATR = attenuated total reflection	衰减全反射法
attenuated total reflection = ATR	衰减全反射法
AUCss = area under the plasma concentration-time curve at steady-state	稳态血药浓度一时间曲线下面积
audit[25]	稽查
audit or inspection	稽查 / 视察
audit report	稽查报告
auditor	稽查员
autoimmune disease, AID	自身免疫病
autologous marrow stem cell transplantation	自体骨髓干细胞移植
autologous structural cells	自体结构细胞
Automated Broker Interface of the Automated Commercial System = ABI/ACS	自动商业系统下的自动经纪人界面
Automated Commercial System	自动商业系统
autonomic neuropathy	自主神经病变
autophosphorylation	自体磷酸化
availability of water	有效水分
Avandia (rosiglitazone)[26]	商品名：文迪雅；通用名：罗格列酮
Avastin = Bevacizumab	阿瓦斯丁；贝伐单抗；抗血管内皮生长因子单克隆嵌合抗体
Avelox (Moxifloxacin) by Bayer	莫西沙星；拜复乐
Aventis Pharma	安万特医药
average concentration/average concentration value = Cav	平均浓度
B. Cereus = Bacillus cereus	蜡状芽孢杆菌

B.atrophaeus	草芽孢杆菌黑色变种
bacilli	芽孢杆菌
Bacillus anthracis	炭疽芽胞杆菌
bacterial endospores	细菌芽孢
bacterial spore	细菌孢子
bar code	条(形)码
barbiturates	巴比妥盐
basal metabolic rate	基础代谢率
baseline	基线
basiliximab (trade name Simulect)	舒莱；治疗肾移植排斥药
batch production	批量生产；分批生产
batch release	批放行
Baycol（cerivastatin sodium）	拜斯亭;西立伐他汀；降血脂新药
Bayer Schering Pharma	拜耳先灵医药
BCG Boston Consulting Group	波士顿咨询公司
BCPNN (Bayesian Confidence Neural Network)	贝叶斯置信传播神经网络法
bench test	实验室试验
benefit	受益
benzodiazepine[27]	苯重氮基盐；苯二氮卓类抗焦虑药[28]
benzoic acid	安息香酸
Best Pharmaceuticals for Children Act 2002	《最好的儿童医药品法案》
beta-blocker	β-受体阻滞剂
Betaferon/ Betaseron[29] (Interferon Beta-1B) by Bayer	倍泰龙（干扰素 β-1b）
Bextra (valdecoxib)	伐地考昔(镇痛类药物)
BfARM = Bundesinstitut für Arzneimittel und Medizinprodukte	德国联邦药品和医疗器械管理局
BHC = Bayer HealthCare	拜耳医药保健有限公司
bias[30]	偏倚
bicohort study	双队列研究
bilirubin	胆红素
BIMO Bioresearch Monitoring Program[31]	生物研究监测(监督)项目
binding antibody	结合抗体
bioassay	生物检定
bioavailability (F)[32]	生物利用度
bioburden[33]	菌落总数
biochemical drugs	生化药品
biocides	生物杀灭剂；杀生物剂
biocompatibility[34]	生物相容性；
biodegradable	生物分解
bio-engineered, transgenic food	转基因食物
bioequivalence; bioequivalent i.e., performs in the same manner as the innovator drug	生物等效
biofilm[35]	细菌薄膜，生物膜
biologic[36]	生物制品
biological response modifiers BRM[37]	生物应答调节剂
biological therapeutic agents	生物治疗药剂
Biologics Price Competition and Innovation Act	《生物药价格竞争及创新法》

(BPCI Act）	
biomarker[38]	生物标志物
biometrics	生物统计；生物识别技术
bion stimulator	生物体刺激器
bionic knee	仿生膝关节
biopharma: biopharmaceutical products	生物药物产品
biopharmaceutic study[39]	
biosimilar[40]	生物仿制药，生物类似物，生物拟似物
bipolar	双极燥郁症
birth defect	出生缺陷，新生儿缺陷，先天缺陷
bisphosphonate	双磷酸盐
BiTEs (Bi-specific T-cell engagers) [41]	双特异性 T-细胞扣合
BLA = biologic license application	生物制品许可申请
blank control	空白对照
blend uniformity analysis[42]	混合均匀度分析
blind[43]	盲法
blind codes	编制盲底
blind review[44]	盲态审核
blinding method	盲法
blinding/ masking	盲法，设盲
blister packaging	泡罩包装；水泡眼
block	分段;层
block size	每段的长度
blocked randomization	区组随机
blood biochemistry	血生化
blood thinner	血液稀释药
blood urea nitrogen = BUN	尿素氮
Blue Book Memoranda[45], ODE	
BMP = bone morphogenetic proteins	骨形成蛋白
BMS（Bristol-Myers Squibb）	百时美施贵宝公司
BNF = biotechnology notification file	生物工程通报档案
Board Certified	专科认证
Board Certified rheumatologist	美国专科认证的风湿病学家
Body Mass Index = BMI	体质指数
bolus amounts	大剂量
bone grafting	骨移植
bone marrow suppression	骨髓抑制
bone turnover marker BTM	骨转换标志物
botulinum	肉毒杆菌
botulism	肉毒中毒
boxed warnings	黑框警告
brachytherapy seeds	放射性粒子源近距离治疗
bradycardia	心动过缓
Breakthrough Therapy Designation[46]	突破性疗法认定
breast implants, Polyurethane-coated	乳房植入物，聚亚安酯包囊;隆胸
bridging study[47]	桥接研究
bromfenac	溴 xi ù 酚酸

BSE = Bovine Spongiform Encephalopathy; mad cow disease	疯牛病;牛海绵状脑病
BsUFA (Biosimilar User Fee Act)	生物相似药品用户费用法
BU = Business Units	事业单位
bubble leak test	漏泄气泡测试
BUN = blood urea nitrogen	尿素氮
Bureau of Customs and Border Protection = CBP	美国海关与边境保护局
C. botulinum (proteolytic) = Clostridium botulinum	肉毒梭状芽孢杆菌（蛋白质水解型）
CABG = coronary artery bypass graft	冠状动脉旁路移植术；冠状动脉搭桥手术
CAD coronary artery disease	冠心病
CAGR = Compound Annual Growth Rate	年均复合增长率
calcium antagonists	钙拮抗剂
calcium channel blockers = CCB	钙道阻滞剂
calibration	校准；标定;校验
campylobacter	弯曲杆菌
campylobacter fetus	胚胎弯曲杆菌
campylobacter Jejuni	空肠弯杆菌
cannulas	套管
CAP = corrective action plan by drug sponsor	纠正行动计划
CAPA (Corrective & Preventive Action) system	纠正与预防措施系统
Capitation[48]	按人头付费
carc study, carcinogenecity study	致癌性研究
carcinogenic risk assessment, procedures for	致癌风险评估程序
cardiac arrhythmia	心律失常
Cardiac EP (electrophysiology)	心脏电力生理
cardiac resynchronization therapy	心脏再同步化治疗
Carelink Monitor	Carelink 监护
carryover effect	延滞效应
Carticel	组织工程软骨移植疗法
cartilage matrix	软骨基质
case history	病历
case record form = CRF	病例报告表/病例记录表
case report form	病例报告表
cash curve	现金曲线
cash trap	现金陷阱；现金套牢
categorical variable	分类变量
catheters	导管
cathlab bypass	导管室搭桥
Cav	平均浓度
CBC = complete blood count	血常规
CBE supplement “Changes Being Effected” supplement (FDA)	“正在进行修改”补充申请
CBP (U.S. Customs and Border Protection)	美国海关与边境保护局
CBRN chemical, biological, radiological and nuclear	化學，生物，輻射，核（威脅）
CCDS[49] = company core data sheet	公司核心数据表
CCFAC = Codex Committee on Food Additives and Contaminants	食品添加剂和污染物法典委员会
CCFH = Codex Committee on Food Hygiene	食品卫生法典委员会

CCT = controlled clinical trial	对照临床试验
CCyR[50] = complete cytogenetic response	细胞遗传学完全应答
CD = circular dichroism	圆二色谱
CDER = Center for Drug Evaluation & Research	药品审评和研究中心
CDR[51] Challenge-dechallenge-rechallenge	给药-停药- 再次给药
CDRH = Center for Devices and Radiological Health	器械与辐射保健中心
CE mark[52]	CE 认证标记
Celebrex (celecoxib)	西乐葆；COX－2 特异性抑制剂；塞来考昔
cell bank	细胞库
cell line	细胞株
censored data	删失数据
censoring	【统计】 -删截
Center for Biologics, Food and Drug Administration	生物制品中心
Center For Food Safety and Applied Nutrition = CFSAN	食品安全与应用营养中心
CEP = Certificate of Suitability to the Monograph of the European Pharmacopoeia; Certificate of Suitability to the EP	欧洲药典适应性证书
cephalosporins	头孢菌素类抗生素；
cerebellar atrophy	小脑萎缩
cerebellar malformation	小脑畸形;小脑发育畸形
cerebral infarction	脑梗塞
cerezyme	伊米苷酶,治疗罕见戈谢病(高雪氏病)
Certificate of Suitability to the EP (CEP)	欧洲药典适用性证书
cetuximab; Erbitux[53]	爱必妥
CFG = Certificate for Foreign Government	致外国政府证书
CFR = code of federal regulations	（美国）联邦法规；《美国联邦管理条例》
CFSAN = Center For Food Safety and Applied Nutrition	食品安全与应用营养中心
CFU = colony forming unit	菌落形成单位
cGMP's = current good manufacturing practice	现行生产质量管理规范
CGMS = continuous glucose monitoring system	动态血糖监测
Chagas disease (also called American trypanosomiasis)	美洲锥虫病；恰加斯病
Challenge-dechallenge-rechallenge = CDR	给药-停药- 再次给药
Change Control	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities, systems, equipment or processes
channeling bias[54]	渠道偏倚
CHB = customs house broker	报关行
chemotherapeutics in seafood (aquaculture drug residues)	药
CHF congestive heart failure	充血性心力衰竭
Child-Pugh	Child-Pugh 分级标准
Chi-square test/Chi-Square Goodness-of-Fit Test	卡方检验
chlorambucil	苯丁酸氮芥
CHMP = Committee for Medicinal Products for	人用药品委员会

Human Use	
cholestatic hepatitis	胆汁郁积型肝炎
Cholestyramine	考来烯胺
CHR = Complete hematologic response[55]	血液学完全应答
chromatography	色谱
chronic myelocytic leukemia, chronic granulocytic leukemia, CML, CGL	慢性粒细胞白血病
chronic obstructive pulmonary disease = COPD	慢性阻塞性肺疾病
Chronic Wasting Disease (CWD)	鹿慢性消耗性疾病
CIOMS = Council for International Organizations of Medical Sciences	国际医学科学组织委员会
circular dichroism[56] = CD	圆二色谱;
cirrhosis	肝硬化
cirrhosis of liver without mention of alcohol	未提及酒精的肝硬化
citation	传唤
CJD = Creutzfeld-Jakob disease	克–雅病
CL = clearance rate	清除率
claims	宣示
CLASS (Celecoxib Long-term Arthritis Safety Study) [57]	塞来考昔长期关节炎安全研究
class effect[58]	药物类效应
clearance rate = CL	清除率
cleft palate	腭裂
CLIA Clinical Laboratory Improvement Amendments	临床实验室改进修订案
clinical (human) data	临床数据
clinical endpoint	临床终点
clinical equipoise[59]	临床均势原则
clinical equivalence	临床等效应
clinical hold	临床试验暂停(通知)
clinical investigator[60]	临床研究者
Clinical Pharmacists	临床药师
Clinical Research Coordinator = CRC	临床研究协调者
clinical study	临床研究
Clinical Study Application = CSA	临床研究申请
clinical study report	临床试验的总结报告
clinical trial[61]	临床试验
clinical trial application = CTA	临床试验申请
clinical trial exemption = CTX	临床试验免责
clinical trial protocol = CTP	临床试验方案
Clinical Trial Report = CTR	临床试验报告
clinically inactive pituitary adenoma，CIPA	临床无活性垂体腺瘤
clinically significant results	有临床意义
Clopidogrel	氯吡格雷| 抑制血小板药物| 保栓通|
closed loop system	闭路系统
Clostridium botulinum	肉毒杆菌
Clostridium difficile[62]	艰难梭菌
Clostridium sporogenes	产孢梭菌;

Cmax	峰浓度
CMC = chemistry, manufacturing and control	化学、生产和控制
CMDh = Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human	相互认可和分散化规程合作组织
CME = continuing medical education	继续医学教育
CMS = Centers for Medicare & Medicaid Services	美国老年医疗保险基金中心与穷人医疗救助基金服务中心;美国医疗保险和医疗补助服务中心
CMS = Compliance Management System	(拜耳医药保健有限公司的)规范管理系统
CMS = Concerned Member States	有关成员国
CMV = Cytomegalovirus	巨细胞病毒
CNS abnormalities	中枢神经系统异常
CNV choroidal neovascularization	脉络膜新生血管
COA = certificate of analysis	分析证书
co-administered drug	合并用药； 与其它药物联合使用
coating	涂层
Codex Alimentarius	国际食品法典委员会
coexistent physiological state	并存生理状况
CofA = Certificate of Analysis	分析证明书
COGS = Cost of goods sold	主营业务成本
cohort[63]	队列
cohort studies	队列研究
co-investigator = CI	合作研究者
collagen	胶原
collagenase	胶原酶
colonization (of bacteria)	寄殖
colony- stimulating factors (CSF, GM-CSF, G-CSF)	集落刺激因子
colorectal cancer (CRC)	结直肠癌
combination product	复合产品
combination therapy	组合用药；联合用药治疗
commercial release	商业发行
community-acquired bacterial pneumonia	社区获得性细菌性肺炎
community-based clinical trial = CBCT[64]	基于社区的临床试验
co-morbid condition; co-morbidity	并存疾病；共患病；合并疾病
COMP= Committee for Orphan Medicinal Products	罕用药委员会
comparison	对照
compassionate use[65]	体恤使用
competitive inhibition	竞争性抑制
competitive labeling	优越标签
complementary and alternative therapy[66]	补充性和非传统治疗
complete response = CR	完全有效
complete response letter	完全答复函（FDA 不批准通知）
compliance	合规；遵守；对遵守法规情况的监管
compliance, patient	病人顺从性，依从性
composite variable	复合变量
compounding pharmacy	复方药房；调剂药房
compression test	压缩试验
computer modeling	原子计算机建模

computer-assisted trial design = CATD	计算机辅助试验设计
con meds = concomitant medications	联合用药
concentration = C	浓度
concurrent control	平行对照
condemnation	报废
cone beam CT, CBCT	锥形束 CT
confidence interval = CI	可信区间；置信区间
confidence level	置信水平
confidentiality regarding trial participants[67]	为试验参与者保密
confirmatory trial	验证性试验
confounding variable	混淆变量
congenital analgesia	先天无痛
congenital anomaly	先天性异常
congenital long QT syndrome	先天性长 QT 综合征
conjugate[68]	结合物
consent decree	服罪判决书；同意判决书
consignee	收货人
consistency test	一致性检验
contagious disease	接触传染病
context of vulnerability[69]	肿瘤的薄弱基因环境
Continuous Process Verification	An alternative approach to process validation in which manufacturing process performance is continuously monitored and evaluated
contract research organization = CRO	合同研究组织
contraindication[70]	禁忌；禁忌症
contrast agent	造影剂
control	对照
control group[71]	对照组
controlled clinical trials	临床对照实验
controlled substance	管控物质；管制药物
controlled substance scheduling	管控物质归类（调度）；
controlled trials[72]	对照试验
convulsion	惊厥;又叫抽风
coordinating committee	协调委员会
coordinating investigator = COI	协调研究者
CO-Oximeter, pulse	脉搏血氧计
COPD = chronic obstructive pulmonary disease	慢性阻塞性肺疾病
COPE = International Coalition of Pacing and Electrophysiology Organizations	国际整律与电生理学组织联盟
coronary artery disease	冠状动脉疾病
coronary heart disease = CHD	冠心病
coronary stents	血管支架
coronary vascular disease	冠状血管疾病
cortical stimulation	刺激皮层
corticosteroid	皮质甾类(的),皮质类固醇
cortisol; glucocorticosteroid	糖皮质激素
cost overrun	成本超支;费用超支

coumadin	苄丙酮香豆素钠[抗凝血药]；香豆定，3-(α-丙酮基苄基-4-羟基香豆素)
Covington and Burling, LLP limited liability partnership	科温顿•柏灵律师事务所
COX = cyclooxygenase	环氧化酶
COX-2 inhibitor	COX-2 抑制剂；e.g. 罗非昔布
coxachie virus	柯萨奇病毒
Cp = Process Capability[73]	工序能力
CPAP = Continuous Positive Airway Pressure	持续气道正压通气治疗(仪)；for sleep apnea;
CPDER = Center For Post-market Drug Evaluation and Research	上市后药品评价研究中心
CPG (Compliance Policy Guides) [74]	合规政策指南 (CPG)
CPGM Compliance Program Guidance Manuals[75]	合规项目指导手册
CPIC = Clinical Pharmacogenetics Implementation Consortium	临床药物基因组学实施联盟
Cpk = Process Capability Index[76]	工序能力指数
CPMP = Committee for Proprietary Medicinal Product	专卖医疗产品委员会
CPP = Critical Process Parameter	关键工序参数
CQA = critical quality attribute[77]	关键质量属性
cranial nerve	颅神经
CRC = colorectal cancer	结直肠癌
creatine[78] = Cr	肌酸
creatine kinase = CK	肌酸激酶
creatinine[79] = Cr/Crea	肌酐 gan
CRF = case report form	病例报告表
Crimean-Congo haemorrhagic fever virus	克里米亚 — 刚果出血热病毒
critical path[80]	关键路径
Crizotinib[81] (Xalkori)	克里唑蒂尼胶囊
CRM = continual reassessment method	连续重新评估方法
crossover design	交叉设计
cross-over study[82]	交叉研究
crossover therapy	交义治疗
CRP (C-reactive protein)[83]	血清 C-反应蛋白
CRPC[84] castration-resistant prostate cancer	去势抵抗性前列腺癌
cryptosporidium parvum	小球隐孢子虫
Css = steady-state concentration	稳态血药浓度；稳浓度
CT Computed tomography	计算机断层技术
CTCAE = Common Terminology Criteria for Adverse Events	不良事件的通用术语标准
CTD = Common Technical Document[85]	通用技术文件
CTLA4 (Cytotoxic T-Lymphocyte Antigen 4)	细胞毒性 T 淋巴细胞 4
CTP = Comprehensive Toxicological Profile	全面毒理学综述
Ctrough,ss	稳态谷值浓度
cure	痊愈
CV = cardiovascular event	心血管事件
CVMP = Committee for Medicinal Products for Veterinary Use	兽用药品委员会
CVTE = cardiovascular thrombolic events	心血管血栓事件

CyA = cyclosporin A	环孢素 A;
CYA = cyanocycline A	蓝环素 A
CYA[86] mentality (Cover Your Ass)	撇清责任；明哲保身的心态
cyanosis[87]	紫绀
cyclin-dependent kinase; CDK	週期素激酶
cyclophosphamide (Cytoxan)	环磷酰胺
Cyclospora cayetanesis	圆孢子球虫
cyclosporin A = CyA	环孢素 A;
CYP[88] = Cytochrome P450 (abbreviated P450, infrequently CYP450)	细胞色素 P450 酶
CYP 2D6 poor metabolizer	CYP 2D6 弱代谢者
CYP probe substrates	CYP 酶探针底物
cystic fibrosis = CF	囊肿性纤维化，亦称为囊性纤维化、囊肿性纤维变性或囊纤维变性；囊性纤维性变病
cytochrome	细胞色素
cytokine	细胞因子
cytokine storm	细胞因子风暴[89]
cytostatic	细胞抑制
cytotoxic drugs	细胞毒(性)药物
Dabigatran (Pradaxa)	达比加群酯； 新型口服抗凝药,由德国勃林格殷格翰公司开发
Daraprim（pyrimethamine）	乙胺嘧啶;息疟定
Data And Safety Monitoring Board = DSMB[90]	数据及安全监测委员会
data mining	数据挖掘
Data Monitoring Committees [91](DMCs) (also known as Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Committees (DSMCs))	数据监测委员会
Data Universal Numbering System[92] D-U-N-52 S (DUNS)	邓白氏编码
DBS = deep brain stimulation	脑深部电刺激技术
DDMAC = Division of Drug Marketing, Advertising, and Communications	药品销售、广告和信息处
de novo AML; de novo acute myeloid (myelogenic, myelogenous) leukemia	从头急性髓细胞白血病；初治急性髓性白血病
De novo pathways; De novo synthesis[93]	从头合成途径
de novo process[94]	(医疗器械)重新分类程序
DEA (Drug Enforcement Administration)	美国缉毒局
DEA = Drug Enforcement Administration	美国缉毒局
deamidation	脱酰胺
dear doctor letters	致医疗卫生人员的一封信
dear healthcare professional letter	致医疗保健人员信件
deep brain stimulators DBS; deep brain stimulation	深部脑刺激器；脑深部电刺激术
degenerative disc disease	椎间盘退变； 椎骨退化疾病
degenerative joint disease	退行性骨关节病
delayed effect	迟发反应
deli meats	熟肉制品
demographic risk factor	人口统计学风险因子
Dengue virus	登革病毒

denominator	分母
dental reconstruction	埋植型牙齿改建； 牙再生
denture cushions	假牙衬垫
Department of Health and Human Services	卫生与公众服务部
depression	抑郁(症)
depyrogenation	去除热原法；去热原
dermal fibroblast	真皮成纤维细胞
DES = Drug Eluting Stent; a.k.a "drug coated stents" or "medicated stents"	药物洗脱支架
descriptive statistical analysis	描述性统计分析
design space[95]	设计空间；
design validation – customer requirements	设计验证：确认符合客户需求
design verification – internal testing	设计确认：内部检验
destructive analysis	破坏性分析
detention	海关扣留
detergent	除垢剂
development value chain	开发价值链
developmental toxicity	发育毒性
deviation	偏差
deviation/ Out of Specification (OOS) procedures	偏差/OOS（不合格）程序
device listing	医疗器械产品登记
dexamethasone suppression test	地塞米松抑制试验
DF = degree of fluctuation[96]	波动度
DFS = disease free survival	无病生存期
DHR = device history record	医疗器械历史记录
DIA = Drug Information Association	药品信息协会
diabetic foot ulcer	糖尿病足溃疡
diabetic neuropathy	糖尿病神经病变
diagnostic imaging	诊断影像学；
diagnostic trials	诊断性试验
diagnostics	诊断药品
dialysis fluid	透析液
diazepam; valium	地西泮(安定)
dichotomies	二分类
diclofenac；Pennsaid	双氯芬酸
dietary supplement	膳食补充剂
Dietary Supplement Health and Education Act of 1994 (DSHEA)	膳食补充品健康与教育法
diethylene glycol = DEG	二甘醇
differentiated thyroid carcinoma,DTC	分化型甲状腺癌
Differentiation	差别化；与众不同；
Differentiation Marketing	差异化营销
Diffuse alveolar damage	弥漫性肺泡损伤
Digoxin	地高辛
DILI = drug-induced liver injury	药物性肝损伤
dioxin	二恶英
direct-to-consumer advertising = DTCA	直接面向患者作广告

discretionary good	可有可无的货物 Coffee is closer to a staple than a discretionary good
discretionary power	裁量权
discretionary rules	任意性的规则;自由裁量的;非强制性
disinfection	消毒
dissolution	[药理学]溶出度
distributor	经销商
Division of Clinical Trial Design and Analysis	临床试验部
DLT = dose-limiting toxicity[97]	剂量限制毒性
DMARD = disease-modifying antirheumatic drugs	病情缓解抗风湿药;
DMARD-naïve patients	未使用过 DMARD 的患者
DME diabetic macular edema	糖尿病黄斑水肿
DMF = drug master file	药物主文件[98]
DMSO = dimethyl sulfoxide	二甲亚砜
DNA modification	DNA 修饰作用
DNA sequence	DNA 序列
DOE[99] (design of experiments) or experimental design	实验设计
dolomite	白云石
dopamine	多巴胺
dosage form	剂型:包括片剂、胶囊剂、颗粒剂、干混悬剂、凝胶剂;
dosage regimen or dose rate	给药方案或给药速度
dose-ranging study[100]	剂量范围研究
dose-reaction relation	剂量一反应关系
dose-related adverse reactions	剂量相关的不良反应
double blinding	双盲
double dummy[101]	双模拟
double-blind study[102]	双盲研究
double-masked study: see double-blind study	双盲研究
double-strand DNA breaks，DSBs	DNA 双链断裂
DRGs = Diagnosis Related Group System	疾病诊断相关分组
drop out[103]	脱落
drop test	落震试验;跌落试验
Drug electronic supervision code (China)	药品电子监管码
drug eluting coronary stents	药物洗脱支架
drug interaction	药物相互作用
drug product	药物产品
drug response[104]	药物反应
drug substance	原料药
drug-drug interaction[105]	药物-药物相互作用
drug-food interaction	药物-食物的相互作用
drug-infusion systems	植入式药泵
DSC = Differential Scanning Calorimetry	差示扫描量热仪
DSHEA = Dietary Supplement Health and Education Act of 1994	膳食补充剂健康与教育法
DSI Division of Scientific Investigations	科學調查處
DSMB = Data Safety and Monitoring Board	数据安全及监控委员会

DSMICA = Division of Small Manufacturers, International and Consumer Assistance	小型制造商、国际及消费者协助分部[106]
DTA = differential thermal analysis	差热分析;差示热分析
Duchenne's muscular dystrophy[107] DMD	裘馨氏肌营养性萎缩症；进行性肌营养不良；杜興氏肌肉營養不良症；假肥大型肌营养不良症
Duexis	布洛芬法莫替丁片(复方药)
Dupuytren's contracture	杜普征氏掌挛缩
durable complete response	持续完全缓解
DWPE = detention without physical examination	自动扣留；不经查验即可扣留产品
dysmenorrhea	痛经
dystopia	肌肉张力障碍
E. coli	大肠杆菌;大肠埃希氏菌
EBIT = Earnings Before Interest and Tax	息税前利润
EBITDA= Earnings Before Interest, Taxes, Depreciation and Amortization	未计利息、税项、折旧及摊销前的利润
Ebola virus	埃博拉病毒
EEMEA	东欧、中东和非洲地区
EEPS = Electronic Entry Processing System	电子录入处理系统
effectiveness	疗效
efficacy	有效性测定
efficacy (Of a drug or treatment)	药效；药品疗效
EFPIA = European Federation of Pharmaceutical Industries and Associations	欧洲制药工业联合会
EFSA European Food Safety Authority	欧洲食品安全局
EIR = establishment inspection report by FDA	现场检查报告
electrical impulse	电脉冲
Electronic Batch Recording (EBR)	电子批记录
Electronic Data Capture = EDC	电子数据采集系统
Electronic Data Processing = EDP	电子数据处理
Electronic medical record (EMR)	电子医疗记录
Eli Lilly	礼来制药
eligibility criteria[108]	合格标准
elixir of sulfanilamide tragedy 1937[109]	1937 年磺胺酏（yi）剂(含二甘醇)事件
embolic stroke	栓塞性中风
EMEA = European Medical Evaluation Agency; European Agency for the Evaluation of Medicinal Products; European Medicines Agency	药物评价机构；欧洲医药品管理局
emergency envelope	应急信件
Empiric Bayesian Multiple Gamma-Poisson Shrinker	经验性贝氏法（伽玛泊松分布缩检法）
empirical	经验性
Enbrel, etanercept by Amgen Inc	依那西普（FDA 批准银屑病关节炎药物)□□□由 Immunex 公司研制。用于治疗类风湿性关节炎
encephalitis	脑炎
end-of-life care	临终关怀照护
endogenous system	内源性系统
endometriosis	子宫内膜异位
endoscopes	内诊镜

endotoxin	(细菌)内毒素
endpoint[110]	终点
endpoint criteria	终点指标
enlarged prostate	前列腺增生
enterobacter sakazakii	阪崎肠杆菌
enterococci	肠球菌
entrepreneurs	创业者
enzymatic browning	酶促褐变
enzyme replacement therapy	酶替代疗法
EPA = export application	出口药申请（申请出口不被批准在美国销售的药品）
ephedra	麻黄
epidemiology	流行病学
epiglottis	会厌
epilepsy	癫痫
epinephrine	肾上腺素
Epipen (Epinephrine Syringe)	肾上腺素注射剂
epitope[111]	抗原表位;抗原决定簇
EPO = erythropoietin	促红(细胞生成)素； 促红细胞生成素
equipment qualification	设备验证
equivalence	等效性
equivalence trial[112]	等效性试验
erectile dysfunction	勃起功能障碍
ERISA Employee Retirement Income Security Act of 1974	雇员退休收入保障法
ERK Extracellular signal-regulated kinase	细胞外信号调解蛋白激酶
erosion	糜烂
erythema multiforme	多形糜烂性红斑
erythropoietin	促血红细胞生长素
esomeprazole	埃索美拉唑
esophagus	食道
essential documentation	必须文件
Essential Medicines, WHO Model Lists of	《WHO 基本药物示范目录》
essential tremor	震颤
established name	确定的名称
establishment registration	(生产医疗器械的)厂家设施登记
Etanercept (trade name: Enbrel)	依那西普;治疗类风湿
ETASU (Elements To Assure Safe Use)	确保安全使用要素
ethanol	乙醇
ethics committee, akin to IRB Institutional Review Board	伦理委员会
ethyl alcohol，ethanol	乙醇
ethylene glycol	乙二醇；甘醇
etiology	病因学
EUA emergency use authorization[113]	緊急使用授權
Eudract = European Union Drug Regulating Authorities Clinical Trials = European Clinical Trial Database	欧盟临床试验数据库

EudraLex	欧盟医学产品法律法规集
Eudravigilance = European Union Drug Regulating Authorities Pharmacovigilance	欧盟药物警戒
excellent	显效
excessive daytime sleepiness	嗜睡
excimer laser	准分子激光
excipient[114]	赋形剂；药用辅料
exclusion criteria	病例排除标准
exculpatory evidence	辩护证据
exon-skipping compound	外显子跳越化合物
expanded access[115]	扩大使用
experimental drug	试验性药物
Expiration Date	使用有效期
explant	取出植入式医疗器械
exposure data	药品使用情况数据
express preemption	明示优先适用（law）
external auditory canals	外耳道
external low-pressure air device	外部低压气流装置
externalities	外部性
extrapolate	推断，推知，外推
extrusion	挤出
Fab fragment [116] = fragment antigen-binding	Fab 片段［免疫球蛋白上结合抗原的片段］
Fabry's disease[117]	酰基鞘氨醇已三糖苷脂沉积症；法布里病
facial dysmorphia	脸部畸形
FACP = Fellow[118] of the American College of Physicians	美国内科医师学会会员
factorial design	析因设计
factorial trial	析因试验
failure	无效，失败
Fair Packaging and Labeling Act (1966)	公平包装和标签法
False Claims Act	防制不实请求法
false negative	通常指漏报，也就是说，一个东西是没有被查出来的，但这是错误的(false)；假阴性
false positive	通常指误报，从字面上来看就是说，一个东西是被查出来了，但这是错误的(false)；假阳性
false therapeutic claims	错误的疗效声明
Famotidine	法莫替丁[组胺 H2 受体阻滞药]
FAS = Foreign Agricultural Service	美国农业部海外局
Fast track[119]	快速通道
FCA = Field Corrective Actions	产品纠正行动
FCE= Food Canning Establishment	所有罐头类食品企业都要有一个 FCE 号；和加工过程呈报号
FD& C Act	美国联邦食品、药品和化妆品法
FD&C Act of 1938 = Food, Drug & Cosmetic Act of 1938	食品药物及化妆品法
FDA	美药管局；美国食品及药物管理局
FDA Adverse Event Reporting System (FAERS) (formerly AERS)	FDA 不良事件报告系统
FDAAA = Food and Drug Administration	食品药品管理局修正案法

Amendments Act of 2007	
FDAMA 1997	《食品和药品管理局现代化法案》
FDASIA = Food and Drug Administration Safety and Innovation Act signed into law on July 9, 2012	FDA 安全和创新法
Federal Import Milk Act (1927)	牛奶制品进口法
Federal Register[120] FR	联邦公报；联邦文件记录册（总汇）
feedback inhibition	反馈抑制
fee-for-service	按项目收费制;付费服务
FERN = Food Emergency Response Network	食品紧急反应网络
fibromyalgia syndrome	纤维肌痛综合征
fibrosis	纤维化
field correction	产品纠正行动
field notification	产品通知
final point	终点
Final Report = FR	总结报告
finfish	鳍鱼 qi yu
FIP = Federation International Pharmaceutical	国际药学联合会
first dose effect = syndrome of first dose = first dose phenomenon	首剂效应;又称首剂综合征或首剂现象
first line therapy	一线治疗用的药品
Fish and Fishery Products Hazards and Controls Guidance	鱼类与渔产品危害与管制准则
fixed-dose procedure	固定剂量法
Flector Patch (diclofenac epolamine superficial patch)	Flector 补丁；双氯芬酸依泊胺<消炎镇痛药>
Flex-Foot	飞毛腿碳纤储能系列假脚
flexible endoscopes	软式内镜
flocculation	絮凝
fluoroquinolones	氟喹诺酮类药物 antibiotic
flurazepam; (marketed under the brand names Dalmane and Dalmadorm)	氟西泮(氟安定)
FMEA[121] = failure modes and effects analysis	故障模式影响分析;
FMECA = Failure Modes, Effects and Criticality Analysis	故障模式影响及危害性分析
focal glomerular sclerosis; also called Focal segmental glomerulosclerosis 局灶节段性肾小球硬化 FSGS; focal nodular glomerulosclerosis 局灶性结节性肾小球硬化	焦肾小球硬化
folate	叶酸盐
folding, protein	蛋白质摺叠
follow-on biologics = biosimilars	生物仿制药
follow-up	随诊；随访；追踪
food additives	食品添加剂
food adulteration	食品掺假
food alerts	食物警报
Food And Drug Administration = FDA	美国食品与药品管理局
food borne diseases	食源性疾病
Food Canning Establishment (FCE)	罐头类工厂；食品罐头企业
Food Chemical Codex	食品化学法典

Food Code	食品法典；食品代码
Food Contact Notifications = FCN	食品接触通告
Food Contact Substances = FCS	食品接触物质
food contaminant	食品污染物质
food technology	食品工艺学
food-borne diseases	食源性疾病
force multiplier	事半功倍效应；加力工具;倍增效应；
forced titration	强制滴定
Foreign Agricultural Service (USDA), FAS	农产品外销局
Formal Experimental Design[122]	
formulation, drug	药物配方
Fosamax	福善美；骨质疏松症的药物
Francisella tularensis	土拉杆菌
fraudulent intent	欺诈意图
fresh-cut produce	鲜切果蔬
FSCA = Field Safety Corrective Action	产品安全性纠正行动
FSIS = Food Safety and Inspection Service USDA	食品安全与检查局
FTA[123] = Fault Tree Analysis	故障树分析
FTE = full time employee	专职(雇员)
full analysis set[124] (FAS)	全分析集
full factorial design	全因子试验法
functional (molecular) imaging	功能性（分子）成像
fungus	真菌
furan	呋喃
Fusarium moniliforme	串珠镰孢霉
fusion systems	脊椎融合系统
G-6-PD	葡萄糖-6-磷酸脱氢酶
GACC = General Administration Of Customs Of The People's Republic Of China	中国海关总署
gamma glutamyltransferase[125] = GGT	γ-谷氨酰(xian)转移酶
GAMP = Good Automated Manufacture Practice	自动化生产质量管理规范
gangrene	坏疽
GAO	美国审计总署
GAPs = Good Agricultural Practices	良好农业规范
GAqPs = Good Aquacultural Practices	良好水产养殖规范
gas chromatography-Fourier transform infrared spectrometry = GC-FTIR	气相色谱一傅利叶红外联用
gas chromatography-mass spectrometry = GC-MS	气相色谱一质谱联用
Gastro/Uro Stimulators	胃肠/泌尿刺激系统
Gastroparesis	胃轻瘫
Gaucher's Disease	戈谢病(高雪氏病)
GC-FTIR = gas chromatography Fourier transform infrared	气相色谱一傅利叶红外联用
GC-MS = gas chromatography-mass spectrometry	气相色谱一质谱联用
GCP = Good Clinical Practice	药物临床试验质量管理规范
G-CSF (granulocyte-colony stimulating factor)[126]	粒细胞集落刺激因子
GD = Global Development	全球开发
GDD = Global Drug Discovery	全球发掘新药

GDNF Glial Cell Line-derived Neurotrophic Factor	胶质细胞源神经营养因子
GDUFA = Generic Drug User Fee Amendments of 2012	仿制药用户费用法
gene expression[127]	基因的表达
gene regulation[128]	基因调节
General Administration Of Customs Of The People's Republic Of China = GACC	中国海关总署
generic drug	仿制药品；非专利药品；通用名药；
generic name	非专利名称
Genetech	基因泰克
genetic toxicity tests	遗传毒性试验
genetic transcription	基因转录
genetic vulnerability	遗传脆弱性
genome sequencing	基因组测序
genotype[129]	基因型
genotypic resistance[130]	基因型耐药
Gentamicin	庆大霉素
gentamicin sulfate	硫酸庆大霉素
GFI = Guidance for Industry	行业指南；研制指导原则
GGP = Good Guidance Practices	
GHTF = Global Harmonization Task Force	全球医疗器械法规协调组织
GIDB leflunomide global integrated database	来氟米特全球综合数据库
GlaxoSmithKline (GSK)	葛兰素史克
glioma	胶质瘤
global assessment variable	全局评价变量；全局评价指标
GLP = Good Laboratory Practice/Good non-clinical laboratory practice	药物非临床研究质量管理规范
GLU = glucose	血糖
glucagon	高血糖素
Glucobay; Precose (acarbose tablets) by Bayer	阿卡波糖片,阿卡糖,阿克波什糖，拜唐苹（原名：拜糖平）拜唐平,宝易唐,希糖停
glucose = GLU	血糖
glucose monitor	血糖仪
glucose monitoring	血糖检测
glucose test strip	血糖测試條
glucose uptake	葡萄糖摄取
glycated or glycosylated hemoglobin	糖化血红蛋白
glycerin	丙三醇；甘油
glycosylation	糖基化
GMO = Genetically Modified Organisms	转基因生物
GMP = Good manufacturing practice	药品生产质量管理规范
Good Clinical Practice = GCP	药物临床试验质量管理规范
Good Laboratory Practice/Good non-clinical laboratory practice = GLP	药物非临床试验质量管理规范
good manufacturing practice = GMP	药品生产质量管理规范
good non-clinical laboratory practice = GLP	药物非临床研究质量管理规范
Good Review Practices	审核质量管理规范
GPF = general project frame	项目总框架

GPOs = group purchasing organizations	团体采购组织
GPS = Gamma-Poisson Shrinker	伽玛泊松分布缩检法
GRA = Global Regulatory Affairs	全球监管事务
gram-negative bacilli	革兰阴性杆菌
grandfathered drugs[131]	法规前批准药品
granularity[132] of data	數據的粒度
granulation tissue[133]	肉芽组织
GRAS = generally recognized as safe	公认安全
group sequential design	成组序贯设计
GSP = Good Supply Practice of Pharmaceutical Products, China's	药品经营质量管理规范
GTP good tissue practice	良好组织规范
Guanarito virus	瓜纳瑞托病毒
Guidance for Industry Botanical Drug Products	植物药研制指导原则
guiding catheter	导引导管
GWAS[134] genome-wide association study	全基因组关联分析
H. pylori	幽门螺杆菌
H2RA H2-Receptor Antagonists	H2-受体拮抗剂
HACCP [135]= Hazard Analysis and Critical Control Points	危害分析关键控制点
HAI = healthcare-associated infections	医院感染
hallucinogens	致幻剂
halophiles	嗜盐生物
handling and storage	储存及转运
Hantavirus	汉坦病毒
haplotype [136]	单元型
hazard function	危險函數；風險函數
HAZOP Hazard and operability studies	危害和可操作性分析
HbA1c[137] = hemoglobin A1c	糖化血红蛋白
HBV = Hepatitis B virus	乙型肝炎病毒
HCC = hepatic cell carcinoma	肝细胞癌
HCV = hepatitis C virus	丙型肝炎病毒
HDE = humanitarian device exemption	人道主义器械豁免
health claims	健康功效宣称
health economic evaluation = HEV	健康经济学评价
health science analysts	卫生科学分析员
heart failure	心衰
hemachromatosis	血色病
hematopoietic growth factors	造血因子
hematopoietic system[138]	造血系统
hemodialyzers	血液透析器
hemoglobin A	血红蛋白 A
hemolytic anemia	溶血性贫血
hemophilia	血友病
hemopoietic cell	造血 or 生血细胞
hemostatic	止血
Hendra virus	亨德拉病毒
HEOR = Health Economics and Outcomes Research	卫生经济学结果研究

Heparin	肝素钠
hepatic cell carcinoma = HCC	肝细胞癌
hepatic coma	肝昏迷
hepatic necrosis	肝坏死
hepatitis C	丙型肝炎
hepatocellular injury	肝细胞损伤
hepatocellular jaundice	肝细胞性黄疸
hepatology	肝脏病学
hepatotoxicity	肝毒性
Herceptin[139] (Trastuzumab) by Genentech	赫赛汀(曲妥珠单抗冻干粉针剂)
hERG = human ether-à-go-go-related gene	potassium channel enhancer
Herniated discs	椎间盘突出
Herpes simiae virus (B virus)	猴疱疹病毒(B 病毒)
Herxheimers reaction	赫氏反应
Hgb = hemoglobin	血红蛋白
HHS = Department of Health and Human Services	美国卫生与公众服务部
HICPAC = Healthcare Infection Control Practices Advisory Committee	美国医院感染控制顾问委员会
HIF Hypoxia Inducible Factor	缺氧诱导因子
HIF Prolyl Hydroxylase Inhibitor	缺氧诱导因子（HIF）脯氨酰羟化酶（PH）抑制剂
High intensity focused ultrasound HIFU	高强度聚焦超声；高能超声聚焦刀
Hip Replacement	髋关节置换
HIPAA = Health Insurance Portability and Accountability Act	健康保险流通与责任法案
Hippocratic Oath	希波克拉底誓约
HIS, Hospital Information System	医院信息管理系统
histamine	组胺
HMO = health maintenance organizations	健康维持组织
HMPC = Committee on Herbal Medicinal Products	草药委员会
holder	DMF 持有者
homologous	同源;同源性
HOPE (Heart Outcomes Prevention Evaluation) Study	心脏后果预防评估
Hospice	临终关怀
Hospital Epidemiology	医院流行病学
HPAI highly pathogenic avian influenza	高致病性禽流感
HPLC = High-performance liquid chromatography [140];also sometimes referred to as high-pressure liquid chromatography	高效液相色谱；高效液相层析;制备色谱
HQA Hospital Quality Alliance	医院质量联合体
HR Hazard ratio	风险比
HSA = Health Saving Account	健康储蓄账户保险
HSE	健康、安全、环境
HSV = herpes simplex virus	单纯疱疹病毒
HTA = health technology assessment	卫生技术评估
HTN = Hypertension	高血压
hub	轮毂

HUDs = humanitarian use devices	人道主义使用器械
human papillomavirus	人类乳头瘤病毒
humanized monoclonal antibody	人源化的单克隆抗体
Humira (adalimumab)	阿达木单抗
HVAC = heating, ventilating, and air conditioning	暖通空调
HWA486A Product code of leflunomide	来氟米特产品码
hydralazine	肼屈嗪
Hydrocephalus	脑水肿,又称脑积水或水脑症
hydroxyapatite[141]	羟基磷灰石
hydroxychloroquine	羟氯喹 qiang3 lü kui2
hygroscopic	吸湿
hyperglycemia	高血糖症
hyperlipidemia	高脂血症
hyperostosis; hyperosteogenesis; osteophyte	骨质增生
hypoglycemia	低血糖
hypokalemia	低血钾症
hypomagnesaemia	低镁血症
hypoproteinemia	低(白)蛋白血症
hypothesis	假说
hypothesis test	假设检验
hypoxia imaging	心肌乏氧显像
Hy's rule[142]	Hy's 定律
IACP International Academy of Compounding Pharmacists	国际复方药剂师学会
IB = Investigator's brochure	研究者手册
IBS = irritable bowel syndrome	过敏性肠综合症
ibuprofen	布洛芬
ICD implanted cardiac device	植入式心脏器械
ICD International Classification of Diseases (of the World Health Organization)	国际疾病分类
ICDs = Implantable cardioverter defibrillators	植入型心律转复除颤器；植入式心脏除颤器（ICDs）
ICH = International Conference of Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use)	国际协调会议；人用药品注册技术要求国际协调会
ICH Q10	药品质量体系简
ICH Q9	质量风险管理
IDE = Investigational Device Exemptions	研究器械豁免
identity	真伪；鉴别；特性
idiopathic pulmonary fibrosis，IPF	特发性肺纤维化
idiosyncratic reaction	特异质反应
IDMC = Independent Data Monitoring Committees	独立数据监测委员会
IFN = interferon	干扰素
IFPMA = International Federation of Pharmaceutical. Manufacturers & Associations	国际制药工业协会联合会
IFU	使用说明书
IHNs = Integrated Health Networks	整合医疗保健网
IL-2 = Interleukin-2	白细胞介素 2

ILD (Interstitial lung disease), also known as diffuse parenchymal lung disease (DPLD)	肺间质病变
imaging agents	显像剂
immediate release drug	速释剂
immune complex[143]	免疫复合物
immune modulation	免疫调节
immune suppression	免疫抑制
immuno-compromised	免疫受损
immunogenicity[144]	致免疫力；免疫发生；免疫原性
immunoglobulin[145] = Ig	免疫球蛋白；
immunomodulatory agent (e.g. leflunomide)	免疫调节剂
immunosuppressive cytokine therapy	免疫抑制细胞因子疗法
implantable defibrillators	植入式除颤器
implantable diagnostic recorders	植入式诊断性纪录系统
implantable drug pumps	植入式药泵
implantable gastric stimulation systems	植入式胃部刺激系统
implantable neurostimulation systems	植入式脊柱刺激系统
implantable sacral stimulation systems	植入式腰椎刺激系统
implantable shunts	神经外科用脑积水分流管
implantable stent grafts	植入式血管内支架
implantable stents	植入式支架
implied preemption	默示优先适用（law）
IMPs = investigational medicinal products	临床试验研究用药
in utero stem cell transplantation	造血干细胞宫内移植
in vitro diagnostic = IVD[146]	体外诊断（产品）
in vitro reagent	体外试剂
inclusion criteria	病例入选标准
inclusion criteria	入选标准
inclusion/exclusion criteria[147]	入选/排除标准
incremental exposure	食品中递增摄入量
incubation period/latency period	潜伏期
IND = Investigational New Drug	临床研究新药
INDA = investigational new drug application	NDA 前申报阶段
indacaterol[148]	茚达特罗;长效吸入 β（2）-激动剂支气管扩张剂 bronchodilator
indemnity insurance	赔偿保险
Independent Data Monitoring = IDM	独立数据监察
Independent Data Monitoring Committee = IDMC	独立数据监察委员会
independent ethics committee = IEC	独立伦理委员会
indications	适应症
Indomethacin	吲哚美辛
Industrial chemicals	工业化学品
inert surface	惰性表面
Infant Formula Act of 1980	婴儿配方食品法
infectious agents	感染原
Infectious Disease	传染病
Inflammatory pain	炎症痛
infliximab (trade name: Remicade)	英夫利昔单抗；抗类风湿药;是一种特异性阻断

	肿瘤坏死因子 α（TNF-α）的人鼠嵌合型单克隆抗体
Influenza virus type A (subtype H2, H5 and H7)	甲型流行性感冒病毒(H2、H5 及 H7 亚型)
informed consent	知情同意
informed consent form/informed consent document = ICF	知情同意书
INFOSAN = International Food Safety Authorities Network	国际食品安全当局网络
infrared = IR	红外吸收光谱
infusion pump	输液泵
infusion sets	输液器具
INH = isoniazid	异烟肼（抗结核药）
inhibitory cytokine	抑制性细胞因子
initial meeting	启动会议
in-licensing agreement	产品授权合伙协议
INN = international nonproprietary name	国际非专有名称
innovator drug	原创新药
in-process testing	过程测试
INR[149] = international normalized ratio	国际标准化比率
inspection	视察 / 检查
Institute of Medicine = IOM	医学研究所（National Academy of Sciences 国家科学学院下设）
institution inspection	机构检查
Institutional Review Board = IRB[150]	机构审查委员会（伦理委员会）
Insulin delivery	胰岛素注入
insulin pumps	胰岛素泵
intended population	适应人群
intended use	预期用途
intention-to-treat analysis[151] = ITT analysis	（治疗）意向性分析;
Interactive Voice Response System = IVRS	互动语音应答系统
Inter-American Institute For Co-Operation On Agriculture	泛美农业科学学会
interferon	干扰素
interim analysis[152]	期中分析
interleukin-6	白细胞介素-6
intermediate	中间体
International Classification of Diseases, Ninth Revision (ICD-9)	国际疾病分类第 9 版
International Conference of Harmonization = ICH	人用药品注册技术要求国际技术协调会，国际协调会议
Internet-based information technology system	基于互联网的信息交换系统
interstitial cystitis IC	间质性膀胱炎
intervention[153].	干预措施
intestinal flora	肠道菌群
Intravenous infusion and blood transfusion	静脉输液与输血
invasive fungal infection	入侵性霉菌感染
inversion [154]	倒位（遗传学）
investigational new drug = IND	临床研究新药
investigational product[155]	试验用药品 ；试验用药物

investigator	研究者(临床试验)
investigator's brochure = IB	研究者手册
iodophor germicidal detergent solution	碘伏消毒液
IPAB = Independent Payment Advisory Board[156],	
IPC = in-process control	(生产过程)中间过程控制
IPO = Initial Public Offerings	首次公开募股
IQM = Integrated Quality Management	集成质量管理
IR	红外吸收光谱
IRB = Institutional Review Board	机构审查委员会
IRR = Internal Rate of Return	内部收益率
Irradiation	辐射
ischemic/viable myocardial tissues	缺血/存活心肌
Ishikawa Diagram; Cause and Effect Diagram	因果图
Isolator System	无菌隔离舱
Isoniazid = INH	异烟肼
isopropyl alcohol	2-丙醇；异丙醇
isotope tracer	同位素示踪物
isotype antibody	同种型抗体
ISPE = International Society for Pharmaceutical Engineering	国际制药工程协会
ISS（Integrated Summary of Safety）	安全性综合总结
ITT dataset, now known as FAS (full analysis set)	全分析集
IV push	静脉推注
IVD device = In vitro diagnostic device	体外诊断设备
IVDMIA = In Vitro Diagnostic Multivariate Index Assay	体外诊断多变量索引化验
IVIVC (In Vitro-In Vivo Correlation)[157]	制剂的体内外相关性
Janus kinase JAK[158]	JAK 激酶
Japanese encephalitis virus	日本脑炎病毒
JCAHO = Joint Commission on the Accreditation of Healthcare Organizations	保健组织认证联合委员会
JECFA = Joint FAO/WHO Expert Committee on Food Additives	联合国粮农组织和世界卫生组织下的食品添加剂联合专家委员会
JEMRA, the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment	微生物危险性评估专家联合会议
JIFSAN = Joint Institute of Food Safety and Applied Nutrition	食品安全和应用营养联合研究所
Johnson & Johnson	美国强生
joint tenderness (as opposed to pain)	关节压痛
JPMA = Japan Pharmaceutical Manufacturers Association	日本制药工业协会
Junin virus	鸠宁病毒
Ka = absorption rate constant	吸收速率常数
Ketek, also known as Telithromycin	肯立克,又称泰利霉素
ketoconazole	酮康唑
kits	器械包
Kogenate FS (Antihemophilic Factor) by Bayer	拜科奇；重组因子Ⅷ；抗血友病注射剂，重组人凝血Ⅷ因子

KOL key opinion leaders	关键意见领袖
Konjac	魔芋
Koseisho	日本厚生省
KPI：key performance indicator	企业关键绩效指标
Kyasanur Forest disease virus	基萨诺尔森林病病毒
labeled amount	标示量
labels and labeling[159]	药品标签(Label、Labeling）。药品标签分为两种,一种称为“Label”,是指直接接 触药品的内容器、外容器或外包装上的书写物、印刷物、绘制物；另一种称为“Labeling”， 包括所有的 Label、药品说明书和其他附加于药品的书写物、印刷物、绘制物
LACF = low acid canned foods	低酸罐装食品
lactobacilli	乳酸菌
Laetrile, Amygdalin, Vitamin B17	杏素，苦杏仁苷
Lamictal®[160] (la-MIK-tal) XR™ (lamotrigine) Extended-Release Tablets	利必通 24 小时缓释片，成分拉莫三嗪片
laminar flow hood	层流净化罩
larynx	喉
laser pointer	激光笔
LASIK[161] = laser-assisted in situ keratomileusis	准分子激光原位角膜磨镶术；激光辅助角膜重塑术
Lassa virus	拉沙病毒
last observation carry forward = LOCF[162]	结转；最接近一次观察数据的结转；末次观测值结转法
late stent thrombosis	药物支架晚期血栓
LCC = Low Cost Country	低成本国家
LC - MS	液相色谱一质谱联用
LD = longest diameter	(肿瘤）最大直径
LD10[163] = lethal-dose 10%	亚致死剂量
LD50	半数致死剂量
lead arsenate	砷酸铅
lead compound	先导化合物
leak testing	检漏
Leflunomide: to treat rheumatoid arthritis	来氟米特
Lenalidomide/Revlimid[164]	来那度胺
lethal dose,50% = LD50	半数致死剂量
leukemia	白血病
levofloxacin hydrochloride Levaquin	盐酸左氧氟沙星
LFTs = Liver function tests	肝功能检测
librium; chlordiazepoxide	利眠宁;氯氮卓
licensed pharmacist	执业药师
licensing authorities	发证机构
life expectancy	预期寿命
ligand	配体
Limit of Quantitation[165] = LOQ	定量限
Line Extension	延伸性新药（新适应证、新剂型和现有药物的新复方）

line extensions, product	产品线扩展
lipase	脂肪
lipid oxydation	油脂氧化
lipid virus	亲脂病毒
lipitor	立普妥（阿托伐他汀钙）降胆固醇药物
Liquid Chromatography Mass Spectrometry = LC-MS	液-质联用
Listeria	李斯特菌
Listeria monocytogenes	单核细胞增多性李斯特菌；单核细胞增生李斯特菌
listeriosis	李氏杆菌病
liver assist devices	肝脏辅助装置
liver biopsy	肝组织活检
liver death; hepatic death	肝性死亡
Livor mortis	尸斑[166]
loading dose	负荷剂量;是指首剂增大的剂量，能使血药浓度迅速达到所希望的 Css
Local Quality Representative (LQR)	地方质量代表
LOCF = last observation carried forward	末次观察值结转法
log rank test	时序检验
logic check	逻辑检查
Long QT syndrome = LQTS [167]	先天性长 QT 综合征
Longitudinal patient reported surveillance program	纵向患者报告监督项目
LOQ = Limit of Quantitation	定量限
loss to follow-up	失访
low molecular weight heparin = LMWH	低分子肝素
LPN = licensed practical nurse	持证职业护士
L-Tryptophan	L-色氨酸
lumbar tapered fusion device	腰椎椎间融合器
lumen	管腔
lymphocyte antigen	淋巴细胞抗原
lymphoma	淋巴瘤
M. bovis	牛分枝杆菌
M. tuberculosis	结核分枝杆菌
MAA = Marketing Authorization Application （EMA）	上市许可申请；营销授权申请 （欧洲药管局术语）
MAB = monoclonal antibody	单抗；单克隆抗体
MACE = major adverse cardiovascular events	主要不良心脏事件
Machupo virus	马秋波病毒
macroconstituent	常量成分
Macronutrients	常量营养元素
MAD = Multiple Ascending Dose studies	渐增型多药剂量浓度测试
MAH = Marketing Authorization Holder	销售许可持有者；药品上市许可持有人;持证商；
maladministration	用药不当
malignant hyperthermia = MH	恶性高热症
malpractice claims	医疗过失索赔
managed care	管理式医疗

manipulated autologous structural cells (MAS cells)	经处理自体结构细胞
MAO (monoamine oxidase) inhibitor	单胺氧化酶抑制剂
Marburg virus	马尔堡病毒
market basket survey.	市场菜篮子调查
market clearance	市场准入批准件
market exclusivity[168]= exclusive marketing rights granted by the FDA	市场独占；市场专卖权
market withdrawal	撤市
marketing	营销
marketing approval/ authorization = MA	上市许可证
marketing authorization application = MAA	上市许可申请
masked	设盲
Mass Spectrometry = MS	质谱
mass-balance	质量平衡
MAST = Minimal Access Spinal Technologies	微创脊柱技术；微创脊椎修复技术
matched pair	匹配配对
matrix protein	基质蛋白
maximum tolerated dose = MTD	最大耐受剂量
MCO = Managed Care Organization	医疗管理组织
MCyR = major cytogenetic response	细胞遗传学应答
MDFP medical device fellowship program	
MDMA = Medical Device Manufacturers Association	医疗器械生产商协会
MDR = Medical Device Reporting	医疗器械强制报告系统
MDUFA III = Medical Device User Fee	医疗器械用户费用法
MDUFMA = Medical Device User Fee and Modernization Act	医疗器械用户费用和现代化法
MDUFSA = Medical Device User Fee Stabilization Act	医疗器械用户费用稳定法
mean absorption time = MAT	(药物在体内的)平均吸收时间
mean disintegration time = MDIT	(药物在体内的)平均崩解时间
mean dissolution time = MDT	(药物在体内的)平均释放时间
mean residence time = MRT	(药物在体内的)平均滞留时间
measurable disease	可测量病变
measurable lesion	可测量病灶
mechanism of action	作用机制
MedDRA[169] = Medical Dictionary for Regulatory Activities	国际医学用语词典；药事管理的标准医学术语集
Medicaid	贫困医疗补偿制度；贫困医保；
medical device[170]	医疗器械
Medical Device Amendments	医疗器械修正案》1976
medical governance	医药治理
Medicare	老年医疗保险制度；联邦老年医保
medication guides (for patients)	用药指南
Medicines Control Agency = MCA	英国药品监督局
MedSun = Medical Product Surveillance Network	
Medtronic	美敦力
MedWatch[171]	医药警戒项目；

MEK (methyl ethyl ketone)	甲乙酮；丁酮
Melamine	三聚氰胺
melanoma	黑色素瘤
Meloxicam	美洛昔康；(左旋)苯丙氨酸氮芥[消炎镇痛药]
MEMS = Micro Electromechanical System	微电子机械系统
Meniere's Disease	美尼尔氏病
meningitis	脑膜炎
meningitis B	乙型脑炎
meningococcal meningitis	脑膜炎球菌性脑膜炎
Merck Sharp & Dohme = MSD, part of Merck	美国默沙东(Merck）制药
mesothelin[172]	间皮素
messenger RNA	信使核糖核酸
meta-analysis[173]	荟萃分析；元分析
metabolite	代謝物
metabolizer	代谢改变剂
metabolomics	代谢组学
metastatic	转移
metformin	甲福明；二甲双胍 gua；抗糖尿病药
metformin hydrochloride	盐酸二甲双胍 （gua）
methadone	美沙酮[镇痛药]
Methicillin	甲氧西林
Methotrexate, MTX treatment of cancer, autoimmune diseases, ectopic pregnancy, and for the induction of medical abortions	甲氨喋呤；应用于白血病、淋巴瘤、头颈部肿瘤、骨肉瘤以及多种自身免疫性疾病最为广泛的一种抗代谢药物
methylation of DNA	DNA 的甲基化
methylmercury	甲基汞；二甲基汞
methylphenidates	哌醋甲酯
methylprednisolone	甲强龙，甲基强的龙醋酸盐，甲基强的松龙
metronidazole MNZ	甲硝唑（灭滴灵）
MGPS = Multi-Item Gamma Poisson Shrinker	多项伽玛泊松分布缩检法
MHLW = Ministry of Health，Labour and Welfare	(日本)厚生劳动省
MHRA = Medicines and Healthcare products Regulatory Agency	英国药品和健康产品管理局
MI = myocardial infarction	心肌梗死；心肌梗塞
MIC = Minimum Inhibitory Concentration	最低抑菌浓度
microbial flora	微生物菌群
microcephaly	小头畸形
micrococci	微球菌
microneedles	微针
microphthalmia	小眼球
micropumps	微型泵
midodrine	甲氧胺福林
minimal effective dose	最小有作用剂量
minimally invasive spinal surgery	微创脊椎手术
minimum inhibitory concentration = MIC	最低抑菌浓度
Ministry of Health and Welfare = MHW	日本卫生福利部
minocycline	米诺环素

Mirena (Levonorgestrel Intrauterine System)	曼月乐（左炔诺孕酮宫内节育器）
MIS: minimally invasive surgery	微创外科手术
misbranding	标签误导；错误标签；冒牌
miscoding	编码错误
Misoprostol	迷索前列醇
missing value	缺失值
mixed effect model	混合效应模式
MLD = minimal lethal dose	最小致死剂量
MoA = mechanism of action[174]	作用机制;作用机理
MoA = memorandum of agreement[175]	协定备忘录
modem	调制解调器
modernization	与时具进
modified atmosphere packaging (MAP)	气调包装
modified fats	改良脂肪
modified release capsule	缓释胶囊
molecular characterization	分子特征
molecular diagnostics	分子诊断学
molecular pathogenesis	致病的分子机制
molecular targeted therapy	分子靶向治疗
monitor[176]	监查员
monitoring plan	监查计划
monitoring report	监查报告
monkeypox virus	猴痘病毒
monoclonal antibody	单克隆抗体
movement disorders	运动障碍
MQSA = mammography quality standards act	乳房 X 线造影术质量标准法
MR = moderate response	好转
MRA = Agreement on Mutual Recognition	相互承认协定
MRCT Multi-Regional Clinical Trials	多中心临床试验
MRI = magnetic resonance imaging	磁共振成像
MRSA = Methicillin resistant staphylococcus aureus	抗甲氧西林金黄色葡萄球菌
MRT = mean residence time	平均滞留时间
MS = multiple sclerosis	多发性硬化症
MS-MS	质谱-质谱联用
MTD = maximal tolerance dose	最大耐受剂量
MTX = methotrexate	甲氨喋呤 jia an die ling
MUCOSA trial [177](Misoprostol Ulcer Complications Outcomes Safety Assessment)	迷索前列醇溃疡并发症结果安全评估
multicenter trial	多中心试验
multi-drug resistance	多药物抗药性
multi-kinase inhibitor	多激酶抑制剂
multi-omics	多组学
multiple arm trials	多治疗组的试验
multiple sclerosis = MS	多发性硬化症
Multiple-system atrophy (MSA)	多系统萎缩
mutual recognition procedure (EU)	相互承认程序

mycobacteria	分枝杆菌
mycobacterium tuberculosis (multidrug-resistant)	结核分枝杆菌(耐多药)
Mycophenolate mofetil (MMF)[178]	吗替麦考酚酯
mycotoxins	真菌毒素;霉菌毒素;
myelin	髓鞘
myocardial electrode	心肌电极
myocardial ischemia	心肌供血不足，缺血
NABP = National Association of Boards of Pharmacy	美国全国药房理事会协会
NAI = No Action Indicated	无需采取行动
Naproxen Caps	萘普生胶囊
NARA = National Archives and Records Administration	国家档案和记录管理局
narcotics	麻醉药品
narrative summary	记叙体概要
National Formulary	国家处方集
National Institutes of Health = NIH	美国国家卫生研究所
Natural History Study[179]	自然发展研究
NCE = new chemical entity	新化合物
NCI CTEP = National Cancer Institute Cancer Therapy Evaluation Program	国家癌症研究所的癌症治疗评价计划
NDA new drug application[180]	新药申请
neoplasm	肿瘤
Neupogen(filgrastim)	优保津注射剂；非格司亭
neural interface	神经接口系统
neurodegenerative treatments	神经退行性疾病
neurogenic pain	神经源性痛
neurological stimulators	神经刺激系统
neuromodulation[181]	神经调控
neuromodulator	神经调质
neuron	神经元
neuropathic pain	神经病理性疼痛
neurotransmitter	神经递质
neutralizing antibody	中和抗体
neutropenia	嗜中性白血球减少症
new chemical entity = NCE	新化学实体
new drug application = NDA[182]	新药申请
Nexavar = sorafenib tosylate	多吉美（索拉非尼片）用于治疗晚期肾细胞癌
NF = national formulary	美国国家处方集
NICE[183] National Institute for Health and Clinical Excellence	英国国家卫生与临床优化研究所
NIH = National Institute Of Health	美国全国卫生研究所
Nipah virus	尼巴病毒
nitrazepam[184]	硝西泮(硝基安定)
nitrite	亚硝酸盐
NLEA = Nutrition Labeling and Education Act	营养标识与教育法
NME = new molecular entity	新分子实体
NMR spectroscopy = nuclear magnetic resonance	核磁共振谱

NOAA / NMFS	国家大洋大气管理局 / 国家海洋渔业局
NOAEL = no observed adverse effect level[185]	未见不良反应剂量水平
nociceptive pain	伤害性疼痛
nociceptor	伤害性感受器
NOH = neurogenic orthostatic hypotension	神经源性体位性(直立性)低血压;
nominal significance level	名义显著性水平
Non-CF Bronchiectasis	非囊性纤维化支气管扩张
non-dose-related adverse reactions	剂量不相关的不良反应
non-enzymatic browning	非酶褐变
non-inferiority margin[186]	非劣效性界值
non-inferiority trial[187]	非劣效性试验
non-lipid virus	亲水病毒
non-parametric statistics	非参数统计方法
non-significant-risk (NSR)	非显著的危险性
norepinephrine	去甲肾上腺素
norovirus	诺瓦克病毒
Northera by Chelsea = Droxidopa	屈昔多巴 (抗震颤麻痹药)
nosocomial[188] infections	医院感染
notification	备案
notified body NB	认证机构
Novartis Pharmaceuticals	诺华制药有限公司
NPV: net present value	净现值
NPWT = negative pressure wound therapy	伤口负压治疗技术
NSAID = non-steroidal anti-inflammatory drug	非甾(zai)体抗炎药; 非甾类消炎药
NSE (non-substantially equivalent) letter	非实质等同性质的信函
nucleotide	核苷酸
null hypothesis[189]	无效假设; 原假设, 或称为零假设; 通常将研究者想要收集证据予以反对的假设
numerator	分子
nurse practitioner NP	护理医生
Nutrition Labeling and Education Act of 1990	营养标签和教育法
OA = osteoarthritis	骨性关节炎
OAI = official action indicated	需采取监管行动
OASIS = Operational and Administrative System for Import Support	OASIS 进口支援操作行政系统
OBD = optimal biological dose[190]	最佳生物学剂量
obedience	依从性
obsessive -compulsive disorder	强迫症
obturators	封闭器
OCI = Office of Criminal Investigations	犯罪调查办公室
OCTGT = Office of Cellular Tissue and Gene Therapies	FDA 细胞组织和基因治疗办公室
ODE (Office of Drug Evaluation)	FDA 药物评估办公室
ODE = organ drug exclusivity	器官用药市场独占权
ODS = Office of Dietary Supplements of NIH	膳食补充剂办公室
ODS = Office of Drug Safety	药品安全办公室
Office of Surveillance and Epidemiology = OSE	药品监测和流行病学办公室
official = pharmacopeial = compendial	药典的; 法定的; 官方的

official compendium	法定药典（主要指 USP、 NF）
off-label use[191]	标示外使用;超标签使用
off-target adverse events[192]	脱靶效应
off-the-shelf components	成品元件; Commercial-Off-The-Shelf，商用现货
OH = orthostatic hypotension	体位性低血压
oligonucleotide	寡核苷酸
OLT = orthotopic liver transplant	原位肝移植
Omapro = Omacetaxine mepesuccinate	高三尖杉酯，申请用于慢性骨髓性白血病 Chronic myeloid leukemia
ombudsman	申诉专员;
Omeprazole	奥美拉唑[抗溃疡病药]
Omsk haemorrhagic fever virus	鄂木斯克出血热病毒
oncolytic agent	溶瘤细胞剂
OND = Office of New Drugs	新药办公室
OOS = out of specification	超标;不合格
open-blinding/open-label	非盲
open-cell foam	开孔泡沫
open-chest Surgery Devices	开胸手术器材
open-heart surgery perfusion and stabilization systems	开胸手术灌注及稳定系统
open-label	非盲
open-label trial[193]	开放标记试验; 开放性试验
operating margin	营业利润率
opioid	阿片样物质
opportunistic infections	机会性感染
OPQ (Office of Pharmaceutical Quality) [194]	藥品質量辦公室
optical sensor	光学传感器
optional titration	随意滴定;选择滴定
ORA = Office of Regulatory Affairs	监管事务办公室
oral solid dosage forms	口服固体剂型
Orange Book[195]	橙皮书
ORD = optical rotatory dispersion	旋光光谱
orexin	食欲素
organ replacements and assists	替代; 辅助装置
organic impairment	器质性损害
organoleptic quality	感官; 口感
original medical record	原始医疗记录
orphan drugs[196]	罕见病用药,孤儿药
ORR（Objective Response Rate）	客观缓解率
orthopedic implants	整形外科植入
orthopedic surgery	矫形外科学
orthopedics	骨科
orthostatic hypotensionm = OH	体位性低血压
orthotics	矫形器
OS = Overall survival	总生存率
OSA = obstructive sleep apnea	阻塞性睡眠呼吸暂停

OSHA = Occupational Safety And Health Act [administration]	职业安全与卫生条例[管理局]
osmophilic yeasts	耐高渗透酵母
osteoblast	成骨细胞
osteoclast	破骨细胞
osteomyelitis	骨髓炎
OTC drug = over-the-counter drug	非处方药
OTC Switch, Rx-to-OTC Switch	处方药改列成药
ototoxicity	耳毒性
outcome	结果
outcome assessment	结果指标评价
outcome measurement	结果指标
outlier	离群值
outpatient	门诊
outreach	沟通
overactive bladder	膀胱过度活动症
oxazepam; (marketed under brand names Alepam, Murelax, Oxascand, Serax, Serepax, Seresta, Sobril)	奥沙西泮(去甲羟基安定，舒宁)
oxidative stress	氧化应激
oxycodone	羟可酮
P/E Ratio	市盈率
P4P = Pay for performance systems	按绩效付费制度
pacemakers	心脏起博器
package insert (for physicians) = label	药品说明书；“专业标签”(“Professional labeling”)、“处方信息”(“Prescribing information”);包装插页
package seal	包装密封
PACS = Picture Archiving Communication System	医学影像存档和通讯系统
palivizumab (Synagis)	帕利珠单抗
palliative care unit	临终照顾病房
palpitation	心悸
pancytopenia	全血细胞减少症
paracetamol	对乙酰 xian 氨基酚（又称扑热息痛，或醋氨酚）
paragraph IV certification[197] CFR 314.94(a)(12)(i)(A)(4)	第四段认证;第四段专利挑战
parallel group design	平行组设计
parameter estimation	参数估计
parametric release [198]	参数放行
parametric statistics	参数统计方法
Paraplegia	截瘫
parasympathetic nervous system (autonomic nervous system)	副交感神經系統（ 自律神經系統）
parathyroid hormone deficiency	甲状旁腺激素缺乏
Parkinsonism	震颤麻痹
partial (onset) seizure[199]	局部发作型癫痫症；部分发作
partial response = PR	部分缓解
PAS （Prior Approval Supplement）	先前批准补充申请

Pasteurization	巴氏灭菌法
PAT = Process Analytical Technology[200]	过程分析技术
patent term restoration[201]	专利期补偿
pathogen	病原体
pathogenic cocci	病原性球菌
patient file	病人档案
patient global; pt global	病人总体评价
patient history	病历
payroll tax[202]	每个雇主都要支付给国税局“工资税”，目前是雇员总收入（就是没有扣除任何费用之前的总薪水）的 7.65%
PBM = Pharmacy Benefits Manager	药房福利管理公司
Pbo or Pla = placebo	安慰剂
PCB = polychlorinated biphenyls	多氯联苯同类物
PCI Percutaneous coronary intervention[203]	经皮冠状动脉介入
PCR assays; polymerase chain reaction	PCR 检测；聚合酶链反应
PD = pharmacodynamics[204]	药物效应动力学；简称药效学
PDA = Parenteral Drug Association	注射用药物协会
PDA = Photo Diode Array	光电二极管阵列
PDCO = Pediatric Committee	小儿科委员会
PDGFR (Platelet Derived Growth Factor Receptor)	血小板衍生生长因子受体
PDP product development protocol[205]	产品发展协议
PDUFA = Prescription Drug User Fee Act 1992	美国处方药申报者付费法；
peer review[206]	专家评审
Pegasys (peginterferon alfa-2a)	派罗欣；聚乙二醇干扰素 α-2a 注射液（to treat hepatitis）
pegylated enzyme	聚乙二醇修饰酶
pegylated interferon alfa-2a	聚乙二醇化干扰素 alfa-2a
PEGylation is the process of covalent attachment of polyethylene glycol (PEG) polymer chains to another molecule, normally a drug or therapeutic protein	聚乙二醇化
penicillamine	青霉胺
penicillium verrucosum	疣孢青霉
Pennsaid	双氯芬酸钠商品名；外用的类固醇消炎药- 被用于治疗膝关节骨性关节炎
peptides	肽
per protocol (PP) analysis[207]	符合方案分析
per protocol set (PPS)[208]	符合方案集
perchlorate	高氯酸
percutaneous transluminal balloon angioplasty	经皮腔内气囊血管成形术
perforated ulcer	穿孔性溃疡
perfusion	灌注
perioperative antibiotic prophylaxis	围手术期抗菌药物的使用；
peripheral disease	周边血管疾病
personalized medicine	个体化给药
pesticide residue	农药残留
PET = positron emission tomography	正电子发射断层显像

PFGE[209]（pulsed field gel electrophoresis）	脉冲场凝胶电泳
Pfizer	辉瑞制药
PFO = patent foramen ovale	卵圆孔未闭
PFS = progression-free survival	无疾病进展存活率
PGE = patient global evaluation	病人总体评价
PGt pharmacogenetics	药物遗传学；
PGx pharmacogenetic	药物遗传学；遗传药理学
PHA = preliminary hazards analysis	预先(初步)危险(危害源)分析
pharmaceutical equivalence	药剂等效性
pharmaceutics	药剂学
Pharmacia	法玛西亚
pharmacodynamics[210] = PD	药物效应动力学；简称药效学
pharmacoepidemiology	药物流行病学
pharmacogenetics[211] (PGt)	药物遗传学
Pharmacogenomics[212] (PGx)	药物基因组学
pharmacokinetics = PK[213]	药代动力学；简称药动学
pharmacology	药理学
Pharmacovigilance[214]	药物警戒
pharmacy	配药学
PharMetrics Integrated Database[215]	PharMetrics 索赔数据库
pharynx	咽
phenergan	非那根；异丙嗪
Phenol	苯酚
phenotype[216]	表型
phenotypic resistance[217]	表型耐药
phenylbutazone; butazolidin	保泰松
PHF = potentially hazardous food	有潜在危险的食品
phlebotomy	静脉放血术
phocomelus[218] phocomelia	短肢畸形；海豹肢畸胎；海豹肢畸形
phosphorylation	磷酸化
photodynamic therapy PDT[219]	光动力疗法
PhRMA = Pharmaceutical Research and Manufacturers of America	美国药物研究与生产商协会
PI3K Phosphoinositide 3-kinase	磷脂酰肌醇激酶-3
PIB dosage form: powder in bottle	
PIC = Pharmaceutical Inspection Convention	药品检查协定
PIC/S Pharmaceutical Inspection Cooperation Scheme	药物检查合作计划
pillar procedure, struts	小柱软腭植入术
pipeline assets	开发中产品
PK = pharmacokinetics[220]	药物代谢动力学；药动学，药代动力学
placebo	安慰剂
placebo control	安慰剂对照
placebo controlled study	安慰剂对照研究
placebo effect	安慰剂效应
plant sterol esters	植物甾醇酯
Plant sterols; phytosterols	植物甾醇

PLAS = performance-linked access systems[221]	动态链接系统
plasma concentrations	血药浓度
plasma protein binding[222]	血浆蛋白结合
Plavix (Clopidogrel bisulfate)	波立维；氯吡格雷硫酸氢盐
pleiotropy[223]	基因多效性，多向性
pleural effusion	胸腔积液
Plt = platelet	血小板
PMA = pre-market application	上市前申请
PMA = premarket approval	上市前许可；销售前批准
PMCs = post marketing commitments[224]	承诺药品上市后的继续研究
PMDA Pharmaceuticals and Medical Devices Agency, Japan	医药品医疗器械综合机构；医薬品医療機器総合機構
PMDRA = Post Marketing Drug Risk Assessment	上市后药品风险评估(办公室)
PMHx = past medical history	既往病史
PMN = premarket notification	销售前通知
PMS = premenstrual syndrome	经前综合症
POC (proof-of-concept) Clinical Trials[225]	概念证明
POC = point-of-care testing	床旁分析
polio	脊髓灰质炎
polymer wafer	高分子缓释片
polymorphism	多态性
polymyxin	多粘菌素
polypharmacy[226]	复方用药， 混杂给药， 过多给药
polyphenol oxidase	多酚氧化酶
polytomies	多分类
pooled analysis = PA	荟萃分析
poor motor coordination	运动协调困难
pop pk, population pk	群体药动学评价
PoS = point-of-sales	销售点
post hoc analysis	事后分析
postmarket surveillance	上市后监督
post-marketing surveillance; postmarket safety surveillance	销售（上市）后监督
Post-translational modification，PTM	蛋白质的翻译后修饰
postural hypotension	直立性低血压
potency	效价
power[227]	把握度；检验效能
Pp = Process Performance[228]	工序绩效
Ppk = Process Performance Index[229]	工序绩效指数
PPO = preferred provider organizations	优先提供者组织
PPS[230] = Per-Protocol Set	符合方案集
PQR (Product Quality Review)	产品质量审查
PR = partial response	部分缓解
practolol affair	心得宁事件
Prasterone for VV atrophy tx	普拉睾酮
Prasugrel[231] 商品名: Effient	普拉格雷
prazoxin	α1 受体阻滞剂 哌唑嗪 pai zuo qin

PREA = the Pediatric Research Equity Act	儿科研究公平法
Preamble[232] (Federal Register)	序言
precautions	慎用；注意事项
precision	精密度
preclinical (animal) data	临床前(动物实验)数据
preclinical study	临床前研究
predicate device = legally marketed device that is not subject to premarket approval (PMA)	和已合法在市场上销售的且不需要做 PMA“销售前批准”的
predicate rule[233]	已发布的 FDA 法规
prednisolone	泼尼松龙
prednisone	泼尼松，泼尼松等皮质激素是广泛应用的免疫抑制剂
premarket notification (510(k)s)	上市前通知
pre-marketing surveillance	销售（上市）前监督
prescription drug	处方药
preservation	保藏
prevalence	患病率
prevention trials	预防试验
primary (coronary) event	原位病变
primary endpoint	主要终点
primary mode of action = PMOA[234]	首要作用模式
primary pulmonary hypertension PPH	原发性肺动脉高血压
primary variable	主要变量
principal investigator = PI	主要研究者
Principles of Qualification	确认（验证）原则
prion	朊病毒
Prior Notice (PN) System Interface	提前通报系统界面
Priority Review designation[235]	优先审查
private label	贴牌生产
private label distributor	商标发行商
PRO patient-reported outcome	患者报告结局
probability	概率
probe substrate	探针底物
procedure trays	操作盘
process controls	工艺控制
pro-drug [236] prodrug	前体药物,**也称前药、药物前体、前驅藥物等**
product codes	产品的号码
product differentiation	产品差异化，产品特色化
product license = PL	产品许可证
product life cycle (PLC)[237]	产品生命周期
progesterone	黄体酮，孕酮
prognosis	预后；归转
progression-free survival = PFS	无进展生存
progressive disease = PD	病情进展
proof of principle study[238]	原理循证研究
propensity score	倾向性评分
propionic acid	丙酸

propranolol	普萘洛尔
proprietary name	专有名称
Propulsid (Cisapride)	西沙必利；优尼比利，西沙普雷特，优尼必利，西沙比利，普瑞博斯，西沙比得
prostaglandin	前列腺素
prosthetics	假肢
protease inhibitor	蛋白酶抑制剂
proteasome	蛋白酶体
protein purification	蛋白纯化
proteomics	蛋白质组学
prothrombin	凝血酶原；凝血原
protocol[239]	临床试验方案
protocol amendment	方案补正
prototype design	原型设计
protozoa	原生动物门
proven acceptable range = PAR[240]	确定可接受范围
Prozac	百忧解
PSA = prostate specific antigen	前列腺特异抗原
PsA = psoriatic arthritis	银屑病关节炎
pseudomonas	假单孢菌；假单胞杆菌
PSMA prostate specific membrane antigen	前列腺特异性膜抗原
psoriasis	银屑病；俗称牛皮癣
psoriatic arthritis PsA	银屑病关节炎
PSUR[241] = periodic safety update report	定期安全性更新报告
psychotropics	精神药品
psychrotrophic pathogens	嗜冷致病菌
Pt global = patient global assessment	患者总体评价
PTBA = percutaneous transluminal balloon angioplasty	经皮腔内气囊血管成形术
PTC = product technical complaints	药品技术投诉
PTCA = percutaneous transluminal coronary angioplasty	经皮冠状动脉成形术
PTM = post-translational modifications	蛋白质的翻译后修饰
PTS = probability of technical success	技术成功概率
public goods	公共产品
pulmonary arterial hypertension, PAH	肺动脉高压
pulmonary embolism	肺栓塞
Pure Food and Drug Act of 1906	1906 年颁布的《纯净食品和药品法》
PVAR = preliminary variation assessment report	初步改变评估报告
pyloric sphincter	幽门括约肌
pylorus	幽门
pyrimidine synthesis inhibitor (e.g. leflunomide)	嘧啶合成抑制剂
QSIT = Quality Systems Inspection Technique	美国 FDA 质量体系检查指南
QSR = Quality Systems Regulation	质量体系规章
QT interval[242]	QT 间期
QTc = Corrected QT	校正 QT 间期
QTPP: quality target product profile[243]	目标药品的质量概况
qualification system for licensed pharmacist	执业药师资格准入制度

qualification vs validation[244]	确认 vs 验证
qualification, Design (DQ)[245]	设计确认
qualification, Installation (IQ)[246]	安装确认
qualification, Operational (OQ)[247]	运行确认
qualification, Performance (PQ)[248]	性能确认
qualification, Process[249]	工艺确认
qualification: Prequalification	预确认
qualified health claims	有保留的健康宣称
qualified person = QP[250]	药品放行责任人；质量受权人
quality assurance = QA	质量保证
quality assurance unit = QAU	质量保证部门
quality by design，QbD	“药品的质量是设计出来的”即“质量源于设计”
quality control = QC	质量控制
quality management systems	质量管理体系
quality of life trials or supportive care trials	生存质量试验
quality risk management = QRM	质量风险管理
quantitative modeling	定量模型
quantitative risk assessment	量化风险评估
quaternary ammonium compound	季铵化合物
query list, query form	应用疑问表
qui tam[251]	公益代位诉讼制度；要求取得罚金的起诉(此项罚金由起诉人与官方均分)
qui tam relators, or whistleblowers	代位诉讼告发人
R & D portfolio	R&D 项目组合
RA = refractory anemia	难治性贫血
RA = regulatory authorities	监督管理部门
RA = rheumatoid arthritis	类风湿关节炎
rabies or rabies-related virus	狂犬病毒或类狂犬病毒
radiation emitting products	辐射电子产品
radiation-emitting electronic products	有辐射电子产品
radio frequency ablation RFA	射频消融
radioactive pharmaceuticals	放射性药品
radiological health	辐射卫生
radionuclides (radioactive contaminants)	放射性核素
radiopharmaceutical	放射性药物
radiosurgery	放射线手术
randomization	随机化
randomized trial	随机化试验
randomized, double blinded clinical trial	随机双盲对照研究
range check	范围检查
rating scale	量表
raw agricultural commodities	未加工农产品
RBA = risk benefit assessment	利弊衡量
RCC = renal cell carcinoma	肾细胞癌
RCHSA = Radiation Control for Health and Safety Act	1968《控制辐射、确保健康安全法》
RCT = randomized clinical trials	随机临床试验

RCT = randomized controlled trial	随机对照试验
RDE: remote data entry	远距数据输入
ready-to-eat foods	即食食品
reagents	试剂
real-time continuous glucose monitoring systems	实时连续血糖检测系统
recall	召回；强制回收
RECIST[252] = Response Evaluation Criteria in Solid Tumors	实体瘤的疗效评价标准
recombinant protein	重组蛋白
reconditioning	整改；货物重整理；货物重包装
recycled plastics	可循环利用塑料制品
reference listed drug (RLD)[253]	原研药；参比药物 as opposed to generics;
reference product	参比制剂
reference samples[254] for analysis	对照样品
refractory solid tumors	难治性实体瘤
Regorafenib[255]	瑞格非尼，商品名为 Stivarga
regression	消退
regulatory methodology	质量管理方法[256]
regulatory methods validation	管理用分析方法的验证（FDA 对 NDA 提供的方法进行验证）
regulatory specification	质量管理规格标准（NDA 提供）
rejection	排异
Remicade (trade name of infliximab)	
remission	疾病缓解
remote monitoring system	远程监测系统；远程监控
REMS = Risk Evaluation and Mitigation Strategies	风险评估和减缓战略
REPFED = refrigerated processed food of extended durability	冷藏加工食品的长期保存
replicate data sets	重复研究的数据集
replication	可重复
rescue medication	缓解用药
residual risk	剩余风险
respiratory distress syndrome = RDS	呼吸窘迫综合征
respiratory paralysis	呼吸麻痹
response rate	缓解率
retention samples[257] for identification	留样
retinal implant	视网膜移植
retrovirus	逆转录酶病毒(一种致肿瘤病毒)
reverse engineering	逆向工程；反求工程；
review copy	审查用副本
RF ablation surgical probes	射频消融手术探针
rhabdomyolysis	横纹肌溶解
rhinovirus, RhV	鼻病毒
Rift Valley fever virus	立夫特谷热病毒
rigor mortis	尸僵[258]
riociguat[259] (Adempas)	利奥西呱
risk	受害
risk assessment (risk analysis + risk evaluation)	风险评估，论证

risk classification	风险分类;
Risk Communications Advisory Committee	风险交流咨询委员会
risk evaluation (part of risk assessment)	风险评价
risk/ benefit analysis	风险-效益分析
risk-benefit ratio	效益/风险比
RiskMAP[260] = Risk Minimization Action Plan	风险最小化行动计划
Ritalin	利他林;
rituximab， Mabthera, 美罗华	利妥昔单抗
RKI = Raf kinase inhibitor	Raf 激酶抑制剂
RM = rhabdomyolysis[261]	横纹肌溶解
RMS = reference member state[262]	参考成员国
Roche	罗氏
Rogaine	落健; 生发类产品
rolling review[263]	滚动审查
Rosetta	罗塞塔
route of administration	给药途径
royalties	专利使用费
RPM[264] (FDA Regulatory Procedures Manual)	监管程序手册
RPN = risk priority number[265]	风险优先指数
RR = response rate	缓解率
RSD = (intra-day and inter-day) relative standard deviations	(日内和日间) 相对标准差
RSV = respiratory syncytial virus[266]	呼吸道合胞体病毒
RTE (ready-to-eat) foods	即食食品
RTF (refue to file) [267]	拒绝受理; 退审
rugged individual	自强者，个人
run-in	准备期
RVD reference vascular diameter	参考血管直径
S. aureus = Staphylococcus aureus	金黄色葡萄球菌
Sabia virus	萨比亚病毒
sacral nerve stimulation (SNS)	骶神经刺激
SAD = single ascending dose	渐增型单一药剂量浓度测试
SAE = serious adverse event	严重不良事件
safety advisory	安全建议
safety evaluation	安全性评价
safety evaluators	安全性评估人员
safety set	安全性评价的数据集
Safety Set, SS	安全集
salicylic acid	水杨酸
Salmonella	沙门氏菌
Salmonella enteritidis	肠炎沙门氏菌
salmonella typhimurium	鼠伤寒沙门氏菌
salvage treatment[268]	挽救性治疗
sample size (number of subjects in a clinical trial)	样本含量; 样本量，样本大小
Sanofi-Aventis	赛诺菲一安万特集团
saving clause	1962 年的修正案增加的保留条款（saving clause）指明，州法律只有在与 FDCA 有“直接

	正面冲突”的情况下无效
SBA = serum bactericidal activities	血清杀菌活性分析；测定血清杀菌效价
SBA = summary basis of approval = approval package	批准依据摘要 = 批准药品信息包
scaffold	仿生支架
scale of ordered categorical ratings	有序分类指标
SCFX[269] = supercritical fluid extrusion	超临界流动相挤压
Schering-Plough	先灵葆雅
SCHIP State Children's Health Insurance Program	儿童医疗保险计划
SCID = severe combined immunodeficiency disease	严重联合免疫缺陷病
SCID mouse	SCID 小鼠
scleroderma	硬皮病
screening trials	筛选性试验
SD = stable disease	病情稳定
SD = standard deviation	标准(偏)差
SE = substantial equivalence	实质上的等同
seal strength test	密封强度试验
SEC = Securities and Exchange Commission	美国证券交易委员会
secondary effect	继发反应
secondary endpoint	次要终点
secondary infection	继发感染
secondary variable	次要变量
seed brachytherapy	放射性粒子组织间近距离治疗
seeding trials[270]	撒播试验
seizure	扣押
sensitized lymphocyte	致敏淋巴细胞
Sentinel Initiative[271] (of the FDA)	哨点行动
sepsis	败血病；脓毒症
sequence	试验次序
serine	丝氨酸
severe	重度
severe acute respiratory syndrome─coronavirus	严重急性呼吸系统综合症——冠状病毒
severely debilitating means diseases or conditions that cause major irreversible morbidity	
SFDA [272]= State Food And Drug Administration	国家食品药品监督管理局
SG & A= sales, general and administration	销售、管理和一般费用
shaft	传动轴
SHEA = Society for Healthcare Epidemiology of America	美国医院流行病学学会
sheaths	护套
shelf life	保存期限；保质期
shift table[273]	变化表
Shiga toxin	志贺毒素
shipping test	包装运输测试
SIC codes = Standard Industrial Classification codes	标准产业分类代码
side chain	**侧链**
side effects	副作用
significance level	显著性水平

significant risk (SR)	显著的危险性
Sildenafil	西地那非 drug for erectile dysfunction; viagra
simple randomization	简单随机
simulation model	仿真模型
Simulect = Basiliximab	舒莱 = 巴利昔单抗（诺华制药有限公司）
single blinding	单盲
single-blind study	单盲研究
single-masked study	单盲研究
sinus surgery devices	鼻窦手术器材
site assessment = SA	现场评估
site audit	试验机构稽查
Six Sigma[274]	六標準差，又稱六西格玛
SMDA = Safe Medical Devices Act of 1990	1990 年安全医疗器械法
SMF = Site Master File	生产场所主文件
sNDA = supplemental NDA	(疗效)补充新药(上市)申请
SNP single nucleotide polymorphism	单核甘酸多形态现象
sodium hypochlorite	次氯酸钠;
soft palate	软腭
solutions	溶液剂
SOP = standard operating procedure	标准操作规程
Sorafenib[275] = Nexavar	索拉非尼
sorbic acid	山梨酸
source data = SD	原始数据
source data verification = SDV	原始数据核准
SPA[276] = special protocol assessment	特殊方案评估
specific antibody	特异抗体
specification	規格；標準；
specificity	特异性
spinal deformities	脊柱畸形
spinal fusion cage	椎间融合器
spinal implants/ biologics	脊柱植入修复/生物制剂
spiral CT scan	螺旋 CT
spoilage	腐败
sponsor (of a new drug)	申办者;（指负责并着手临床研究者）
sponsor-investigator = SI	申办研究者
spontaneous reports; voluntary reports	药品不良反应自愿报告
SPS = Agreement on the Application Of Sanitary and Phytosanitary Measures	卫生与植物卫生措施实施协议;简称 SPS 协议
SSI = surgical site infection	手术部位感染
SSOPs = Sanitation Standard Operating Procedures	卫生标准操作规程
standard curve	标准曲线
standard deviation	标准(偏)差
standard drug	标准药物
standard operating procedure = SOP	标准操作规程
Standard Review[277]	标准审查
standard treatment	标准治疗
standards of care[278]	医护标准

staphylococcus	葡萄球菌属
startup companies	创业公司
STAT[279] protein (Signal Transducer and Activator of Transcription, or Signal Transduction And transcription)	信号转导转录（信号转导子和转录激活子）蛋白
State Food and Drug Administration = SFDA	国家食品药品监督管理局
statistic	统计量
statistical analysis plan = SAP	统计分析计划
statistical model	统计模型
statistical significance	统计显著性；统计学意义
statistical tables	统计分析表
Statisticians in the Pharmaceutical Industry = PSI	制药业统计学家协会
steady-state Area Under the Curve = AUCss	稳态药时曲线下面积/稳态血药浓度一时间曲线下面积
stenosis	狭窄
stent grafts	血管内支架血管；带膜支架
STEPS（System for Thalidomide Education and Prescribing Safety）	沙利度胺处方安全教育系统
sterile manufacturing facilities	无菌生产设施
sterility testing	无菌测试
sterilization	灭菌
steroid	类固醇； 甾体化合物
steroid eluting electrode	激素释放电极；激素电极起搏
steroid hormone	甾体激素；
Stevens Johnson Syndrome = SJS	Stevens-Johnson 综合征；斯-约二氏综合征(多形糜烂性红斑的一型)
stratified	分层
Strattera = atomoxetine hydrochloride,	盐酸托莫西汀-多动症治疗药
strength	规格；规格含量（每一剂量单位所含有效成分的量）
strep test	链球菌（分泌物)试纸；咽部病原菌抗原检查
Streptomycin	链霉素
study audit	研究稽查
study endpoint[280]	研究终点
Study Personnel List = SPL	研究人员名单
study site	研究中心
study type[281]	研究类型
subchronic toxicity studies	亚慢性毒性研究
subgroup	亚组
subgroup analysis	亚组分析
sub-investigator	助理研究者
subject	受试者
subject diary = SD	受试者日记
subject enrollment	受试者入选
subject enrollment log = SEL	受试者入选表
Subject Identification Code List = SIC	受试者识别代码表
subject recruitment	受试者招募
subject screening log = SSL	受试者筛选表

submission	申报；递交
subspecialties, internal medicine	亚专科,内科
substantial equivalence to legally marketed (predicate) device	和已合法在市场上销售的且不需要做 PMA“销售前批准”的相似产品有**实质上的等同**
sucrose	蔗糖
sudden cardiac arrest	心脏骤停
sudden cardiac death	心脏性猝死
sudden death	猝死
suicidal ideation	自杀意念
sulfanilamide elixir	磺胺酏 yi 剂
sulfasalazine = SSZ	柳氮磺吡啶 bi ding
sulfonamides	磺胺类药物
SUPAC scaled-up and Postapproval Changes	放大生产和批准后变更
superinfection	二重感染
superiority trial	优效性试验
supplier qualification	供应商资格审查
surfactant	表面活性剂
surgical instruments	手术器械
Surgical Navigation	手术导航系统
surrogate endpoint[282]	替代终点
survival analysis	生存分析
susceptible population	易感人群
Sutent[283] (Sunitinib Malate Capsules)	舒尼替尼；苹果酸舒尼替尼
sutures	外科手术缝线
SVR (sustained virologic response)[284]	持續性病毒學反應
SXRD = single-crystal x-ray diffraction	单晶 X一射线衍射
sympathomimetic drug	拟交感神经药
symptomatic uterine fibroids	症状性子宫肌瘤
Synagis[285] (palivizumab) by Abbott	帕利珠单抗；预防呼吸道感染药物 by MedImmune
syringe pump	注射泵
system audit	系统稽查
systemic infection	全身感染
systemic lupus erythematosus SLE	系统性红斑狼疮
T1/2 = elimination half-life (of a drug)	消除半衰期
tablets	片剂
tachycardia	心动过速
tamarind color	罗望子色素
tamper-resistant packaging	防撬包装□
Tamper-Resistant Packaging Regulations	FDA 颁布《反篡改包装规章》
tampons	衛生棉條
Tarceva	它赛瓦；特罗凯
target variable	目标变量
Taxol (paclitaxel)	他克唑；泰素：紫杉醇制剂；anti-cancer drug;
Taxotere (Docetaxel)	多西他赛；泰素帝
T-BIL = Total Bilirubin	总胆红素

TBT technical barrier to trade	技术性贸易壁垒
T-CHO = total cholesterol	总胆固醇
TDI = tolerable daily intake	每日允许摄入量
TDP = torsade de pointes	尖端扭转型室性心动过速
TDS = total diet study	总膳食研究
Technical Barriers to Trade (TBT) Agreement	技术性贸易壁垒协议
tensile test	拉伸试验；材料张力试验
teratogenic	致畸
teratogenic effects	致畸性；致畸(胎)效应
test and reference product = T&R	受试和参比试剂
test product	受试制剂；试验药
testosterone	睾丸酮
testosterone enantate	庚酸睾丸素
tetanus antitoxin	破伤风抗毒素
TG = thermogravimetry	热重分析
thalidomide	沙立度胺；反应停，酞胺哌啶酮
thalidomide incident[286]	"反应停（沙立度胺）事件"
therapeutic equivalence	治疗等效
therapeutic window[287]	治疗窗
thiamin	硫胺(维生素 B1)
threonine	苏氨酸
threshold concentration	阈浓度
thrombin	凝血酶
thrombocytopenia	血小板减少症
thrombolytic agents	溶栓药物
thrombolytic stroke	溶解血栓性中风
thrombotic diathesis	血栓素质(倾向)
thymus gland	胸腺
thyroid surgery	甲状腺手术
TIA = transient ischemic attacks	短暂性脑缺血发作
tick-borne encephalitis virus	蜱(pronounced pi2)传脑炎病毒
tilapia	罗非鱼
time to tumor progression	肿瘤进展时间
time-to-event endpoint or survival time[288]	存活时间
titer	浓度测定
Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title (or volume) of the CFR is revised once each calendar year	美国联邦法规第 21 卷
titration	滴定
TKI = Tyrosine kinase inhibitor	酪氨酸激酶抑制物,能制止不受调控的细胞生长，也经常被用来治疗癌症
TLC = thin layer chromatography[289]	薄层色谱法;制备色谱
Tmax	峰时间
TMS = transcranial magnetic stimulation	经颅磁刺激
TNF = tumor necrosis factor s	肿瘤坏死因子
TNK = Tenecteplase	替奈普酶
tocopherols	维生素 E
toluene	甲苯

tongue depressor	压舌板，压舌器
TOPRA | The Organisation for Professionals in Regulatory Affairs	
total diet study = TDS	总膳食研究
toxicant	毒剂
toxicity	毒性
toxicity scale/toxicity grading scale	毒性标度/毒性分级标度
toxics	毒性药品
toxigenic moulds	产毒素霉菌
TP = total protein	总蛋白
tPA = tissue plasminogen activator[290]	组织纤溶酶原激活物；抗栓塞药物
TPA = tissue polypeptide antigen	组织多肽抗原
TPP[291] = Target Product Profile	目标产品规格；
tracer	示踪剂
train-the-trainer program	培训者培训计划
trans fat	反式脂肪
transcranial magnetic stimulation	经颅磁刺激
transdermal patch	透皮贴剂
transformation	变量变换
transgene	转基因
translational science[292], translational research	转化科学
translocation[293]	易位
transmissible spongiform encephalopathy TSE	传染性海绵状脑病
transvenous catheter pacemaker	经静脉导管起搏器
traumatic pain	外伤性疼痛
treatment group	试验组
treatment IND[294]	治疗性试验性新药申请
treatment trials	治疗性试验
trial error	试验误差
trial initial meeting	试验启动会议
trial master file	试验总档案
trial objective	试验目的
trial site	试验场所
TRICARE	军队医疗系统
triple blinding	三盲
trocars	套针
troglitazone	曲格列酮
Trovan (Trovafloxacin) by Pfizer	曲伐沙星
TSE = transmissible spongiform encephalopathy	可传播性海绵体脑炎；传染性海绵状脑病
TSR = Total Shareholder return	股东总回报
TTB = Alcohol and Tobacco Tax and Trade Bureau	美国烟酒征税及贸易局
TTM = Time to Market	上市时间；产品从开发工作开始到上市所用的时间
TTP = Time to progression	到进展时间
tumor context of vulnerability[295]	肿瘤薄弱基因环境
tumoricidal (kill residual tumor cells)	杀瘤作用
tumorstatic (prevent the growth of tumor cells)	抑瘤作用
TVR = target vessel revascularization	靶血管重建；靶血管再血管化治疗

two one-side test	双单侧检验
Tylenol	泰诺；止痛药
type I error[296]	Ⅰ类错误
type II diabetes	二型糖尿病
type II error[297]	Ⅱ类错误
tyrosine kinase	酪氨酸激酶
TZDs = thiazolidinediones	噻唑烷（sai zuo4 wan2）二酮类
UAE = unexpected adverse event	预料外不良事件
UC = ulcerative colitis	溃疡性结肠炎
UFI[298] (unique facility identifier) system for drug establishment registration	药品企业注册用唯一设施识别（UFI）系统
ULN = upper limits of normal	正常上限；正常范围上限
UMC = Uppsala Monitoring Centre	乌普沙拉监测中心
unblinding	破盲;揭盲
undenatured collagen	非變性膠原蛋白
under reporting bias	少报偏差
unexplained syncope	不明原因晕厥
UNITAID[299]	联合援助国际药品采购机制,简称「联合援助」
unresectable	不能手术切除
Upjohn	厄普约翰
urinary retention	尿滞留
URS = user requirements specification	用户需求说明
urticaria	荨麻疹;俗称风团、风疹团、风疙瘩、风疹块（与风疹名称相近，但非同一疾病）
US Federal Food Drug and Cosmetic Act of 1938	1938 的美国《联邦食品、药品和化妆品法》
USDA FSIS (Food Safety and Inspection Service)	美国农业部食品安全检验部
user fees: Prescription drug provisions (PDUFA V); Medical device provisions (MDUFA III); Generic Drug User Fee Amendments of 2012 (GDUFA) Biosimilar User Fee Act (BsUFA)	
USP = United States Pharmacopeia	美国药典（现已和 NF 合并一起出版）
USP/NF = U.S. Pharmacopeia / National Formulary	《美国药典/国家处方集》
USSC = U.S Sentencing Commission	美国司法部量刑委员会
UV-VIS Ultraviolet/Visible	紫外一可见光
VAC = vacuum-assisted closure	真空辅助闭合
VAI = voluntary action indicated	应该由厂方采取志愿行动
validation	验证
validation master plan	验证主计划
validation of aseptic processing	无菌工艺验证
Validation, Cleaning[300]	清洗验证
Validation, Concurrent[301]	同步型验证
validation, process[302]	工艺验证
Validation, Product[303]	产品验证
Validation, Prospective[304]	预期型验证/前验证
Validation, Retrospective[305]	回顾性验证
validation: Revalidation	再验证
value chain[306]	价值链
vancomycin resistance	对万古霉素的抗药性

vandetanib	凡德他尼；是一种合成的苯胺喹唑啉化合物,为口服的小分子多靶点酪酸激酶抑制剂(TKI),可同时作用于肿瘤细胞 EGFR、VEGFR 和 RET 酪氨酸激酶
variability	变异
variable	变量
variola virus	天花病毒 small pox
vascular catheter	血管内插管
vasculitis	血管炎
vasopressin receptor antagonist	血管加压素受体拮抗剂
vector sequences[307]	载体序列
vegetative bacteria	植物细菌
vegetative organism	活微生物
VEGF[308] = vascular endothelial growth factor	血管内皮生长因子
VEGFR = vascular endothelial growth factor receptor	血管内皮生长因子受体
vemurafenib[309] = V600E mutated BRAF inhibition	威罗菲尼
ventilator	呼吸机
ventricular fibrillation	心室纤颤
ventricular tachycardia	室性心动过速
verification[310]	确认
veterinary products	兽用药品
Vibrio cholerae	霍乱弧菌
Vibrio parahaemolyticus	副溶血弧菌
Vibrio vulnificus	创伤弧菌
VIGOR study (Vioxx Gastrointestinal Outcomes Research)[311]	万络肠胃结果研究
Vioxx (rofecoxib)	万络;罗非昔布；COX-2 抑制剂；抗炎止痛药
VIPPS = Verified Internet Pharmacy Practice Site	“互联网药品营业认证”标志；互联网药店认证
viral load	病毒载量
virtual cath lab	虚拟导管室
virus inactivation	病毒灭活
visual analogy scale	直观类比打分法
visual check	人工检查
vital signs	生命体征
Voltaren gel	扶他林片凝胶
VRE vancomycin-resistant enterococci	耐万古霉素肠球菌
vulnerable subject	弱势受试者
vulvovaginal atrophy	外阴萎缩
Vytorin	为包含依折麦布（ezetimibe）和辛伐他汀（simvastatin）的复方药品
W/D due to adverse events	因不良反应事件而撤药
WACC = weighted average cost of capital	加权平均资本成本
Warfarin	华法林[抗凝药]
warning letter	警告信函
warranty claims	保证期索赔
wash-out; washout period	洗出期；洗脱,清洗期；洗脱期
water activity[312] (Aw)	水分活度，又称水活性，水活度

water binding agents	亲水试剂
water-for-injection system = WFI	注射用水系统
WBC = white blood cell	白细胞
Weber effect [313]	韦伯效应
Wegener's granulomatosis	韦格纳肉芽肿病
well-being	福利，健康
Wellcome	惠康
West Nile virus	西尼罗河病毒
WHO International Collaborating Center for Drug Monitoring	(世界卫生组织)国际药物监测合作中心
WHO International Conference of Drug Regulatory Authorities = WHO-ICDRA	WHO 国际药品管理当局会议
WHO Programme for International Drug Monitoring = PIDM	WHO 国际药物监测合作计划
WHO-ART Adverse Drug Reaction Terminology	WHO 不良反应术语集
WHO-Drug	WHO 药品词典（该词典是依据 INN 命名法和 ATC 分类法编辑）
whole grains	全谷食品
withdrawal symptoms	撤药反应症状
withdrawal syndrome	撤药综合征
within-run precision	批内精密度
wound drainage	积液引流
wound dressing	创面敷料
wound management	伤口护理
WTO/SPS = Agreement on the Application of Sanitary and Phytosanitary Measures	《实施卫生与植物卫生措施的协定》
Xarelto®, Rivaroxaban (Bayer drug for atrial fibrillation)	拜瑞妥薄膜衣片；成份：利伐沙班；[314]
Xeljanz (tofacitinib[315] citrate) by Pfizer	托法替尼
xenotransplantation	异种移植
Xerophilic fungi	喜旱真菌
Ximelagatran	希美加群，抗凝药物
Xofigo by Bayer	2013 年 5 月 15 日，美国食品药品监督管理局（FDA）批准了二氯化镭 Ra 223（Xofigo 注射剂，拜耳医药保健制药公司）用于治疗去势抵抗性前列腺癌
X-ray	X 射线
Yasmin (Ethinyl Estradiol/Drospirenone Birth Control Pills)	优思明（炔雌醇~屈螺酮避孕药）
Yellow fever virus	黄热病毒
Yersinia enterocolitica	小肠结肠炎耶尔森菌
Yersinia pestis	鼠疫耶尔森菌
Zenapax[316] = Daclizumab 达克珠单抗	赛尼哌；抗 Tac 单抗；抗排异药 anti-rejection;
Zeneca	泽尼卡
Zevalin, Prep Yttrium-90/Ibritumomab Tiuxetan/Albumin Human	泽娃灵，替伊莫单抗/人血白蛋白；抗癌药物->治疗非霍奇金淋巴瘤药物
Zocor（simvastatin）	舒降之；他汀类降胆固醇药；辛伐他汀
Zyprexa (Olanzapine)	再普乐；奥氮平；精神分裂症

α1-receptor blocker	α1 受体阻滞剂
β-lactames	ß-内酰氨

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

Laws & Regulations

Animal Drug User Fee Act 2003	《兽药用户付费法》
Anti–drug Abuse Act 1988	反毒品滥用法
Best Pharmaceuticals for Children Act[317] 2002 BPCA	儿童最佳药品法；最佳儿童医药品法；
Biologics Control Act 1902	生物制品管制法
DSHEA = Dietary Supplement Health and Education Act of 1994	膳食补充品健康与教育法
Drug Price Competition and Patent Term Restoration Act, more commonly known as the "Hatch-Waxman Act" 1984	海切一维克茨曼法案
Fair Packaging and Labeling Act 1966	公平包装和标识法
Federal Food, Drug and Cosmetic Act 1938[318]	食品、药品和化妆品法
Food and Drug Administration Modernization Act of 1997[319]	美国食品和药品管理局现代化法
Kefauver-Harris Amendment to the FD&C Act [320] 1962	克发尔–哈里斯修正案
Medical Device Regulation Act 1976	医疗器械管制法
Medical Device User Fee and Modernization Act = MDUFMA 2002	医疗器械收费和现代化法案
Nutrition Labeling and Education Act = NLEA 1990	《营养标签及教育法》
Pediatric Research Equity Act of 2003	《2003 年儿科研究公平法》
Prescription Drug Marketing Act 1987	《处方药销售法》
Prescription Drug User Fee Act [321] = PDUFA 1992	处方药收费法
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act)	《2002 年公共健康安全和生物恐怖预备应对法》（简称《生物恐怖法》）
Public Health Service Act 1944	公共健康服务法；公共卫生服务署法
Pure Food and Drug Act 1906	纯食品和药品法

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

FDA Structure

美国卫生与人类服务部（HHS）美国卫生与公共服务部(HHS)部长(December 2013) 凯瑟琳·瑟比列斯(Kathleen Sebelius) http://www.hhs.gov

FDA Organization chart December 2013 http://www.fda.gov/

Office of the Commissioner	
Immediate Office of the Commissioner	
National Center for Toxicological Research	
Office of Foods and Veterinary Medicine	
Center for Food Safety and Applied Nutrition	
Center for Veterinary Medicine	
Office of Medical Products and Tobacco	

Center for Devices and Radiological Health	
Office of Special Medical Programs	
Center for Tobacco Products	
Center for Biologics Evaluation and Research	
Center for Drug Evaluation and Research	
Office of Global Regulatory Operations and Policy	
Office of International Programs	
Office of Regulatory Affairs	
Office of Operations	
Office of Management	
Office of Information Management	
Office of Finance, Budget and Acquisition	
Office of Equal Employment Opportunity	
Associate Commissioner Linda Tollefson, DVM, MPH , FDA Office of Foods and Veterinary Medicine	美国食品药品管理局助理局长琳达·托尔夫森

Acting Principal Deputy Commissioner	代理第一副局长
ATF = Bureau of Alcohol, Tobacco, Firearms and Explosives	酒精、烟草、枪支和爆炸物管理局
CBER = Center For Biologics Evaluation and Research	生物制品评价和研究中心 （职位：主任 Director）
CDER = Center For Drug Evaluation and Research	药品评价和研究中心（职位：主任 Director）
CDRH = Center For Devices and Radiological Health	器械和辐射健康中心（职位：主任 Director）
CFSAN = Center For Food Safety and Applied Nutrition	食品安全和应用营养中心（职位：主任 Director）
Commissioner of Food and Drugs	食品和药品局长
CVM = Center For Veterinary Medicine	兽药中心（职位：主任 Director）
Division of (Drug) Risk Evaluation	风险评估部
Division of Medication Errors and Technical Support	投药出错和技术支持部
Division of Surveillance, Research and Communication Support	监测、研究和交流支持部
Drug Safety and Risk Management Advisory Committee	药品安全和风险管理咨询委员会
NCTR = National Center for Toxicological Research	国家毒理学研究中心（职位：主任 Director）
OAP = Office of Antimicrobial Products (under CDER)	抗菌产品办公室
OBP = Office of Biotechnology Products (under CDER)	生物技术产品办公室
OCC = Office of Chief Counsel	首席法律顾问办公室
OCI = Office of Criminal Investigations	犯罪调查办公室
OCP = Office of Clinical Pharmacology	临床药理学办公室 (under CDER); supercedes

	OCPB
ODS = Office of Drug Safety	药品安全办公室
Office For Human Research Trials	人体研究试验办公室
Office of Applied Research and Safety Assessment	应用研究和安全性评估办公室
Office of Biostatistics and Epidemiology (under CBER)	流行病学和生物统计学办公室
Office of Blood Research and Review	血液研究和审查办公室
Office of Cellular, Tissue and Gene Therapy (under CBER)	细胞组织基因治疗办公室
Office of Clinical Pharmacology and Biopharmaceutics (OCPB)	临床药理学和生物制药学办公室
Office of Communication, Education, and Radiation Programs (under CDRH)	交流、教育和放射项目办公室
Office of Communication, Training and Manufacturers Assistance	交流、培训和帮助制造商办公室
Office of Compliance	执法办公室
Office of Compliance and Biologics Quality	执法和生物制品质量办公室
Office of Constituent Operations	选民工作办公室
Office of Consumer Affairs	消费者事务办公室
Office of Cosmetics and Colors	化妆品和色素办公室
Office of Counter-Terrorism and Emergency Coordination (under CDER)	反恐紧急协调办公室
Office of Device Evaluation	器械评价办公室
Office of Drug Evaluation I	药品评价办公室 I
Office of Drug Evaluation II	药品评价办公室 II
Office of Drug Evaluation III	药品评价办公室 III
Office of Drug Evaluation IV	药品评价办公室 IV
Office of Drug Evaluation V	药品评价办公室 V
Office of Enforcement	强制执法办公室
Office of Equal Opportunity	均等机会办公室（职位：主任 Director）
Office of Executive Operations	行政运行办公室
Office of Executive Programs (under CDER)	
Office of Executive Secretariat	行政秘书处办公室
Office of Facilities, Acquisitions, & Central Services	设备、办公用品和中心服务办公室
Office of Field Programs	现场项目办公室
Office of Financial Management	财务管理办公室
Office of Food Additive Safety	食品添加剂安全办公室
Office of Generic Drugs	仿制药品办公室
Office of Health and Industry Programs	健康和产业项目办公室
Office of Human Resources & Management Services	人类资源和管理服务办公室

Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) under CDRH	体外诊断器械评估和安全性办公室
Office of Information Resources Management	信息资源管理办公室
Office of Information Technology	信息技术办公室
Office of Information Technology (under CBER)	信息技术办公室
Office of Information Technology Management	信息技术管理办公室
Office of Internal Affairs	内部事务办公室
Office of International & Constituent Relations	国际和选民关系办公室（职位：副专员 Deputy Commissioner）
Office of International Programs	国际项目办公室
Office of Legislation	立法办公室
Office of Management	管理办公室
Office of Management & Systems	管理和系统办公室（职位：资深准专员 Senior Associate Commissioner）
Office of Management and Communications	管理和交流办公室
Office of Management Operations (under CDRH)	管理运作办公室
Office of Management Services (under NCTR)	管理服务办公室
Office of Management Systems (under CFSAN)	管理系统办公室
Office of Medical Policy	医学政策办公室
Office of Minor Use and Minor Species Animal Drug Development (under CVM)	少使用和少数动物兽药发展办公室
Office of New Animal Drug Evaluation	新动物药评价办公室
Office of New Drug Chemistry	新药化学办公室
Office of New Drugs = OND	新药办公室
Office of Nonprescription Products (under CDER)	非处方药产品办公室
Office of Nutritional Products, Labeling and Dietary Supplements	营养产品、标识和饮食添加剂办公室
Office of Oncology Drug Products (under CDER)	肿瘤学药品办公室
Office of Operations	运行办公室
Office of Orphan Products Development	罕见病产品开发办公室
Office of Pharmaceutical Science	制药科学办公室
Office of Planning	计划办公室
Office of Planning, and Resource Management (under NCTR)	规划资源管理办公室
Office of Planning, Finance, and Information Technology	计划、财务和信息技术办公室
Office of Plant and Dairy Foods and Beverages	植物和牛奶食品及饮料办公室
Office of Policy	政策办公室
Office of Policy, Planning, and Legislation	政策、计划和立法办公室（职位：资深准专员 Senior Associate Commissioner）

Office of Post-Marketing Drug Risk Assessment	上市后药品风险评估办公室
Office of Premarket Approval	上市前审批办公室；上市前批准事宜办公室
Office of Public Affairs	公共事务办公室
Office of Regional Operations	地区性运行办公室
Office of Research	研究办公室
Office of Resource Management	资源管理办公室
Office of Review Management	审查管理办公室
Office of Science	科学办公室
Office of Science and Engineering Laboratories under CDRH	科学与工程试验室办公室
Office of Science and Technology	科学和技术办公室
Office of Science Coordination and Communication	科学协调和交流办公室（职位：主任 Director）
Office of Scientific Analysis and Support	科学分析和支持办公室
Office of Seafood	海产食品办公室
Office of Special Health Issues	特殊健康问题办公室
Office of Surveillance and Biometrics	监督和生物统计办公室
Office of Surveillance and Compliance	监督和执法办公室
Office of Surveillance and Epidemiology = OSE, formerly “Office of Drug Safety”	药品监测和流行病学办公室, 前“药品安全办公室”
Office of Systems and Management	系统和管理办公室
Office of Testing and Research	试验和研究办公室
Office of The Administrative Law Judge	行政法官办公室（职位：行政法官 Administrative Law Judge）
Office of the Commissioner OC	局长办公室
Office of The Ombudsman	监察专员办公室
Office of The Senior Associate Commissioner	资深准专员办公室（职位：资深准专员 Senior Associate Commissioner）
Office of Therapeutics Research and Review	治疗学研究和审查办公室
Office of Training and Communication	培训和交流办公室
Office of Translational Science	转化科学办公室
Office of Vaccines Research and Review	疫苗研究和审查办公室
Office of Women's Health	妇女健康办公室
OIVDDES = Office of In Vitro Diagnostic Device Evaluation and Safety	体外诊断器械评价与安全办公室
ONDQA = Office of New Drug Quality Assessment (under CDER)	新药质量评价办公室
OODP = Office of Oncology Drug Products (under CDER)	肿瘤学药品办公室
ORA = Office of Regulatory Affairs	监管事务办公室

OSEL = Office of Science and Engineering Laboratories (under CDRH)	科学与工程试验室办公室
Regional Field Office, Central Region, Philadelphia, PA	地区性现场办公室—中部地区
Regional Field Office, Northeast Region, Jamaica, NY	地区性现场办公室—东北地区
Regional Field Office, Pacific Region, Oakland, CA	地区性现场办公室—太平洋地区
Regional Field Office, Southeast Region, Atlanta, GA	地区性现场办公室—东南地区
Regional Field Offrice, Southwest Region, Dallas, TX	地区性现场办公室—西南地区
USDA = Food Safety and Inspection Service	美国食品安全与检查局

（据董 耿编译：《浙江药品监督管理》2001 年第 7 辑第 82—85 页）

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

CFDA China Food and Drug Administration 国家食品药品监督管理局 http://www.sda.gov.cn

CFDA Structure 局长: 张勇 Organizational chart December 2013

厅		Office	
司		Department	
处		Division	
局		Bureau	
办公厅	综 合 处	General Office	Division of General Affairs
	秘书一处（值班室）		Division of Secretariat I (Office of Duty)
	秘书二处		Division of Secretariat II
	文 电 处		Division of Documentation and Communication
	督查处（信访办公室）		Division of Superintendance (Office of Letters and Calls)
综合司（政策研究室）	综合协调处	Comprehensive Department (Office of Policy Research)	Division of General Coordination
	政策研究一处		Division of Policy Research I
	政策研究二处		Division of Policy Research II
	督查考评处(统计办公室)		Division of Supervision and Evaluation (Office of Statistics)
法制司	综 合 处	Department of Legal Affairs	Division of General Affairs
	法规一处		Division of Regulations I
	法规二处		Division of Regulations II
	执法监督处 (行政复议办公室)		Division of Enforcement Supervision (Office of Administrative Reconsideration)
食品安全监管一司	综 合 处	Department of Food Safety Supervision I	Division of General Affairs
	监管一处		Division of Supervision I
	监管二处		Division of Supervision II

	监管三处		Division of Supervision III
	监管四处		Division of Supervision IV
食品安全监管二司	综 合 处	Department of Food Safety Supervision II	Division of General Affairs
	监管一处		Division of Supervision I
	监管二处		Division of Supervision II
	监管三处		Division of Supervision III
	监管四处		Division of Supervision IV
食品安全监管三司	综 合 处	Department of Food Safety Supervision III	Division of General Affairs
	监管一处		Division of Supervision I
	监管二处		Division of Supervision II
	监管三处		Division of Supervision III
	监管四处		Division of Supervision IV
药品化妆品注册管理司（中药民族药监管司）	综 合 处	Department of Drug and Cosmetics Registration (Department of TCMs and Ethno-Medicines Supervision)	Division of General Affairs
	中药民族药处		Division of Traditional Chinese Medicines and Ethno-Medicines
	化学药品处		Division of Pharmaceuticals
	生物制品处		Division of Biological Products
	药物研究监督处		Division of Drug Research Supervision
	化妆品处		Division of Cosmetics
医疗器械注册管理司	综 合 处	Department of Medical Device Registration	Division of General Affairs
	注册一处		Division of Registration I
	注册二处		Division of Registration II
	研究监督处		Division of Research Supervision
药品化妆品监管司	综 合 处	Department of Drug and Cosmetics Supervision	Division of General Affairs
	药品生产监管处		Division of Drug Manufacturing Supervision
	药品流通监管处		Division of Drug Distribution Supervision
	药品监测评价处		Division of Drug Monitoring and Re-evaluation
	特殊药品监管处		Division of Controlled Drug Supervision
	化妆品监管处		Division of Cosmetics Supervision
医疗器械监管司	综 合 处	Department of Medical Device Supervision	Division of General Affairs
	生产监管处		Division of Drug Manufacturing Supervision
	流通监管处		Division of Distribution Supervision
	监测评价处		Division of Monitoring and Re-evaluation
稽查局	综 合 处	Bureau of	Division of General Affairs

	稽查一处	Investigation and Enforcement	Division of Investigation and Enforcement I
	稽查二处		Division of Investigation and Enforcement II
	稽查三处		Division of Investigation and Enforcement III
应急管理司	综 合 处	Department of Emergency Management	Division of General Affairs
	应急监测处		Division of Emergency Monitoring
	应急指导处		Division of Emergency Guidance
	应急处置处		Division of Emergency Response
科技和标准司	综合处（信息化处）	Department of Science, Technology and Standards	Division of General Affairs (Division of Informationalization)
	科 技 处		Division of Science and Technology
	标准管理处		Division of Standard Management
	检验机构指导处		Division of Testing Institutes Instruction
新闻宣传司	综 合 处	Department of Media and Publicity	Division of General Affairs
	新闻宣传一处		Division of Media and Publicity I
	新闻宣传二处		Division of Media and Publicity II
人事司	综合处（干部监督处）	Department of Human Resources	Division of General Affairs (Division of Personnel Supervision)
	干 部 处		Division of Personnel
	人 才 处		Division of Talents
	直属单位处（工资处）		Division of Affiliated Institutions (Division of Compensation)
规划财务司	综合处（规划处）	Department of Planning and Finance	Division of General Affairs (Division of General Planning)
	基建装备处		Division of Construction and Equipment
	预算与审计处		Division of Budget and Audit
	财务资产处		Division of Finance and Assets
国际合作司（港澳台办公室）	综 合 处	Department of International Cooperation (Office of Hong Kong, Macao and Taiwan Affairs)	Division of General Affairs
	国际组织处		Division of International Organizations
	双边合作处		Division of Bilateral Cooperation
	港澳台处		Division of Hong Kong, Macao and Taiwan Affairs

安全监管处 医疗器械司	Div of Safety Supervision
办 公 室（规划财务司）	General Office = Department of Finance Planning
保健品处 药品注册司	Div of Health Food? Supplements?

标准处 医疗器械司	Div of Standards
财务处 办公室	Div of Financial Affairs
产品注册处 医疗器械司	Div of Product Registration
发展规划处 办公室	Div of Development and Planning
法规处 政策法规司	Div of Regulations
工资调配处 人事教育司	Div of Salary and Deployment
国际合作司	Dept of International Cooperation (Office for Administrative Protection of Pharmaceuticals)
合作处 国际合作司	Div of Cooperation
化学药品处 药品注册司	Div of Pharmaceuticals
监测标准与技术监督处 食品安全协调司	Div of Surveillance Standard and Technical Supervision
经营许可监督处 药品市场监督司	Div of Supervision on Distribution Licensing
考核任免处 人事教育司	Div of Personnel Assessment, Appointment and Removal
联络处 国际合作司	Div of Liaison
秘书处 办公室	Div of Secretaries
培训与技术干部管理处 人事教育司	Div of Training and Management of Technical Personnel
人事教育司	Dept of Personnel and Education
生产监督处 药品安全监管司	Div of Drug Manufacturing Supervision
生物制品处 药品注册司	Div of Biological Products
食品安全监察司	Dept of Food Safety Supervision
食品安全监督处 食品安全监察司	Div of Food Safety Supervision
食品安全协调司	Dept of Food Safety Coordination
特殊药品监管处 药品安全监管司	Div of Controlled Drugs Inspection
文档信息处 办公室	Division of Archives and Information
新闻处 政策法规司	Div of News? or Press?
信息分析处 食品安全协调司	Div of Information Analysis
信息广告监督处 药品市场监督司	Div of Drug Information and Advertising Supervision
药品安全监管司	Dept of Drug Safety and Inspection
药品督察处 药品市场监督司	Div of Drug Supervision and Inspection
药品评价处 药品安全监管司	Div of Drug Re-evaluation
药品市场监督司	Dept of Drug Market Compliance
药品研究监督处 药品安全监管司	Div of Drug Research Supervision
药品注册司	Dept of Drug Registration
医疗器械督察处 药品市场监督司	Div of Medical Devices Supervision and Inspection
医疗器械司	Dept of Medical Devices
预算管理处 办公室	Div of Budget Management

政策法规司	Dept of Policy and Regulations
政策研究处 政策法规司	Div of Policy Research
执法监督处 政策法规司	Div of Law Enforcement Supervision
中药处 药品注册司	Div of Traditional Chinese Medicine
专项督查处 食品安全协调司	Div of Special Supervision and Investigation
综合处 医疗器械司	Div of General Affairs
综合处 食品安全监察司	Div of General Affairs
综合处 = 应急管理办公室 办公室	Div of General Management
综合管理处 国际合作司	Div of General Management
综合管理处 药品市场监督司	Div of General Management
综合管理处 药品注册司	Div of General Management
综合协调处 食品安全协调司	Div of Comprehensive Coordination

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

[1] allowing earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint.
[2]责任制医疗组织（ACO: Accountable Care Organization）是美国奥巴马医改的核心之一，意在解决如何在确保医疗质量的同时降低医疗费用这个久攻不破的难题。
[3] of the Bureau of Customs and Border Protection (CBP)
[4] a biologic response modifier, is a single-chain polypeptide containing 140 amino acids
[5]临床适用于预防和治疗冠心病心绞痛，特别是变异型心绞痛和冠状动脉痉挛所致心绞痛
[6]用于缓解抗风湿性药物(DMARD)治疗无效的结构性损伤的中至重度类风湿性关节炎(RA)成年患者的体征与症状。本品可单独使用，也可与甲氨蝶呤或其他 DMARD 合用
[7] a new class of highly potent biopharmaceutical drugs designed as a targeted therapy for the treatment of people with cancer
[8] an ester of adenosine that is converted to ATP for the storage of energy
[9] Adventitious agents can be viruses, bacteria, mycoplasma, fungi, rickettsia, protozoa, parasites, and TSE agents. • Potential concern that adventitious. agents can be unintentionally. introduced into the manufacturing.
[10] An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time
[11] Organizations and groups that actively support participants and their families with valuable resources, including self-empowerment and survival tools.
[12] A negative experience encountered by an individual during the course of a clinical trial that is associated with the drug.
[13] 是一种重组人融合蛋白，能够结合 VEGF 的 A 亚型和 B 亚型，也能够与胎盘生长因子结合，从而抑制肿瘤血管的生成
[14] The basic premise of AIP is: If FDA determines that a company's applications are not reliable, the agency will not perform substantive review of any of the company's applications until confidence in the data is restored.
[15] An alanine aminotransferase (ALT) test measures the amount of this enzyme in the blood. ALT is measured to see if the liver is damaged or diseased.
[16] to check for liver disease or damage to the liver. Symptoms of liver disease can include jaundice, belly pain, nausea, and vomiting. An ALP test may also be used to check the liver when medicines that can damage the liver are taken or to check bone problems (sometimes found on X-rays), such as rickets, osteomalacia, bone tumors, Paget's disease, or too much of the hormone that controls bone growth (parathyroid hormone).
[17] One of the alternative versions of a gene at a given location (locus) along a chromosome

[18] An allograft is a transplanted organ or tissue from a genetically non-identical member of the same species
[19] A test for antinuclear antibodies (ANA) test is common in people who are suspected of having an autoimmune or connective tissue disorder. The ANA test identifies autoantibodies that target substances contained in the nucleus of cells
[20] is a general linear model with a continuous outcome variable (quantitative) and two or more predictor variables where at least one is continuous (quantitative) and at least one is categorical (qualitative). ANCOVA is a merger of ANOVA and regression for continuous variables. ANCOVA tests whether certain factors have an effect on the outcome variable after removing the variance for which quantitative predictors (covariates) account. The inclusion of covariates can increase statistical power because it accounts for some of the variability
[21] Any of the treatment groups in a randomized trial.
[22] Low levels of AST are normally found in the blood. When body tissue or an organ such as the heart or liver is diseased or damaged, additional AST is released into the bloodstream. The amount of AST in the blood is directly related to the extent of the tissue damage.
[23] A renewable permit granted by the federal government to an institution or research center to conduct clinical trials.
[24] in an "as treated" (or "observed data") analysis only those patients still taking the assigned treatment are analyzed; those who drop out are "censored."
[25] 指由不直接涉及试验的人员所进行的一种系统性检查，以评价试验的实施、数据的记录和分析是否与试验方案、标准操作规程以及药物临床试验相关法规要求相符
[26] 一种批准用于治疗 2 型糖尿病的药物
[27] Benzodiazepines have also been used as a "date rape" drug because they can markedly impair and even abolish functions that normally allow a person to resist or even want to resist sexual aggression or assault
[28] 本类药物也称弱安定药，包括氯氮卓(利眠宁，chlordiazepoxide，商品名 Librium)、地西泮(安定，diazepam，商品名 valium)、硝西泮(硝基安定，nitrazepam)、氟西泮(氟安定，flurazepam)及奥沙西泮(去甲羟基安定，舒宁，oxazepam)。临床主要用于镇静、催眠及对抗癫痫
[29] 1993 年 7 月 23 日，Betaseron 成为美国 FDA 批准的第一个用于治疗多发性硬化的药物
[30] 指在设计临床试验方案、执行临床试验、分析评价临床试验结果时，有关影响因素所致的系统误差，致使疗效或安全性评价偏离真值。
[31] Reports accessible from this site provide updates on the Human Subject Protection (HSP)/Bioresearch Monitoring (BIMO) Initiative. Launched in 2006 as a part of the Critical Path Initiative, the HSP/BIMO Initiative is aimed at modernizing and strengthening the agency's oversight and protection of subjects in clinical trials and the integrity of resulting data.
[32] expression of how much drug reaches the circulation (known to pharmacologists as the **central compartment**) after administration
[33] Bioburden is defined as the number of bacteria living on a surface that has not been sterilized.
[34] The property of being biologically compatible by not producing a toxic, injurious, or immunological response in living tissue
[35] A biofilm is a structured community of microorganisms encapsulated within a self-developed polymeric matrix and adherent to a living or inert surface
[36] A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man. biological therapeutic agents that include blood and blood products, vaccines, allergenics, cell and tissue-based products, and gene therapy products
[37] Substances that stimulate the body's response to infection and disease. The body naturally produces small amounts of these substances. Scientists can produce some of them in the laboratory in large amounts for use in treating cancer, rheumatoid arthritis, and other diseases
[38] A biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment
[39] The study of the physical and chemical properties of drugs and their proper dosage as related to the onset, duration, and intensity of drug action.

[40] Biosimilars or Follow-on biologics are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. Biosimilars are also referred to as subsequent entry biologics (SEBs) in Canada
[41] are a class of artificial bispecific monoclonal antibodies that are investigated for the use as anti-cancer drugs. They direct a host's immune system, more specifically the T cells' cytotoxic activity, against cancer cells. BiTE is a registered trademark of Micromet AG
[42]混合过程是固体制剂生产的重要环节，对于保证制剂活性成分分布均匀、质量长期稳定具有重要意义。混合不充分将导致药品质量严重不均一，而混合过久则是不必要的浪费能源
[43] A randomized trial is "Blind" if the participant is not told which arm of the trial he is on. A clinical trial is "Blind" if participants are unaware on whether they are in the experimental or control arm of the study; also called masked
[44] 在最后一份病例报告表输入数据库后，第一次揭盲之前对数据保持盲态的预分析审核，以便对统计分析计划作最后的决定。
[45] One of the responsibilities of the Office of Device Evaluation (ODE) is to develop and interpret regulations and guidelines regarding premarket notification submissions (510(k)s), premarket approval applications (PMAs), product development protocols (PDPs), device classifications, and investigational device exemptions (IDEs). The ODE guidance memoranda, affectionately referred to as "Blue Book Memos", clarify these guidelines
[46] This new designation helps FDA assist drug developers to expedite the development and review of new drugs with preliminary clinical evidence that indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases
[47] a bridging study is a supplemental study on a medicine that is performed in the new region to build a bridge between the information available from the tests already done and the questions arising from the regulatory authority due to ethnic factors. Bridging studies done to assess the efficacy of new drugs could provide additional drug response data in the population of the new region. A pharmacokinetic study may be accepted as a bridging study too, if the regulatory authority in the new region requires no bridging study to provide clinical data for efficacy.
[48] A flat monthly fee that a health plan pays to a provider (doctor, hospital, lab, etc.) to take care of a patient's needs. Capitation is part of the provider-reimbursement mechanism
[49] Both the FDA and EMEA endorse the use of CCDSs to track safety data and share labeling information. The EMEA requires companies to file Periodic Safety Update Reports (PSURs) regularly and the FDA requires postmarketing reports for some drugs currently on the market and likely more in the future
[50] occurs in the treatment of CML when cytogenetic testing is unable to detect the Philadelphia (Ph) chromosome in bone marrow or blood cells (0% Ph+ cells)
[51] a medical testing protocol in which a medicine or drug is administered, withdrawn, then re-administered, while being monitored for adverse effects at each stage. The protocol is used when statistical testing is inappropriate due to an idiosyncratic reaction by a specific individual, or a lack of sufficient test subjects and unit of analysis is the individual
[52] (an acronym for the French "Conformite Europeenne") certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety
[53] approved for colon cancer, as well as head and neck cancer
[54] Channeling is a form of allocation bias, where drugs with similar therapeutic indications are prescribed to groups of patients with prognostic differences. Claimed advantages of a new drug may channel it to patients with special pre-existing morbidity, with the consequence that disease states can be incorrectly attributed to use of the drug. For the study of adverse drug reactions, large databases supply information on co-medication and morbidity of patients. For diseases with a stepped-care approach, the drug history of patients, as available from some databases, can show channeling of drugs to patients with markers of relatively severe disease.
[55] occurs in the treatment of CML when blood cell counts return to normal, there are no immature cells visible in the blood, and the spleen returns to normal size
[56] a form of spectroscopy based on the differential absorption of left- and right-handed circularly polarized light. It can be used to help determine the structure of macromolecules (including the secondary structure of proteins and the handedness of DNA). 光学活性分子对左、右圆偏振光的吸收也不同，使左、右圆偏振光透过后变成椭圆偏振光，这种现象称为圆二色性

[57] randomized 8059 patients with OA or RA to celecoxib, 400 mg bid (double the recommended maximum dose for RA and 4 times the recommended maximum dose for OA), diclofenac 150 mg/d, or ibuprofen 2400 mg/d
[58] Class effect is usually taken to mean similar therapeutic effects and similar adverse effects, both in nature and extent. If such a class effect exists, then it makes decision-making easy: you choose the cheapest.
[59] Clinical equipoise is satisfied "if there is genuine uncertainty within the expert medical community — not necessarily on the part of the individual investigator — about the preferred treatment." Equipoise allows clinical investigators to continue a trial until they have enough statistical evidence to convince other experts of the validity of their results, without a loss of ethical integrity on the part of the investigators
[60] A medical researcher in charge of carrying out a clinical trial's protocol
[61] A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.
[62] also known as "CDF/cdf", or "C. diff", is a species of Gram-positive bacteria of the genus Clostridium that causes severe diarrhea and other intestinal disease when competing bacteria in the gut flora have been wiped out by antibiotics.
[63] In epidemiology, a group of individuals with some characteristics in common
[64] A clinical trial conducted primarily through primary-care physicians rather than academic research facilities
[65] A method of providing experimental therapeutics prior to final FDA approval for use in humans. This procedure is used with very sick individuals who have no other treatment options.
[66] Broad range of healing philosophies, approaches, and therapies that Western (conventional) medicine does not commonly use to promote well-being or treat health conditions. Examples include acupuncture, herbs, etc. Internet Address:
[67] Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical information. The trial participants' consent to the use of records for data verification purposes should be obtained prior to the trial and assurance must be given that confidentiality will be maintained.
[68] In developing antibody-drug conjugates, an anticancer drug (e.g. a cell toxin or cytotoxin) is coupled to an antibody that specifically targets a certain tumor marker
[69] the molecular and genetic alterations (context) that cause cancer cells to be particularly sensitive (vulnerable) to a drug or combination of drugs--the "context of vulnerability; the genetic configuration in a patient's **tumor** that makes it susceptible to a specific drug.
[70] A specific circumstance when the use of certain treatments could be harmful
[71] The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo
[72] Control is a standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.
[73] A simple and straightforward indicator of process capability
[74] Explain FDA policy on regulatory issues related to FDA laws or regulations and advise field inspection/compliance staff on FDA standards and procedures to be applied when determining industry compliance
[75] FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities.
[76] Adjustment of Cp for the effect of non-centered distribution
[77] A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality
[78] an amino acid, $C_4H_9N_3O_2$

[79] a crystalline end product of creatine metabolism, $C_4H_7N_3O$, occurring in urine, muscle, and blood

[80] A third type of scientific research is urgently needed, one that is complementary to basic and translational research, but focuses on providing new tools and concepts for the medical product development process -- the steps that must be taken to get from selection of a laboratory prototype to delivery of an effective treatment to patients. We call this highly targeted and pragmatic research critical path research because it directly supports the critical path for product development success

[81] 辉瑞公司治疗肺癌的新药 XALKORI 胶囊获得美国食品药品管理局(FDA)批准，这是第一个对间变性淋巴瘤激酶(ALK)进行靶向治疗的药品，可用于治疗 ALK 阳性的局部晚期或转移的非小细胞肺癌

[82] one where patients are given all of the medications to be studied, or one medication and a placebo in random order. These studies are generally done on patients with chronic diseases to control their symptoms.

[83] a protein found in the blood, the levels of which rise in response to inflammation

[84] The cancer chemotherapic docetaxel has been used as treatment for CRPC with a median survival benefit of 2 to 3 months.[120][121] A second-line chemotherapy treatment is cabazitaxel.[122] A combination of bevacizumab, docetaxel, thalidomide and prednisone appears effective in the treatment of CRPC

[85] The 'Common Technical Document' or 'CTD' is a set of specification for application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States. It was developed by the European Medicines Agency (EMEA, Europe), the Food and Drug Administration (FDA, USA) and the Ministry of Health, Labour and Welfare (Japan).

[86] Cover your ass (CYA) or cover your own ass (CYOA) describes professional and organizational practices that serve to protect oneself from legal and administrative penalties, criticism, or other punitive measures. A tactic used by employees to share blame or divert blame should something go wrong. "Covering your ass" is usually done in big projects where an employee may choose to avoid taking credit for doing a critical part of the project just in case it goes bad. C.Y.A. phrase [1950s and still in use] (originally U.S. military): A phrase meaning look after yourself before worrying about anyone else, be it colleagues, customers, the larger world, whatever; the basic admonition to anyone, at any level, working in government or a large corporation.

[87] blueness or lividness of the skin, as from imperfectly oxygenated blood

[88] is a very large and diverse superfamily of hemoproteins found in all domains of life

[89]如果发炎太厉害，身体就会排出过量的 cytokine

[90] An independent committee, composed of community representatives and clinical research experts, that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

[91] A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial

[92] The Data Universal Numbering System, abbreviated as DUNS or D-U-N-S, is a proprietary system developed and regulated by Dun & Bradstreet (D&B) that assigns a unique numeric identifier, referred to as a "DUNS number" to a single business entity. It was introduced in 1963 to support D&B's credit reporting practice. It is a common standard worldwide

[93] the synthesis of complex molecules from simple molecules such as sugars or amino acids, as opposed to their being recycled after partial degradation

[94] Prior to the FDA Modernization Act of 1997 (FDAMA), all devices on the market as of May 28, 1976 were classified according to their risk. Any new type of device that was found not substantially equivalent for a reason other than performance data required a Premakert Approval (PMA) application. A device could be moved out of Class III only through a reclassification process. The De Novo process provides a possible route to market low risk device types. This process does not apply to devices that have been classified by regulation into class III, i.e., preamendment class III devices or class III devices for which a premarket approval application or a reclassification petition is appropriate.

FDAMA amended Section 513(f)(2) to provide a new mechanism for classifying new Class III devices for which there is no predicate device. The De Novo process is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable

predicate device. It allows the recipient of an NSE (not substantially equivalent) letter to request a risk-based classification determination to be made for the device.
An applicant of a 510(k) who receives a Not Substantially Equivalent (NSE) determination placing the device into a Class III category can request a de novo classification of the product into Class I or II. The request must be in writing and sent within 30 days from the receipt of the NSE determination. In addition, the request should include a description of the device, labeling for the device, reasons for the recommended classification (into Class I or II), and information to support the recommendation. The de novo process has a 60 day review period. If FDA classifies the device into Class I or II, the applicant will then receive an approval order to market the device. This device type can then be used as a predicate device for other firms to submit a 510(k). However, if FDA determines that the device will remain in the Class III category, the device cannot be marketed until the applicant has obtained an approved PMA.

[95] The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. Working within the design space is not considered as a change. Movement out of the design space is considered to be a change and would normally initiate a regulatory postapproval change process. Design space is proposed by the applicant and is subject to regulatory assessment and approval

[96] (Cmax-Cmin)/Cave

[97] The dose of a drug that produces side effects severe enough to prevent larger doses being given.

[98]持有者为谨慎起见而准备的保密资料，可以包括一个或多个人用药物在制备、加工、包装和贮存过程中所涉及的设备、生产过程或物品。只有在 DMF 持有者或授权代表以授权书的形式授权给 FDA，FDA 在审查 IND、NDA、ANDA 时才能参考其内容

[99] is the design of any information-gathering exercises where variation is present, whether under the full control of the experimenter or not. However, in statistics, these terms are usually used for controlled experiments.

[100] A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.

[101] 在临床试验中，当两种处理（如药物的剂型、给药方法等）不能做到相同时，使试验保持双盲的一种技术。即为试验药与对照药各准备一种安慰剂，以达到试验组与对照组在用药的外观与给药方法上的一致。

[102] A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called double-masked study. See Blinded Study, Single-Blind Study, and Placebo.

[103]指由于任何原因不能继续按试验方案进行到所要求的最后一次随访的受试者。

[104] Drug response includes the processes of drug absorption and disposition (e.g., pharmacokinetics (PK)), and drug effects (e.g., pharmacodynamics (PD), drug efficacy, and adverse effects of drugs).

[105] A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

[106] FDA 中的一个特别办公室

[107] Sarepta Therapeutics Inc. (formerly AVI BioPharma Inc.) wowed clinicians and investors Tuesday with Phase IIb findings for its exon-skipping compound, eteplirsen, in Duchenne's muscular dystrophy (DMD).

[108] Summary criteria for participant selection; includes Inclusion and Exclusion criteria. (See Inclusion/Exclusion Criteria)

[109] over 100 people died after using a drug formulated with a toxic, untested solvent diethylene glycol instead of ethanol.

[110] Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

[111] An epitope, also known as antigenic determinant, is the part of a macromolecule that is recognized by the immune system, specifically by antibodies, B cells, or T cells. The part of an antibody that recognizes the epitope is called a paratope 抗体结合部位, 抗体决定簇;〔抗原〕互补位

[112]是确认两种或多种治疗效果的差别大小在临床上并无重要意义的试验

[113] Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.
[114] inert substance used as a diluent or vehicle for a drug
[115] any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants
[116] The fragment antigen-binding is a region on an antibody that binds to antigens.
[117] Fabry disease is caused by the lack of or faulty enzyme needed to metabolize lipids, fat-like substances that include oils, waxes, and fatty acids. The disease is also called alpha-galactosidase-A deficiency. A mutation in the gene that controls this enzyme causes insufficient breakdown of lipids, which build up to harmful levels in the eyes, kidneys, autonomic nervous system, and cardiovascular system. Fabry disease is one of several lipid storage disorders and the only X-linked lipid storage disease. Since the gene that is altered is carried on a mother's X chromosome, her sons have a 50 percent chance of inheriting the disorder and her daughters have a 50 percent chance of being a carrier. A milder form is common in females, and occasionally some affected females may have severe manifestations similar to males with the disorder
[118] Fellows are recommended by their peers, endorsed by their local chapter leadership, and reviewed by a national credentials subcommittee
[119] a process designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious diseases.
[120] Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.
[121] Failure Mode and Effects Analysis (FMEA) was one of the first systematic techniques for failure analysis. It was developed by reliability engineers in the 1950s to study problems that might arise from malfunctions of military systems. A FMEA is often the first step of a system reliability study. It involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes, and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. There are numerous variations of such worksheets. A FMEA is mainly a qualitative analysis; An FMEA is an inductive reasoning (forward logic) single point of failure analysis.
[122] A structured, organized method for determining the relationship
between factors affecting a process and the output of that process. Also known as "Design of Experiments." DOE
[123] Fault tree analysis (FTA) is a top down, deductive failure analysis in which an undesired state of a system is analyzed using Boolean logic to combine a series of lower-level events
[124] 指尽可能接近符合意向性治疗原则的理想的受试者集。该数据集是从所有随机化的受试者中以最少的和合理的方法剔除受试者后得出的。
[125] It is produced by the liver cell microsomes and is widely distributed in cells that are involved in the secretion and absorption of bile. It is a useful laboratory marker as an indicator of early liver cell damage or cholestatic disease
[126] stimulates the bone marrow to produce more white blood cells
[127] The phenotypic manifestation of a gene or genes by the processes of genetic transcription and genetic translation
[128] Gene regulation is the process of turning genes on and off. During early development, cells begin to take on specific functions. Gene regulation ensures that the appropriate genes are expressed at the proper times. Gene regulation can also help an organism respond to its environment. Gene regulation is accomplished by a variety of mechanisms including chemically modifying genes and using regulatory proteins to turn genes on or off.
[129] The genetic constitution (the genome) of a cell, an individual or an organism. The genotype is distinct from its expressed features, or phenotype
[130] 指在 HBV 聚合酶基因区检测出与耐药相关的基因突变，并发生相关的氨基酸被替换

[131] unapproved drugs whose makers claim the drugs are "grandfathered" under older standards and therefore don't require approval under the current regulatory framework
[132] Granularity is the level of depth represented by the data in a fact or dimension table in a data warehouse. High granularity means a minute, sometimes atomic grade of detail, often at the level of the transaction.
[133]乃由旺盛增生的毛细血管及纤维结缔组织和各种炎性细胞组成，肉眼表现为鲜红色，颗粒状，柔软湿润，形似鲜嫩的肉芽故名
[134] In genetic epidemiology, a genome-wide association study (GWA study, or GWAS), also known as whole genome association study (WGA study, or WGAS) or common-variant association study (CVAS), is an examination of many common genetic variants in different individuals to see if any variant is associated with a trait.
[135]危害分析关键控制点(HACCP)是一个保证食品安全的预防性技术管理体系.它运用食品工艺学、微生物学、化学和物理学、质量控制和危险性评估等方面的原理和方法,对整个食品链,即食品原料的种植/饲养、收获、加工、流通和消费过程中实际存在和潜在的危害进行危险性评估,找出对最终产品质量影响的关键控制点
[136] A haplotype is a set of DNA variations, or polymorphisms, that tend to be inherited together. A haplotype can refer to a combination of alleles or to a set of single nucleotide polymorphisms (SNPs) found on the same chromosome.
[137] 糖尿病患者最容易被检测的生物标志物之一; a test that measures the amount of glycated hemoglobin in your blood
[138] The bodily system of organs and tissues, primarily the bone marrow, spleen, tonsils, and lymph nodes, involved in the production of blood.
[139] 赫赛汀是一种重组 DNA 衍生的人源化单克隆抗体，选择性地作用于人表皮生长因子受体-2(HER2)的细胞外部位。在原发性乳腺癌患者中观察到有 25%-30%的患者 HER2 过度表达。研究表明，HER2 过度表达的肿瘤患者较无过度表达的无病生存期短。赫赛汀?在体外及动物实验中均显示可抑制 HER2 过度表达的肿瘤细胞的增殖。另外，赫赛汀是抗体依赖的细胞介导的细胞毒反应(ADCC)的潜在介质。在体外研究中，赫赛汀介导的 ADCC 被证明在 HER2 过度表达的癌细胞中比 HER2 非过度表达的癌细胞中更优先产生。
[140] a form of column chromatography used frequently in biochemistry and analytical chemistry. It is also sometimes referred to as high-pressure liquid chromatography. HPLC is used to separate components of a mixture by using a variety of chemical interactions between the substance being analyzed (analyte) and the chromatography column
[141] an inorganic mineral primarily consisting of calcium and phosphate, is the principal inorganic component of bone
[142] Hy Zimmerman, a legendary pioneer in DILI research, observed that the combination of severe acute hepatocellular injury with clinical jaundice (i.e., total bilirubin > 2.5 mg/dL) was associated with a poor prognosis (i.e., a case-fatality rate of ~10%) for many drugs. This observation has been called Hy's rule and is often used by the U.S. Food and Drug Administration and other regulatory agencies in the evaluation of investigational drugs to show potential hepatotoxic signals during clinical trials.
[143] An immune complex is formed from the integral binding of an antibody to a soluble antigen. The bound antigen acting as a specific epitope, bound to an antibody is referred to as a singular immune complex
[144] ability of a substance to provoke an immune response
[145] An antibody (Ab), also known as an immunoglobulin (Ig), is a large Y-shaped protein produced by B-cells that is used by the immune system to identify and neutralize foreign objects such as bacteria and viruses.
[146] In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body
[147] The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

[148] an ultra-long-acting beta-adrenoceptor agonist developed by by Novartis.It was approved by the European Medicines Agency (EMA) under the trade name Onbrez on November 30, 2009, and by the United States Food and Drug Administration (FDA), under the trade name Arcapta Neohaler, on July 1, 2011. It needs to be taken only once a day, unlike the currently available formoterol and salmeterol. It is licensed only for the treatment of chronic obstructive pulmonary disease (COPD) (long-term data in patients with asthma are thus far lacking). It is delivered as an aerosol formulation through a dry powder inhaler

[149] the prothrombin time ratio that would have been obtained if a standard reagent had been used in a prothrombin time determination; the prothrombin time ratio is expressed as the patient prothrombin time divided by the mean of the prothrombin time reference interval

[150] A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected.

[151] In epidemiology, an intention to treat (ITT) analysis (sometimes also called Intent to Treat) is an analysis based on the initial treatment intent, not on the treatment eventually administered. ITT analysis is intended to avoid various misleading artifacts that can arise in intervention research. For example, if people who have a more refractory or serious problem tend to drop out at a higher rate, even a completely ineffective treatment may appear to be providing benefits if one merely compares those who finish the treatment with those who were never enrolled in it.

[152] 指正式完成临床试验前，按事先制订的分析计划，比较处理组间的有效性和安全性所作的分析

[153] Primary interventions being studied: types of interventions are Drug, Gene Transfer, Vaccine, Behavior, Device, or Procedure

[154] a chromosome rearrangement in which a segment of a chromosome is reversed end to end. An inversion occurs when a single chromosome undergoes breakage and rearrangement within itself.

[155] 用于临床试验中的试验药物、对照药品或安慰剂

[156] a fifteen-member United States Government agency created in 2010 by sections 3403 and 10320 of the Patient Protection and Affordable Care Act which has the explicit task of achieving specified savings in Medicare without affecting coverage or quality. Under previous and current law, changes to Medicare payment rates and program rules are recommended by MedPAC but require an act of Congress to take effect. The new system grants IPAB the authority to make changes to the Medicare program with the Congress being given the power to overrule the agency's decisions through supermajority vote.

[157] An In-vitro in-vivo correlation (IVIVC) has been defined by the U.S. Food and Drug Administration (FDA) as "a predictive mathematical model describing the relationship between an in-vitro property of a dosage form and an in-vivo response".

[158] JAK（janus kinase）是一类非受体酪氨酸激酶家族，JAK 的底物为 STAT，即信号转导子和转录激活子，STAT 被 JAK 磷酸化后发生二聚化，然后穿过核膜进入核内调节相关基因的表达，这条信号通路称为 JAK-STAT 途径。

[159] Section 201 of the FD&C Act distinguishes between label and labeling Certain provisions in Chapter V of the FD&C Act apply specifically to the "label" of the device, others are related to its "labeling." These terms are related, but not interchangeable. Of the two, the term "label" is more restricted. Generally, it consists of that part of the display confined to the device itself. On the other hand, "labeling" deals with the label on the device, and descriptive and informational literature that accompanies the device.

[160] prescription medicine used together with other medicines to treat partial onset seizures in people 13 years of age and older

[161] LASIK stands for Laser-Assisted *In Situ* Keratomileusis and is a procedure that permanently changes the shape of the cornea, the clear covering of the front of the eye, using an excimer laser. A mechanical microkeratome (a blade device) or a laser keratome (a laser device) is used to cut a flap in the cornea.

[162] 对临床试验中有效性指标缺失值的一种估计方法，即采用缺失值之前最接近一次的观察数据来代替缺失值。

[163] the dosage (in milligrams per surface area) at which 10% of the mouse population died

[164] fda 批准 revlimid 用于治疗骨髓增生异常综合征;美国食品药品管理局（fda）批准了美国细胞基因公司的来那度胺（lenalidomide/revlimid）。 revlimid 为口服制剂 evlimid（lenalidomide）是由 celgene 公司研发的用于治疗致死性血液疾病以及癌症的药物。该品是用于治疗孕吐曾引起数以千

计的婴儿出生缺陷沙利度胺（thalidomide）的加强版，具有抗癌潜力。与沙利度胺相比，其不良反应更少，研究证明其不会引起婴儿出生缺陷。 2005 年 9 月，fda 肿瘤药物顾问委员会建议以 revlimid 用于治疗输液依赖型贫血症。输液依赖型贫血症是由于 5q 染色体异常相关的骨髓增生异常综合征所引起的。10 月，欧洲药品管理局接受了 revlimid 的上市申请。同时，该品在欧洲获得了治疗骨髓增生异常综合征的罕用药物和治疗多发性骨髓瘤的罕用药物的地位。

[165] the lowest amount of analyte in a sample that can be quantitatively determined with suitable precision and accuracy; Suppose you are at an airport with lots of noise from jets taking off. If the person next to you speaks softly, you will probably not hear them. Their voice is less than the LOD. If they speak a bit louder, you may hear them but it is not possible to be certain of what they are saying and there is still a good chance you may not hear them. Their voice is >LOD but <LOQ. If they speak even louder, then you can understand them and take action on what they are saying and there is little chance you will not hear them. Their voice is then >LOD and >LOQ.

[166]是指动物死亡后，血液循环停止，血液停留在尸体的低处，红血球从血清中进一步分离沉积，在表皮下形成可见的紫红色淤斑现象

[167] a heart rhythm disorder that can potentially cause fast, chaotic heartbeats

[168]Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug and can encompass a wide range of claims. Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. Exclusivity was designed to promote a balance between new drug innovation and generic drug competition.

[169] used to report adverse event data from clinical trials, as well as post-marketing and pharmacovigilance

[170] products from the simple toothbrush to complex devices such as implantable brain pacemakers. The CDRH also oversees the safety performance of non-medical devices which emit certain types of electromagnetic radiation. Examples of CDRH-regulated devices include cellular phones, airport baggage screening equipment, television receivers, microwave ovens, tanning booths, and laser products

[171] The MedWatch program provides important safety information associated with FDA-regulated products. Under MedWatch, health care professionals and consumers submit reports to FDA when they find a problem with a drug, medical device, biologic, or other FDA-regulated products.

[172] 是一种分子量为 40 kDa 的细胞表面糖蛋白，高表达于多种 肿瘤组织中，也可表达于正常 胸膜、心包和腹膜的间皮细胞中

[173] In statistics, a meta-analysis combines the results of several studies that address a set of related research hypotheses. In its simplest form, this is normally by identification of a common measure of effect size, for which a weighted average might be the output of a meta-analyses. Here the weighting might be related to sample sizes within the individual studies. More generally there are other differences between the studies that need to be allowed for, but the general aim of a meta-analysis is to more powerfully estimate the true "effect size" as opposed to a smaller "effect size" derived in a single study under a given single set of assumptions and conditions.

[174] For example, the mechanism of action of aspirin involves irreversible inhibition of the enzyme cyclooxygenase, which suppresses the production of prostaglandins and thromboxanes, thereby reducing pain and inflammation.

[175] On Dec. 11, 2007, the U.S. Department of Health and Human Services (HHS) and the State Food and Drug Administration (SFDA) of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of drugs, excipients and medical devices exported to the U.S. from China. gentamicin sulfate (an antibiotic), atorvastatin (a cholesterol-lowering drug), sildenafil (a drug for erectile dysfunction), dietary supplements intended for erectile dysfunction, human growth hormone, oseltamivir (an antiviral product), cephalosporins (a class of antibiotics) manufactured in facilities that also manufacture non-cephalosporin drugs, glycerin, glucose test strips, and condoms

[176] 由申办者任命并对申办者负责的具备相关知识的人员，其任务是监查和报告试验的进行情况和核实数据

[177] a 6 month, randomized, double blind, placebo controlled study to investigate whether concurrent administration of misoprostol would significantly reduce the occurrence of serious upper GI complications in patients with rheumatoid arthritis (RA) who were receiving NSAID

[178] an immunosuppressant used extensively in transplant medicine

[179] Study of the natural development of something (such as an organism or a disease) over a period of time.

[180] An application submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed - for a license to market the drug for a specified indication.
[181] 2008 年 3 月 21 日，美国 FDA 和美敦力公司（Medtronic, Inc）发布通告，对美敦力公司的 Neuromodulation 植入式输液泵进行 I 级召回
[182] An application submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed - for a license to market the drug for a specified indication.
[183] The United Kingdom's National Institute for Health and Clinical Excellence (NICE) is often cited as a model in discussions of potential uses of comparative effectiveness research in the United States. NICE makes recommendations to the British National Health Service (NHS) on coverage for certain technologies or treatments based on cost–effectiveness analysis
[184] (marketed under the trade names Mogadon, Alodorm, Hypnotex, Remnos, Pacisyn, Eunoctin and Pelson)
[185] In toxicology it is specifically the highest tested dose or concentration of a substance (i.e. a drug or chemical) or agent (e.g. radiation), at which no such adverse effect is found in exposed test organisms where higher doses or concentrations resulted in an adverse effect
[186] a noninferiority trial aims to demonstrate that the test product is not worse than the comparator by more than a pre-specified, small amount. This amount is known as the non-inferiority margin, or delta (Δ).
[187] The objective of a non-inferiority trial is sometimes stated as being to demonstrate that the test product is not inferior to the comparator
[188] comes from the Greek word *nosokomeion* (νοσοκομείον) meaning hospital (*nosos* = disease, *komeo* = to take care of
[189] a statistical hypothesis to be tested and accepted or rejected in favor of an alternative; *specifically* **:** the hypothesis that an observed difference (as between the means of two samples) is due to chance alone and not due to a systematic cause; A hypothesis that says that there is no difference, or that asserts the existing knowledge, and is tested for refutation by the study.
[190] the quantity of a radiological or pharmacological treatment that will produce the desired effect with acceptable toxicity
[191] A drug prescribed for conditions other than those approved by the FDA.
[192] Adverse toxicologic effects are categorized as chemical-based, on-target, or off-target effects. Chemical-based toxicity is defined as toxicity that is related to the physicochemical characteristics of a compound and its effects on cellular organelles, membranes, and/or metabolic pathways. On-target refers to exaggerated and adverse pharmacologic effects at the target of interest in the test system. Off-target refers to adverse effects as a result of modulation of other targets; these may be related biologically or totally unrelated to the target of interest.
[193] A clinical trial in which doctors and participants know which drug or vaccine is being administered.
[194] is a new office within CDER that creates a single unit dedicated to product quality. The new structure, to be stood-up in January 2015, is expected to provide better alignment among all drug quality functions at CDER, including review, inspection, and research, but not enforcement.
[195] The publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal® Tablets and Librax® Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the List contains therapeutic equivalence evaluations for approved multisource prescription drug products
[196] An FDA category that refers to medications used to treat diseases and conditions that occur rarely.
[197] To begin the FDA approval process, the generic applicant must: 1) certify in its ANDA that the patent in question is invalid or is not infringed by the generic product (known as "paragraph IV certification")
[198] Parametric release is defined as a sterility release procedure based upon effective control, monitoring, and documentation of a validated sterilization process cycle in lieu of release based upon end-product sterility testing (21 CFR 211.167). All parameters within the procedure must be met before the lot is released

[199] In partial seizures the seizure is generated in and affects just one part of the brain - the whole hemisphere or part of a lobe
[200] defined by the United States Food and Drug Administration (FDA) as a mechanism to design, analyze, and control pharmaceutical manufacturing processes through the measurement of Critical Process Parameters (CPP) which affect Critical Quality Attributes (CQA).
[201] in order to stimulate product development and innovation, Congress in 1984 enacted Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) to extend patent life to compensate patent holders for marketing time lost while developing the product and awaiting government approval
[202] In the United States, employers are required to withhold federal income tax, plus one-half of the Social Security tax, and one-half of the Medicare tax. Together, the employer's and employee's shares of the Social Security and Medicare taxes are known as the FICA tax
[203] commonly known as coronary angioplasty or simply angioplasty, is a non-surgical procedure used to treat the stenotic (narrowed) coronary arteries of the heart found in coronary heart disease.
[204] 研究药物对机体的作用及其规律，阐明药物防治疾病的机制
[205] The PDP is essentially a contract that describes the agreed upon details of design and development activities, the outputs of these activites, and acceptance criteria for these outputs. It establishes reporting milestones that convey important information to the FDA as it is generated, where they can be reviewed and responded to in a timely manner. The sponsor would be able to execute their PDP at their own pace, keeping FDA informed of its progress with these milestone reports. A PDP that has been declared completed by FDA is considered to have an approved PMA
[206] Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations.
[207] Analysis based only on those patients who complete the entire treatment protocol
[208]又称有效病例、有效样本、可评价病例样本。是由充分依从于试验方案的病例子集所产生的数据集，是全分析集的一个子集。依从性包括以下一些考虑，如：所接受的治疗、主要指标测量的可行性以及未对试验方案有大的违反等。
[209] In 1993, a large outbreak of foodborne illness caused by the bacterium Escherichia coli O157:H7 occurred in the western United States. In this outbreak, scientists at CDC performed DNA "fingerprinting" by pulsed-field gel electrophoresis (PFGE) and determined that the strain of E. coli O157:H7 found in patients had the same PFGE pattern as the strain found in hamburger patties served at a large chain of regional fast food restaurants. Prompt recognition of this outbreak and its cause may have prevented an estimated 800 illnesses.
[210] 研究药物对机体的作用及其规律，阐明药物防治疾病的机制
[211] Pharmacogenetics (PGt) is a subset of pharmacogenomics (PGx) and is defined as: the study of variations in DNA sequence as related to drug response
[212] broadly refers to the study of variations of DNA and RNA characteristics as related to drug response
[213] The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.
[214] pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines
[215] The PharMetrics Integrated Database is the largest non-Payer owned integrated claims database of commercial insurers in the U.S. This de-identified, Integrated Database includes medical and pharmacy claims for more than 70 million members from more than 100 health plans across the U.S. The Integrated Database includes inpatient and outpatient claims, diagnoses and procedures based on ICD-9 and CPT-4 codes, as well as retail and mail order pharmacy claims. The records in the PharMetrics Integrated Database are representative of the national commercially insured population, and include a variety of demographic measures such as age, gender and plan type. This longitudinal data has an average member enrollment period of two years.
[216] The appearance of an individual, which results from the interaction of the person's genetic makeup and his or her environment. By contrast, the genotype is merely the genetic constitution (genome) of an individual. For example, if a child's genotype includes the gene for osteogenesis imperfecta (brittle bone disease), minimal trauma can cause fractures. The gene is the genotype, and the brittle bones themselves are the phenotype

[217] 指经体外药物敏感实验证实，发生 HBV 聚合酶基因突变的病毒对某种药物的敏感性下降
[218] An individual exhibiting phocomelia
[219]光动力疗法（ Photodynamic Therapy， PDT ）原称光辐射疗法（ Photoradiation Therapy， PRT ）、光化学疗法（ Photochemical Therapy， PCT ），它是利用光动力反应进行疾病诊断和治疗的一种新技术。在临床上，光动力疗法通常仅指光动力治疗，而将光动力诊断称为荧光诊断（ Photodynamic Diagnosis， PDD ）。
光动力反应的基本过程：生物组织中的内源性或外源性光敏物质受到相应波长（可见光、近红外光或紫外光）光照时，吸收光子能量，由基态变成激发态，处于激发态的光敏物质很不稳定，迅速经过物理退激或化学退激过程释放出能量而返回基态，其物理退激过程可以产生荧光，通过分析荧光光谱能进行疾病的诊断；其化学退激过程可以生成大量活性氧，其中最主要的是单线态氧，活性氧能与多种生物大分子相互作用，损伤细胞结构或影响细胞功能，因而产生治疗作用。

[220] The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine
[221]对少数有特别价值的高风险药品，实行使用、检验相关信息链接，以保证医药学工作者正确处方、正确调剂、合理用药，发挥药品最大效益，实现风险最小化
[222] A drug's efficiency may be affected by the degree to which it binds to the proteins within blood plasma. The less bound a drug is, the more efficiently it can traverse cell membranes or diffuse. Common blood proteins that drugs bind to are human serum albumin, lipoprotein, glycoprotein, and α, β, and γ globulins
[223] Pleiotropy occurs when one gene influences two or more seemingly unrelated phenotypic traits, an example being phenylketonuria, which is a human disease that affects multiple systems but is caused by one gene defect. Consequently, a mutation in a pleiotropic gene may have an effect on some or all traits simultaneously.
[224] As a requirement for approval or continued marketing of some medicines, FDA may require additional information in the form of post marketing commitments. These commitments are agreed to by a company with the FDA, and are used to gather additional information about a medicine's safety, efficacy, or optimal use. These agreements can be reached either before or after FDA has granted approval to a company to market a medicine
[225] In PoC trials, the drug is for the first time given to humans
[226] administration of many drugs together
[227] The number of patients enrolled in a study has a large bearing on the ability of the study to reliably detect the size of the effect of the study intervention. This is described as the "power" of the trial. The larger the sample size or number of participants in the trial, the greater the statistical power
[228] A simple and straightforward indicator of process performance
[229] Adjustment of Pp for the effect of non-centered distribution
[230] PPS 包括除中止治疗或对试验方案至少有一次大的违反的受试者之外的所有随机化的受试者。方案违反的确切定义将在数据审核时最终确定，一般包括以下几种情况：不符合入选标准、入选后存在干扰性治疗、依从性差、随访超出窗口期等。PPS 是本次研究疗效评价的次要数据集。
[231]新型血栓预防药物 Effient(prasugrel，普拉格雷)用于预防接受经皮冠状动脉介入(PCI)治疗后的冠脉综合症患者的血栓形成。Effient 帮助预防血小板凝聚成块，在接受 PCI 手术后使用阿司匹林与 Effient 已证明可降低冠脉综合症患者发生心血管事件的风险。
[232] Each agency publishing a proposed or final rule in the Federal Register is required by 1 CFR 18.12 to include a preamble that informs readers of the basis and purpose for the rule. The preamble must include the following information: Name of issuing agency，Action being taken by agency，Brief statements of the action being taken, the circumstances which created the need for action, and the intended effect of the action，Pertinent dates，Any relevant addresses，Agency contact information，Other information, as applicable
[233] A predicate rule is any requirement set forth in the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or any FDA regulation other than Part 11
[234] The Food and Drug Administration (FDA) is amending its combination product regulations to define "mode of action" (MOA) and "primary mode of action" (PMOA). Along with these definitions, the final rule sets forth an algorithm the agency will use to assign combination products to an agency component for

regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product

[235] is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a new drug application is reduced. The goal for completing a Priority Review is six months

[236] A precursor (forerunner) of a drug. A prodrug must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent. For example, sulfasalazine is a prodrug. It is not active in its ingested form. It has to be broken down by bacteria in the colon into two products -- 5-aminosalicylic acid (5ASA) and sulfapyridine -- before becoming active as a drug.

[237] After a period of development it is introduced or launched into the market; it gains more and more customers as it grows; eventually the market stabilises and the product becomes mature; then after a period of time the product is overtaken by development and the introduction of superior competitors, it goes into decline and is eventually withdrawn.

[238] A study that demonstrates an agent to have the desired biological effect on its target

[239] A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

[240] A characterised range of a process parameter for which operation within this range, while keeping other parameters constant, will result in producing a material meeting relevant quality criteria

[241] The Periodic Safety Update Report (PSUR) is required as part of the FDA Post Marketing Drug Risk Assessment (PMDRA) program

[242] a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle

[243] A prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product.

[244] Qualification is a process of assurance that the specific system, premises or equipment are able to achieve the predetermined acceptance criteria to confirm the attributes what it purports to do. Validation is establishing a documented evidence to provide a high degree of assurance that a specific system, process or facility will consistently produce a product meeting its predetermined specifications and quality attributes. Qualification is documented evidence that a specific equipment, facility or system is fit/ready for intended use. Validation is documenting that the way equipment, facility or system used will result in product meeting its predetermined specifications and quality attributes. Things are qualified: equipments, systems etc. Process/Procedures (the way we use things) are validated. Before you do validation on a process, you have to be sure that the equipment has passed qualification.

[245] The documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose

[246] The documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations.

[247] The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.

[248] The documented verification that the facilities, systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and product specification

[249] Confirming that the manufacturing process as designed is capable of reproducible commercial manufacturing.

[250] no batch of medicinal product can be released for sale or supply prior to certification by a QP that the batch is in accordance with the relevant requirements

[251] 美国联邦《防制不实请求法》规定的公益代位诉讼制度是为了防制政府合同的承包商通过提交虚假的请求谋取不当利益而设计的，所规范的对象涉及到以联邦政府资金支付的各种采购活动。这一制度允许知情人直接对有不实请求的法人或个人进行告发起诉，成功后将获得一定的酬金，并可以获得相应的权益保障。这一程序为美国国库挽回了大量损失，也取得了良好的社会效益

[252] Since the year 2000, an international committee promulgated these unified, easily applicable criteria for measuring tumor response using X-ray, CT and MRI

[253] An approved drug product to which new generic versions are compared to show bioequivalence.
[254] Reference sample: a sample of a batch of starting material, packaging material or finished product which is stored for the purpose of being analysed should the need arise during the shelf life of the batch concerned.
[255] 2012 年 9 月 27 日，美国品药品管理局（FDA）批准拜耳公司研发的新药 Regorafenib(瑞格非尼，商品名为 Stivarga)上市。Regorafenib 是一种新型的多激酶抑制剂，阻断促进肿瘤生长的多种酶，是多个肿瘤通路为作用靶点的多激酶阻滞剂，也是第一个在晚期结直肠癌中被证实有效的口服多激酶阻滞剂
[256] FDA 用于考核原料药或药物产品是否符合批准了的质量管理规格标准的整套步骤
[257] Retention sample: a sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes. For example, presentation, packaging, labelling, patient information leaflet, batch number, expiry date should the need arise during the shelf life of the batch concerned.
[258]是指动物死亡后，肌肉僵硬挛缩的现象
[259] FDA Approves Bayer's New Class of Drug Adempas® (riociguat) tablets to Treat Adults with PAH and Persistent, Recurrent or Inoperable CTEPH
[260] The FDA defines a *RiskMAP* as the "*strategic safety program designed to meet specific goals and objectives in minimizing known risks of a medication while preserving its benefits*"
[261] Syndrome characterized by muscle breakdown and necrosis, resulting in elevated. serum concentrations of creatine kinase (CK) 肌酸激酶
[262] Under the mutual recognition procedure, where the applicant seeks approval in additional member states (concerned member states) for a product already approved in an initial member state (the reference member state), the reference member state prepares an assessment report, which the concerned member states must approve or reject within 90 days.
[263] means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.
[264] Reference manual for FDA personnel
[265] is a measure used when assessing risk to help identify critical failure modes associated with your design or process
[266] Its name comes from the fact that F proteins on the surface of the virus cause the cell membranes on nearby cells to merge, forming syncytia
[267] an important regulatory tool to help CDER avoid unnecessary review of incomplete applications or certain applications that are submitted as an NDA but should have been submitted as an abbreviated new drug application (ANDA).
[268] Salvage chemotherapy is a somewhat morbid term and little used by medical professionals interacting with patients. The phrase is used in medical journals written in cold dispassionate language where it refers to chemotherapy given to a patient when other options are exhausted. The attempt is to "salvage" the person's life with last ditch measures.
[269] Protein, calcium and heat-sensitive vitamins can be added directly to products with supercritical fluid extrusion
[270] A seeding trial or marketing trial is a form of marketing, conducted in the name of research, designed to target product sampling towards selected consumers. In medicine, seeding trials are clinical trials or research studies where the primary objective is to introduce the concept of a particular medical intervention—such as a pharmaceutical drug or medical device—to physicians, rather than to test a scientific hypothesis. In software, seeding trials are commonly termed beta-testing
[271] In response to the FDA Amendments Act (FDAAA) of 2007, in May 2008 the FDA launched the Sentinel Initiative. Sentinel enhances the FDA's ability to proactively monitor the safety of medical products after they have reached the market and complements the Agency's existing Adverse Event Reporting System.
[272] http://www.sda.gov.cn/
[273] shows the number of patients who are low, normal, or high at baseline and at selected time intervals.
[274] seeks to improve the quality of process outputs by identifying and removing the causes of defects (errors) and minimizing variability in manufacturing and business processes. It uses a set of quality management

methods, including statistical methods 是一套商业管理战略，最初于 1986 年由摩托罗拉创立。后来由于杰克•韦尔奇（Jack Welch，時任 GE 執行長）的推广让六西格玛于 1995 年成为通用電氣的核心管理思想，今天广泛应用于很多行业中

[275]拜耳药业开发的多靶点新药 Sorafenib (索拉非尼，商品名 Nexavar)2005 年 12 月经美国 FDA 批准作为治疗晚期肾癌的一线药物上市

[276] Upon request, FDA will evaluate within 45 days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Three types of protocols related to PDUFA products are eligible for this special protocol assessment under the PDUFA goals: (1) animal carcinogenicity protocols, (2) final product stability protocols, and (3) clinical protocols for phase 3 trials whose data will form the primary basis for an efficacy claim if the trials had been the subject of discussion at an end-of-phase 2/pre-phase 3 meeting with the review division

[277] is applied to a drug that offers at most, only minor improvement over existing marketed therapies. The 2002 amendments to PDUFA set a goal that a Standard Review of a new drug application be accomplished within a ten-month time frame.

[278]Treatment regimen or medical management based on state of the art participant care.

[279] regulates many aspects of growth, survival and differentiation in cells. The transcription factors of this family are activated by Janus kinase (or 'Just Another Kinase', JAK) and dysregulation of this pathway is frequently observed in primary tumours and leads to increased angiogenesis, enhanced survival of tumours and immunosuppression. Gene knockout studies have provided evidence that STAT proteins are involved in the development and function of the immune system and play a role in maintaining immune tolerance and tumour surveillance

[280] A primary or secondary outcome used to judge the effectiveness of a treatment.

[281] The primary investigative techniques used in an observational protocol; types are Purpose, Duration, Selection, and Timing.

[282] Surrogate markers are used when the primary endpoint is undesired (e.g., death), or when the number of events is very small, thus making it impractical to conduct a clinical trial to gather a statistically significant number of endpoints. "Death from heart disease" is the endpoint of interest, but "cholesterol" is the surrogate marker.

[283] first-line therapy for metastatic Renal Cell Carcinoma

[284] Sustained virologic response (SVR) is defined as aviremia 24 weeks after completion of antiviral therapy for chronic hepatitis C virus (HCV) infection.

[285] Synagis 是一种人源化的单克隆抗体，于 1998 年获 FDA 批准用于防止呼吸道合胞病毒（RSV）感染高危婴幼儿因 RSV 而引起的严重下呼吸道疾病。Synagis 是首个获准用于防止此类感染的单克隆抗体，也是该类药物中首个可以安全用于儿科患者的药物

[286] 60 年代初，在联邦德国等国家，孕妇因服用反应停而引致成千上万例海豹肢畸胎

[287] 1 : the range of dosage of a drug or of its concentration in a bodily system that provides safe effective therapy <the narrow therapeutic window…the effect may go from therapeutic to toxic with an increase of just 10 micrograms per milliliter [in] blood concentration—Lisa Davis>
2 : a usually short time interval (as after a precipitating event) during which a particular therapy can be given safely and effectively <has a narrow therapeutic window: the drug must be given within three hours of a stroke in order to be effective—Genesis Report-RX>

[288] is the most important type of endpoint that is widely used in clinical cancer research

[289] Chromatography may be preparative or analytical. Preparative chromatography seeks to separate the components of a mixture for further use (and is thus a form of purification).

[290] tPA is used in clinical medicine to treat only embolic 栓塞性中风 or thrombolytic stroke 溶解血栓性中风. Use is contraindicated in hemorrhagic stroke and head trauma

[291] A TPP is a format for a summary of a drug development program described in terms of labeling concepts. A TPP can be prepared by a sponsor and then shared with the appropriate FDA review staff to facilitate communication regarding a particular drug development program. Submission of a TPP is voluntary. The ideal version of what the sponsor would like to claim in labeling guides the design, conduct, and analysis of clinical trials to maximize the efficiency of the development program. Ideally, the final

version of the TPP will be similar to the annotated draft labeling submitted with a new drug application (NDA) or biologics license application (BLA)

[292] It is the responsibility of those of us involved in today's biomedical research enterprise to translate the remarkable scientific innovations we are witnessing into health gains for the nation

[293] A chromosome alteration in which a whole chromosome or segment of a chromosome becomes attached to or interchanged with another whole chromosome or segment, the resulting hybrid segregating together at meiosis; balanced translocations (in which there is no net loss or gain of chromosome material) are usually not associated with phenotypic abnormalities, although gene disruptions at the breakpoints of the translocation can, in some cases, cause adverse effects, including some known genetic disorders; unbalanced translocations (in which there is loss or gain of chromosome material) nearly always yield an abnormal phenotype

[294] Final regulations were issued in May of 1987 establishing conditions under which promising new drugs and biologics that have not yet been approved or licensed for sale may be made available to persons with serious and life threatening illnesses, for whom no comparable or satisfactory alternative drug or therapy is available. The regulation was revised and expanded in 2009, effective October 12, 2009. Treatment IND regulations allow the treatment use of an investigational drug for treatment under a treatment protocol, or treatment investigational new drug application (IND), outside of the clinical trial

[295] the clinical or genomic configuration in a patient's tumor that makes it susceptible to a specific drug

[296]The error of rejecting a true null hypothesis, i.e., concluding that there is a difference when actually there is none. The sample or data might be such that this lead to such a wrong conclusion. This error leads to false positive result 错误的拒绝无效假设，常用 α 表示。

[297]The error of wrongly concluding that there is no difference when actually some difference is present. This error leads to false negative result.错误的不拒绝无效假设，常用 β 表示。安全性数据集：安全性与耐受性评价时，用于汇总的受试者集称为安全性数据集。安全性数据集应包括所有随机化后至少接受一次治疗的受试者。

[298] FDA’s preferred UFI for a drug establishment is the Data Universal Numbering System D-U-N-
52 S (DUNS) number, assigned and managed by Dun and Bradstreet. The FDA has been using the
53 DUNS number as a registration number for drug establishments since the implementation of
54 electronic drug registration and listing

[299] UNITAID is a global health initiative in great part financed by a solidarity levy on airline tickets. Established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom, it provides sustainable funding in order to tackle inefficiencies in markets for medicines, diagnostics and prevention for HIV/AIDS, Malaria and Tuberculosis in developing countries.

[300] Cleaning validation is documented evidence that an approved cleaning procedure will provide equipment which is suitable for processing medicinal products

[301] Validation carried out during routine production of products intended for sale

[302] The documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce a medicinal product meeting its predetermined specifications and quality attributes.

[303]指按生产工艺规程进行的试生产，确认生产工艺及质量保证体系的可靠性

[304] Validation carried out before routine production of products intended for sale

[305] Validation of a process for a product which has been marketed based upon accumulated manufacturing, testing and control batch data.

[306] Porter 认为企业经营的每一活动，均对最终产品有所贡献，而企业赖以生存的便是端赖这些活动所创造的价值

[307] Refers to specific sequences of nucleotides, either DNA or RNA, that have been introduced into a gene therapy vector. The sequence includes all components of the gene therapy vector, the vector backbone, transgene(s), and regulatory elements.

[308] Vascular endothelial growth factor (VEGF) is an important signaling protein involved in both vasculogenesis (the formation of the embryonic circulatory system) and angiogenesis (the growth of blood vessels from pre-existing vasculature).

[309] a B-Raf enzyme inhibitor developed by Plexxikon (now part of Daiichi-Sankyo) and Genentech for the treatment of late-stage melanoma

[310] Verification is a Quality control process that is used to evaluate whether or not a product, service, or system complies with regulations, specifications, or conditions imposed at the start of a development phase. Verification can be in development, scale-up, or production. This is often an internal process.
Validation is a Quality assurance process of establishing evidence that provides a high degree of assurance that a product, service, or system accomplishes its intended requirements. This often involves acceptance of fitness for purpose with end users and other product stakeholders.
It is sometimes said that validation can be expressed by the query "Are you building the right thing?" and verification by "Are you building it right?" "Building the right thing" refers back to the user's needs, while "building it right" checks that the specifications be correctly implemented by the system.
[311] 9 8076 patients with RA were randomized to receive rofecoxib (Vioxx) 50 mg/d or naproxen 500 mg bid. Median duration of follow-up was 9 months, and ASA use was not permitted
[312] the quotient of the water vapor pressure of the substance, divided by the vapor pressure of pure water at the same temperature. Generally speaking, it is the amount of water available in the product to allow bacteria to live and grow.
[313] a phenomenon which states that the number of reported adverse reactions for a drug increases until the middle to end of the second year of marketing
[314]适应症用于择期髋关节或膝关节置换手术成年患者，以预防静脉血栓形成（VTE）；获准用于房颤患者预防卒中;溶栓抗凝药物
[315] In November 2012, the US Food and Drug Administration approved Xeljanz (tofacitinib) for patients with rheumatoid arthritis who have an insufficient or allergic response to methotrexate, as treatment for fiercely active rheumatoid arthritis. Tofacitinib, the active ingredient of Xeljanz, is an immunosuppressant that blocks the action of Janus kinases, enzymes that play a crucial role in the process of inflammation and damage of the joints. It is being studied for treatment of psoriasis, inflammatory bowel disease, and other immunological diseases, as well as for the prevention of organ transplant rejection. Tofacitinib was not approved by the European regulatory agencies because of concerns over efficacy and safety.
[316] Daclizumab (trade name Zenapax) is a therapeutic humanized monoclonal antibody to the alpha subunit of the IL-2 receptor of T cells. It is used to prevent rejection in organ transplantation, especially in kidney transplants
[317] allowed the FDA to request NIH-sponsored testing for pediatric drug testing
[318] also called Title 21, Chapter 9 of the United States Code (21 USC 9).
[319] passes incentives which gave pharmaceutical manufacturers a six-month patent term extension on new drugs submitted with pediatric trial data
[320] represented a "revolution" in FDA regulatory authority. The most important change was the requirement that all new drug applications demonstrate "substantial evidence" of the drug's efficacy for a marketed indication, in addition to the existing requirement for pre-marketing demonstration of safety
[321] in which the industry pays a fee for the review of the new product