FDA 词汇大全

2-(4-hydroxyphenyl) acetamide	2 -（ 4 -羟苯基）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)
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
accelerated approval	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	立案学校
accuracy	准确度
Accutane, a brand of isotretinoin	异维生素 A 酸; 异维 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; 对乙酰(xian)氨基酚
acid reflux	胃酸逆流
acidified food	酸化食品
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[1] = 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)[2]	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
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
adalimumab (Humira)	阿达木单抗
adaptive design	自适应设计
adaptive randomization	自适应随机
ADE = adverse drug event	药物不良事件
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
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
adulterated devices	掺假器械
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) [3]	药物不良反应
advisory	提醒
advocacy and support groups[4]	倡导和支持团体
AE = adverse event [5]	不良事件
AERS = Adverse Event Reporting System	不良事件报告系统
aflatoxin	黄曲霉素; 黄曲霉毒素
african sleeping sickness	非洲昏睡病; 非洲锥虫病
AFSSAPS = Agence Fran çaise de S écurit é Sanitaire des Produits de Sant é	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）

AHA = American Heart Association	美国心脏病协会
AIP = Application Integrity Policy[6] 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[7]	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[8] = ALP	碱性磷酸酶
allergenicity	致敏性
allergic shock	过敏性休克
allograft[9] transplantation	同种异体移植
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
amino acid sequence	氨基酸序列
aminoglycoside antibiotics	氨基糖苷类抗生素
amphetamines	安菲他明
amyotrophic lateral sclerosis = ALS	肌萎缩侧索硬化
analysis of covariance (ANCOVA)[10]	协变量分析
analysis sets	统计分析的数据集
analyte	待测物
anaphylaxis	过敏性反应
ANDA = abbreviated new drug application	简化新药申请
angina pectoris	心绞痛
angioplasty balloons	血管修复气囊
animal trial	动物试验
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
anti-inflammatory agents	抗炎药
anti-metabolites	干扰代谢药物
antimicrobial resistance	耐药性
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 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	原料药
aplastic anemia	再生障碍性贫血
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
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[11]	组
arrhythmia	心律不齐
arsenicals = arsenic compounds	砷化合物
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[12]	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 constancy CA	检验恒定性
assay sensitiviy AS	检验灵敏度
assistant investigator = AI	助理研究者
assurance[13]	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[14]	接受治疗分析
atopic dermatitis = AD	异位性皮炎
atorvastatin	阿伐他汀系列 cholesterol-lowering drug
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[15]	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

availability of water	有效水分
Avandia (rosiglitazone)[16]	商品名：文迪雅；通用名：罗格列酮
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
bench test	实验室试验
benefit	受益
benzodiazepine[17]	苯重氮基盐; 苯二氮卓类抗焦虑药[18]
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
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[19]	偏倚
bicohort study	双队列研究
bilirubin	胆红素
BIMO Bioresearch Monitoring Program	生物研究监测
bioavailability (F)[20]	生物利用度
biochemical drugs	生化药品

biocides	生物杀灭剂; 杀生物剂
biocompatibility[21]	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[22]	细菌薄膜, 生物膜
biologic[23]	生物制品
biological response modifiers BRM[24]	生物应答调节剂
biological therapeutic agents	生物治疗药剂
biomarker[25]	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
biosimilar[26]	生物类似物
bipolar	双极燥郁症
birth defect	出生缺陷, 新生儿缺陷, 先天缺陷
BLA = biologic license application	生物制品许可申请
blank control	空白对照
blend uniformity analysis	混合均匀度分析
blind[27]	盲法
blind codes	编制盲底
blind review[28]	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 thinner	血液稀释药
blood urea nitrogen = BUN	尿素氮
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 rheumatologist	美国国内认证的风湿病学家
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
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
breast implants, Polyurethane-coated	乳房植入物, 聚亚安酯包囊;隆胸
bromfenac	溴酚酸
BSE = Bovine Spongiform Encephalopathy; mad cow disease	疯牛病;牛海绵状脑病
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
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
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[29]	按人头付费
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

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
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
CCDS[30] = 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
CD = circular dichroism	圆二色谱
CDER = Center for Drug Evaluation & Research	药品审评和研究中心
CDR[31] 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[32]	CE 认证标记
Celebrex (celecoxib)	西乐葆；COX－2 特异性抑制剂; 塞来考昔
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[33]	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
channeling bias	渠道偏倚
CHB = customs house broker	报关行
chemotherapeutics in seafood (aquaculture drug residues)	药
Chi-square test/Chi-Square Goodness-of-Fit Test	卡方检验
Child-Pugh	Child-Pugh 分级标准
chlorambucil	苯丁酸氮芥
CHMP = Committee for Medicinal Products for Human Use	人用药品委员会
cholestatic hepatitis	胆汁郁积型肝炎
chromatography	色谱
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[34] = CD	圆二色谱;
cirrhosis	肝硬化
citation	传唤
CJD = Creutzfeld-Jakob disease	克-雅病
CL = clearance rate	清除率
claims	宣示
Cleaning Validation	清洗验证
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 equivalence	临床等效应
clinical hold	临床试验暂停通知
clinical investigator[35]	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[36]	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 significant results	有临床意义
closed loop system	闭路系统
Clostridium botulinum	肉毒杆菌
Clostridium sporogenes	产孢梭菌;
Cmax	峰浓度
CMC = chemistry, manufacturing and control	化学、生产和控制
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
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
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
COGS = Cost of goods sold	主营业务成本
cohort[37]	队列
cohort studies	队列研究
co-investigator = CI	合作研究者
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[38]	基于社区的临床试验
co-morbid condition	并存疾病; 共患病
COMP= Committee for Orphan Medicinal Products	罕用药委员会
comparison	对照
compassionate use[39]	体恤使用
competitive labeling	优越标签
complementary and alternative therapy[40]	补充性和非传统治疗
complete response	完全有效
complete response letter	完全回应函 (FDA 不批准通知)
compliance	合规；遵守；对遵守法规情况的监管
compliance, patient	病人依从性
composite variable	复合变量
compression test	压缩试验
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
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[41]	为试验参与者保密
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
consignee	收货人
consistency test	一致性检验
context of vulnerability[42]	肿瘤的薄弱基因环境
contract research organization = CRO	合同研究组织
contraindication[43]	禁忌；禁忌症
contrast agent	造影剂
control	对照
control group[44]	对照组

controlled clinical trials	临床对照实验
controlled trials[45]	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
cost overrun	成本超支;费用超支
Covington and Burling, LLP limited liability partnership	科温顿•柏灵律师事务所
COX = cyclooxygenase	细胞环氧化酶
COX-2 inhibitor	COX-2 抑制剂; e.g. 罗非昔布
coxachie virus	柯萨奇病毒
Cp = Process Capability[46]	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
Cpk = Process Capability Index[47]	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	关键质量属性
cranial nerve	颅神经
CRC = colorectal cancer	结直肠癌
creatine[48] = Cr	肌酸
creatine kinase = CK	肌酸激酶
creatinine[49] = 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	关键路径

CRM = continual reassessment method	连续重新评估方法
crossover design	交叉设计
cross-over study[50]	交叉研究
crossover therapy	交义治疗
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[51]	通用技术文件
CTP = Comprehensive Toxicological Profile	全面毒理学综述
cure	痊愈
CVMP = Committee for Medicinal Products for Veterinary Use	兽用药品委员会
CVTE = cardiovascular thrombolic events	心血管血栓栓塞事件
CyA = cyclosporin A	环孢素 A;
CYA mentality (Cover Your Ass)	明哲保身的心态
cyanosis[52]	紫绀
Cyclospora cayetanesis	圆孢子球虫
cyclosporin A = CyA	环孢素 A;
CYP[53] = 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
cytokine	细胞因子
cytokine storm	细胞因子风暴[54]
cytostatic	细胞抑制
cytotoxic drugs	细胞毒性药物
data mining	数据挖掘
Data Safety And Monitoring Board = DSMB[55]	数据安全及监控委员会
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 acute myelogenic leukemia	初治急性髓性白血病
de novo process[56]	
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	深部脑刺激器
degenerative disc disease	椎间盘退变； 椎骨退化疾病
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[57]	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
DF = degree of fluctuation[58]	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	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
Differentiation	差别化; 与众不同;
Differentiation Marketing	差异化营销
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
distributor	经销商
Division of Clinical Trial Design and Analysis	临床试验部
DLT = dose-limiting toxicity[59]	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
DMF = drug master file	药物主文件[60]
DMSO = dimethyl sulfoxide	二甲亚砜
DNA sequence	DNA 序列
dolomite	白云石
dopamine	多巴胺
dosage form	剂型
dosage regimen	给药方案
dose-ranging study[61]	剂量范围研究
dose-reaction relation	剂量－反应关系
dose-related adverse reactions	剂量相关的不良反应
double blinding	双盲
double dummy[62]	双模拟

double-blind study[63]	双盲研究
Double-Masked Study: See Double-Blind Study.	双盲研究
DRGs = Diagnosis Related Group System	疾病诊断相关分组
drop out[64]	脱落
drop test	落震试验;跌落试验
drug eluting coronary stents	药物洗脱支架
drug product	药物产品
drug substance	原料药
drug-drug interaction[65]	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
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[66]
DTA = differential thermal analysis	差热分析;差示热分析
DWPE = detention without physical examination	自动扣留; 不经查验即可扣留产品
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
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	厂房检查报告
electrical impulse	电脉冲
Electronic Data Capture = EDC	电子数据采集系统
Electronic Data Processing = EDP	电子数据处理
Eli Lilly	礼来制药
eligibility criteria[67]	合格标准
elixir of sulfanilamide tragedy 1937[68]	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	依那西普 (FDA 批准银屑病关节炎药物)
encephalitis	脑炎
end-of-life care	临终关怀照护
endogenous system	内源性系统
endoscopes	内诊镜
endpoint[69]	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
epitope[70]	抗原表位;抗原决定簇
EPO = erythropoietin	促红细胞生成素
equipment qualification	设备验证
equivalence	等效性
equivalence trial[71]	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
erythropoietin	促血红细胞生长素

esophagus	食道
essential documentation	必须文件
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	依那西普;治疗类风湿
ethanol	乙醇
ethics committee	伦理委员会
ethyl alcohol，ethanol	乙醇
ethylene glycol	乙二醇；甘醇
etiology	病因学
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[72]	赋形剂; 药用辅料
exclusion criteria	排除标准
exclusion/inclusion criteria	排除/入选标准
exculpatory evidence	辩护证据
expanded access[73]	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
extrusion	挤出
facial dysmorphia	脸部畸形
FACP = Fellow of the American College of Physicians	美国内科医师协会会员

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 therapeutic claims	错误的疗效声明
FAS = Foreign Agricultural Service	美国农业部海外局
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
FDAAA = Food and Drug Administration Amendments Act of 2007	食品药品管理局修正案法
FDAMA 1997	《食品和药品管理局现代化法案》
Federal Import Milk Act (1927)	牛奶制品进口法
fee-for-service	付费服务
FERN = Food Emergency Response Network	食品紧急反馈网, 应急反应网络
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 = failure modes and effects analysis	故障模式影响分析; 失效模式与影响分析; 不良模式与效应分析
FMECA = Failure Modes, Effects and Criticality Analysis	故障模式影响及危害性分析
folate	叶酸盐
folding, protein	蛋白质摺叠
follow-on biologics = biosimilars	生物仿制药
follow-up	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
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 = Fault Tree Analysis	故障树分析
FTE = full time employee	专职(雇员)

full analysis set[74] (FAS)	全分析集
full factorial design	全因子试验法
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[75] = GGT	γ-谷氨酰(xian)转移酶
GAMP = Good Automated Manufacture Practice	良好自动化生产规范
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－傅利叶红外联用
gas chromatography-mass spectrometry = GC-MS	气相色谱－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－傅利叶红外联用
GC-MS = gas chromatography-mass spectrometry	气相色谱－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)[76]	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
gene expression[77]	基因的表达
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 vulnerability	遗传脆弱性

genotype[78]	基因型
genotypic resistance[79]	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
GHTF = Global Harmonization Task Force	全球医疗器械法规协调组织
GlaxoSmithKline (GSK)	葛兰素史克
global assessment variable	全局评价变量; 全局评价指标
GLP = Good Laboratory Practice/Good non-clinical laboratory practice	药物非临床试验质量管理规范
GLU = glucose	血糖
glucose = GLU	血糖
glucose monitor	血糖仪
glucose monitoring	血糖检测
glucose test strip	血糖測試條
glycated hemoglobin	糖化血红蛋白
glycerin	丙三醇；甘油
glycosylated hemoglobin	糖化血红蛋白
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[80]	法规前批准药品
granulation tissue[81]	肉芽组织
GRAS = generally recognized as safe	公认安全
group sequential design	成组序贯设计
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
HACCP [82]= Hazard Analysis and Critical Control Point	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
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[83] = hemoglobin A1c	血红蛋白 A1c
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
hematopoetic	造血
hematopoietic growth factors	造血因子
hemodialyzers	血液透析器
hemoglobin A	血红蛋白 A
hemolytic anemia	溶血性贫血
hemophilia	血友病
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
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
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
HIS, Hospital Information System	医院信息管理系统
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 [84];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
HSE	健康、安全、环境
HSV = herpes simplex virus	单纯疱疹病毒
HTA assessment health technology assessment	卫生技术评估
HTN = Hypertension	高血压
hub	轮毂
Humira (adalimumab)	阿达木单抗
HVAC = heating, ventilating, and air	暖通空调

conditioning	
hydralazine	肼屈嗪
Hydrocephalus	脑水肿,又称脑积水或水脑症
hydroxychloroquine	羟氯喹 qiang3 lü kui2
hygroscopic	吸湿
hyperglycemia	高血糖症
hyperlipidemia	高脂血症
Hypoglycemia	低血糖
hypokalemia	低血钾症
hypothesis	假说
hypothesis test	假设检验
hypoxia imaging	心肌乏氧显像
IB = Investigator's brochure	研究者手册
ICD implanted cardiac device	植入式心脏器械
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
idiosyncratic reaction	特异质反应
IDMC = Independent Data Monitoring Committees	独立数据监查委员会
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
imaging agents	显像剂
immediate release drug	速释剂
immune modulation	免疫调节
immune suppression	免疫抑制
immuno-compromised	免疫受损
immunogenicity[85]	致免疫力; 免疫发生; 免疫原性

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	体外诊断
in vitro reagent	体外试剂
inclusion criteria	入选标准
inclusion/exclusion criteria[86]	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
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
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	英夫利昔单抗; 商品名为 Remicade; 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
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
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[87]	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 use	预期用途
intention-to-treat analysis[88] = 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[89]	期中分析
interleukin-6	白细胞介素-6
intermediate	中间体
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	间质性膀胱炎
intervention[90].	干预措施
Intravenous infusion and blood transfusion	静脉输液与输血
invasive fungal infection	入侵性霉菌感染

investigational new drug = IND	临床研究新药
investigational product[91]	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
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
Isoniazid	异烟肼
isopropyl alcohol	2-丙醇; 异丙醇
ISPE = International Society for Pharmaceutical Engineering	国际制药工程协会
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
Japanese encephalitis virus	日本脑炎病毒
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
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
ketoconazole	酮康唑
kits	器械包
Kogenate	重组因子Ⅷ
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
LACF = low acid canned foods	低酸罐装食品
lactobacilli	乳酸菌
larynx	喉
LASIK[92] = 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[93]	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－质谱联用
LD = longest diameter	最大直径
LD50	半数致死剂量
lead arsenate	砷酸铅
lead compound	先导化合物
leak testing	检漏
Leflunomide	来福米特
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
ligand	配体
Limit of Quantitation[94] = LOQ	定量限
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 =	液-质联用

LC-MS	
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
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 [95]	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
lumbar tapered fusion device	腰椎椎间融合器
lumen	管腔
lymphoma	淋巴瘤
M. bovis	牛分枝杆菌
M. tuberculosis	结核分枝杆菌
MAA = Marketing Authorization Application	营销授权申请
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
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, periods of	市场专用权
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
MDFP medical device fellowship program	
MDR = Medical Device Reporting	医疗器械强制报告系统
MDUFMA = Medical Device User Fee and Modernization Act	医疗器械用户费用和现代化法
MDUFMA = Medical Device User Fee and Modernization Act	医疗器械申报者付费法
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
MedDRA[96] = 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[97]	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[98]	医学监视项目
Melamine	三聚氰胺
MEMS = Micro Electromechanical System	微电子机械系统
Meniere's Disease	美尼尔氏病
meningitis	脑膜炎
Merck	默克公司
Merck Sharp & Dohme = MSD, part of Merck	美国默沙东（Merck）制药
meta-analysis	元分析；荟萃分析
metabolite	代謝物
metastatic	转移
metformin	甲福明二甲双胍 gua 抗糖尿病药、降血糖药
metformin hydrochloride	盐酸二甲双胍 （gua）
Methicillin	甲氧西林
Methotrexate, MTX	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
methylmercury	甲基汞; 二甲基汞
methylphenidates	哌醋甲酯
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
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
MIS: minimally invasive surgery	微创外科手术
misbranding	错误标签; 冒牌
miscoding	编码错误
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[99]	作用机制;作用机理
MoA = memorandum of agreement[100]	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[101]	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
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	质谱

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
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
multiple arm trials	多治疗组的试验
multiple sclerosis = MS	多发性硬化症
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)
mycotoxins	真菌毒素;霉菌毒素;
myocardial electrode	心肌电极
myocardial ischemia	心肌供血不足, 缺血
NABP = National Association of Boards of Pharmacy	美国国家药事管理委员会协会
NAI = No Action Indicated	无需采取行动
Naproxen Caps	萘普生胶囊
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[102]	自然发展研究
NCE = new chemical entity	新化合物
NCI CTEP = National Cancer Institute Cancer Therapy Evaluation Program	国立癌症研究所的癌症治疗评价计划
NDA new drug application[103]	新药申请
neoplasm	肿瘤
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[104]	神经调控
neuromodulator	神经调质
neuron	神经元
neuropathic pain	神经病理性疼痛
new chemical entity = NCE	新化学实体

new drug application = NDA[105]	新药申请
Nexavar = sorafenib tosylate	多吉美
NF = national formulary	美国国家处方集
NIH = National Institute Of Health	美国全国卫生研究所
Nipah virus	尼巴病毒
nitrazepam[106]	硝西泮(硝基安定)
nitrite	亚硝酸盐
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
nociceptive pain	伤害性疼痛
nociceptor	伤害性感受器
nominal significance level	名义显著性水平
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[107]	非劣效性界值
non-inferiority trial[108]	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
norovirus	诺瓦克病毒
nosocomial[109] infections	医院感染
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	非甾体抗炎药; 非类固醇类的消炎药
NSE (non-substantially equivalent) letter	非实质等同性质的信函
null hypothesis[110]	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	OASIS 进口支援操作行政系统

for Import Support	
OBD = optimal biological dose[111]	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 = organ drug exclusivity	器官用药市场独占权
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[112]	标示外使用
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
OLT = orthotopic liver transplant	原位肝移植
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	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[113]	开放标记试验; 开放性试验
operating margin	营业利润率
opportunistic infections	机会性感染
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
ORD = optical rotatory dispersion	旋光光谱
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[114]	罕见病用药,孤儿药
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
osteoclast	破骨细胞
osteomyelitis	骨髓炎
OTC drug = over-the-counter drug	非处方药
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
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	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）
parallel group design	平行组设计
parameter estimation	参数估计
parametric release [115]	参数放行
parametric statistics	参数统计方法
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
partial response	部分缓解
Pasteurization	巴氏灭菌法
PAT = Process Analytical Technology[116]	过程分析技术
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[117]	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%
Pbo or Pla = placebo	安慰剂
PCB = polychlorinated biphenyls	多氯联苯同类物
PCR assays; polymerase chain reaction	PCR 检测; 聚合酶链反应
PD = pharmacodynamics[118]	药物效应动力学; 简称药效学
PDA = Parenteral Drug Association	注射用药物协会
PDCO = Pediatric Committee	小儿科委员会
PDP product development protocol[119]	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[120]	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 interferon alfa-2a	聚乙二醇化干扰素 alfa-2a
penicillamine	青霉胺
penicillium verrucosum	疣孢青霉

pennsaid	Pennsaid 双氯芬酸钠
peptides	肽
per protocol (PP) analysis[121]	符合方案分析
per protocol set (PPS)[122]	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
pesticide residue	农药残留
PET = positron emission tomography	正电子发射断层显像
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
PHA = preliminary hazards analysis	预先危险分析
pharmaceutical equivalence	药剂等效性
pharmaceutics	药剂学
Pharmacia	法玛西亚
pharmacodynamics[123] = PD	药物效应动力学; 简称药效学
pharmacoepidemiology	药物流行病学
pharmacokinetics = PK[124]	药代动力学; 简称药动学
pharmacology	药理学
Pharmacovigilance[125]	药物警戒
pharmacy	配药学
PharMetrics claims database	PharMetrics 索赔数据库
pharynx	咽
phenergan	非那根; 异丙嗪
Phenol	苯酚
phenotype[126]	表型
phenotypic resistance[127]	表型耐药
PHF = potentially hazardous food	有潜在危险的食品
phlebotomy	静脉放血术
phocomelus[128]	海豹肢畸胎
photodynamic therapy PDT[129]	光动力疗法

PhRMA = Pharmaceutical Research and Manufacturers of America	美国药物研究与生产商协会
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[130]	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
Plavix (Clopidogrel bisulfate)	波立维；氯吡格雷硫酸氢盐
pleiotropy	基因多效性,多向性
Plt = platelet	血小板
PMA = premarket approval	上市前许可; 销售前批准
PMCs = post marketing commitments[131]	承诺药品上市后的继续研究
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[132]	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
polymyxin	多粘菌素
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
PoS = point-of-sales	销售点
postmarket surveillance	上市后监督
post-marketing surveillance; postmarket safety surveillance	销售（上市）后监督
posttranslational modification，PTM	蛋白质的翻译后修饰

postural hypotension	直立性低血压
potency	效价
power[133]	把握度; 检验效能
Pp = Process Performance[134]	工序绩效
Ppk = Process Performance Index[135]	工序绩效指数
PPO = preferred provider organizations	优先提供者组织
PR = partial response	部分缓解
practolol affair	心得宁事件
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
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
prednisone	泼尼松【药理及应用】泼尼松等皮质激素是广泛应用的免疫抑制剂
pre-market approval (Application) = PMA	上市前许可（申请）
premarket notification	上市前通知
pre-marketing surveillance	销售（上市）前监督
preparing and submitting	起草和申报
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[136]	首要作用模式
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
private label	贴牌生产
private label distributor	商标发行商
probability	概率

probe substrate	探针底物
procedure trays	操作盘
process controls	工艺控制
process validation	工艺验证
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)[137]	产品生命周期
prognosis	预后
progression-free survival = PFS	无进展生存
progressive disease PD	病情进展
proof of principle study[138]	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
prosthetics	假肢
protein purification	蛋白纯化
protocol[139]	试验方案; 方案
protocol amendment	方案补正
prototype design	原型设计
protozoa	原生动物门
proven acceptable Range = PAR	确定可接受范围
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
psoriasis	银屑病; 俗称牛皮癣
psoriatic arthritis PsA	银屑病关节炎
PSUR[140] = 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
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
Pure Foods Act 1906	1906 年颁布的《纯净食品和药品法案》
PVAR = preliminary variation assessment report	初步改变评估报告
pyloric sphincter	幽门括约肌
pylorus	幽门
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[141]	QT 间期
QTc = Corrected QT	校正 QT 间期
qualification system for licensed pharmacist	执业药师资格准入制度
qualified health claims	有保留的健康宣称
Qualified Person = QP[142]	受权人
quality assurance = QA	质量保证
quality assurance unit = QAU	质量保证部门
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 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[143]	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 = 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 = Response Evaluation Criteria in Solid Tumors	实体瘤的疗效评价标准
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	参比药物
reference product	参比制剂
reference samples	标准样品
refractory solid tumors	难治性实体瘤
regulatory methodology	质量管理方法[144]
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
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	冷藏加工食品的长期保存

extended durability	
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	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
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
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[145]	横纹肌溶解
RMS = reference member state[146]	参考成员国
Roche	罗氏
Rogaine	落健；生发类产品
Rosetta	罗塞塔
route of administration	给药途径
royalties	专利使用费
RPN = risk priority number[147]	风险优先指数
RR = response rate	缓解率
RSD = (intra-day and inter-day) relative standard	(日内和日间) 相对标准差

deviations	
RSV = respiratory syncytial virus	呼吸道合胞体病毒
RTE (ready-to-eat) foods	即食食品
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
Salmonella	沙门氏菌
Salmonella enteritidis	肠炎沙门氏菌
salmonella typhimurium	鼠伤寒沙门氏菌
sample size (number of subjects in a clinical trial)	样本含量; 样本量，样本大小
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[148] = 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 = 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 variable	次要变量
seed brachytherapy	放射性粒子组织间近距离治疗
seeding trials[149]	撒播试验
seizure	扣押
sensitized lymphocyte	致敏淋巴细胞
sepsis	败血病; 脓毒症
sequence	试验次序
severe acute respiratory syndrome─coronavirus	严重急性呼吸系统综合症──冠状病毒
SFDA [150]= 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	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 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	舒莱（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
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

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[151] = 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 = special protocol assessment	特殊方案评估
specific antibody	特异抗体
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	卫生标准操作程序
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 treatment	标准治疗
standards of care[152]	医护标准
Staphylococcus	葡萄球菌属
startup companies	创业公司
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－时间曲线下面积
stenosis	狭窄
stent grafts	血管内支架血管; 带膜支架
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；多形糜烂性红斑
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[153]	研究终点
Study Personnel List = SPL	研究人员名单
study site	研究中心
study type[154]	研究类型
subchronic toxicity studies	亚慢性毒性研究
subgroup	亚组
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	和已合法在市场上销售的且不需要做 PMA“销

(predicate) device	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
sulfanilamide elixir	磺胺酏 yi 剂
sulfasalazine = SSZ	柳氮磺吡啶 bi ding
sulfonamides	磺胺类药物
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[155]	替代终点
survival analysis	生存分析
susceptible population	易感人群
Sutent[156]	舒尼替尼
sutures	外科手术缝线
SXRD = single-crystal x-ray diffraction	单晶 X－射线衍射
sympathomimetic drug	拟交感神经药
Synagis (palivizumab)	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	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：紫杉醇制剂的商品名; 泰素 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
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 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[157]	"反应停（沙立度胺）事件"
therapeutic equivalence	治疗等效
therapeutic window[158]	治疗窗
thiamin	硫胺(维生素 B1)
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
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[159]	存活时间
titration	滴定
TLC = thin layer chromatography[160]	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	肿瘤坏死因子
TNK = Tenecteplase	替奈普酶
tocopherols	维生素 E
tongue depressor	压舌板，压舌器
total diet study = TDS	总膳食研究
toxicant	毒剂
toxicity	毒性
toxicity scale	毒性标度
toxics	毒性药品
toxigenic moulds	产毒素霉菌
TP = total protein	总蛋白
tPA = tissue plasminogen activator[161]	组织纤溶酶原激活物
TPA = tissue polypeptide antigen	组织多肽抗原
tracer	示踪剂
train-the-trainer program	培训者培训计划
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[162]	转化科学
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	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
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
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 Ⅰerror[163]	Ⅰ类错误
type II diabetes	二型糖尿病
type Ⅱerror[164]	Ⅱ类错误
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
ULN = upper limits of normal	正常上限
UMC = Uppsala Monitoring Centre	乌普沙拉监测中心
unblinding	破盲;揭盲
under reporting bias	少报偏差
unexplained syncope	不明原因晕厥
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
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》
UV-VIS Ultraviolet/Visible	紫外－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
value chain[165]	价值链
vancomycin resistance	对万古霉素的抗药性
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
vector sequences[166]	载体序列
vegetative bacteria	植物细菌
vegetative organism	活微生物
VEGF[167] = 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
ventilator	呼吸机
verification[168]	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
Vioxx (rofecoxib)	万络；通用名：罗非昔布; COX-2 抑制剂; 抗炎和止痛药
VIPPS = Verified Internet Pharmacy Practice Site	“互联网药品营业认证”标志
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
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
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[169] (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 [170]	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
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》
xenotransplantation	异种移植
Xerophilic fungi	喜旱真菌
X-ray	X 射线
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	赛尼哌; 抗 Tac 单抗; 抗排异药 anti-rejection;
Zeneca	泽尼卡
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

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[171] 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－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[172]	食品、药品和化妆品法
Food and Drug Administration Modernization Act of 1997[173]	美国食品和药品管理局现代化法
Kefauver-Harris Amendment to the FD&C Act [174] 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 [175] = 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	公共健康法案; 公共卫生服务署法
Pure Food and Drug Act 1906	纯食品和药品法

FDA Organization Charts

http://www.fda.gov/ http://www.hhs.gov **美国卫生与人类服务部（HHS）**

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 Office, 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

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

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

注释：

[1] of the Bureau of Customs and Border Protection (CBP)

[2] a biologic response modifier, is a single-chain polypeptide containing 140 amino acids

[3] An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time

[4] Organizations and groups that actively support participants and their families with valuable resources, including self-empowerment and survival tools.

[5] A negative experience encountered by an individual during the course of a clinical trial that is associated with the drug.

[6] 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.

[7] 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.

[8] 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).

[9] An allograft is a transplanted organ or tissue from a genetically non-identical member of the same species

[10] 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

[11] Any of the treatment groups in a randomized trial.

[12] 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.

[13] A renewable permit granted by the federal government to an institution or research center to conduct clinical trials.

[14] in an "as treated" (or "observed data") analysis only those patients still taking the assigned treatment are analyzed; those who drop out are "censored."

[15] 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

[16] 一种批准用于治疗 2 型糖尿病的药物

[17] 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

[18] 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

[19] 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。

[20] expression of how much drug reaches the circulation (known to pharmacologists as the **central compartment**) after administration

[21] The property of being biologically compatible by not producing a toxic, injurious, or immunological response in living tissue

[22] A biofilm is a structured community of microorganisms encapsulated within a self-developed polymeric matrix and adherent to a living or inert surface

[23] 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

[24] 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

[25] A biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment

[26] 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

[27] 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

[28] 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。

[29] 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

[30] 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

[31] 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

[32] (an acronym for the French "Conformite Europeenne") certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety

[33] approved for colon cancer, as well as head and neck cancer

[34] 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

[35] A medical researcher in charge of carrying out a clinical trial’s protocol

[36] 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.

[37] In epidemiology, a group of individuals with some characteristics in common

[38] A clinical trial conducted primarily through primary-care physicians rather than academic research facilities

[39] 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.

[40] 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:

[41] 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.

[42] 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.

[43] A specific circumstance when the use of certain treatments could be harmful

[44] 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

[45] 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.

[46] A simple and straightforward indicator of process capability

[47] Adjustment of Cp for the effect of non-centered distribution

[48] an amino acid, $C_4H_9N_3O_2$

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

[50] 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.

[51] 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).

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

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

[54]如果发炎太厉害，身体就会排出过量的 cytokine

[55] 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.

[56] 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.

[57] 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

[58] (Cmax-Cmin)/Cave

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

[60]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

[61] 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.

[62] 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。

[63] 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.

[64]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。

[65] 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.

[66] FDA 中的一个特别办公室

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

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

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

[70] 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

[71]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

[72] inert substance used as a diluent or vehicle for a drug

[73] any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants

[74] 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。

[75] 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

[76] stimulates the bone marrow to produce more white blood cells

[77] The phenotypic manifestation of a gene or genes by the processes of GENETIC TRANSCRIPTION and GENETIC TRANSLATION

[78] The genetic constitution (the genome) of a cell, an individual or an organism. The genotype is distinct from its expressed features, or phenotype

[79] 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

[80] unapproved drugs whose makers claim the drugs are "grandfathered" under older standards and therefore don't require approval under the current regulatory framework

[81]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

[82]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

[83] 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

[84] 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

[85] ability of a substance to provoke an immune response

[86] 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.

[87] 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.

[88] 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.

[89] 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

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

[91] 用于临床试验中的试验药物、对照药品或安慰剂

[92] 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.

[93] 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。

[94] 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.

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

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

[97] 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

[98] The FDA also receives directly adverse drug event reports through its MedWatch program

[99] 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.

[100] 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

[101] 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

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

[103] 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.

[104] 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

[105] 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.

[106] (marketed under the trade names Mogadon, Alodorm, Hypnotex, Remnos, Pacisyn, Eunoctin and Pelson)

[107] 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).

[108] The objective of a non-inferiority trial is sometimes stated as being to demonstrate that the test product

is not inferior to the comparator

[109] comes from the Greek word *nosokomeion* (νοσοκομείον) meaning hospital (*nosos* = disease, *komeo* = to take care of

[110] 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

[111] the quantity of a radiological or pharmacological treatment that will produce the desired effect with acceptable toxicity

[112] A drug prescribed for conditions other than those approved by the FDA.

[113] A clinical trial in which doctors and participants know which drug or vaccine is being administered.

[114] An FDA category that refers to medications used to treat diseases and conditions that occur rarely.

[115] 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

[116] 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).

[117] 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

[118] 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

[119] 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

[120] 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.

[121] Analysis based only on those patients who complete the entire treatment protocol

[122]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。

[123] 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

[124] The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

[125] pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines

[126] 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

[127] 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

[128] An individual exhibiting phocomelia

[129]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。

[130] The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine

[131] 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

[132] In PoC trials, the drug is for the first time given to humans

[133] 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

[134] A simple and straightforward indicator of process performance

[135] Adjustment of Pp for the effect of non-centered distribution

[136] 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

[137] 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.

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

[139] 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.

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

[141] 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

[142] 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

[143] 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

[144] 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

[145] Syndrome characterized by muscle breakdown and necrosis, resulting in elevated. serum concentrations of creatine kinase (CK) 肌酸激酶

[146] 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.

[147] is a measure used when assessing risk to help identify critical failure modes associated with your design or process

[148] Protein, calcium and heat-sensitive vitamins can be added directly to products with supercritical fluid extrusion

[149] 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

[150] http://www.sda.gov.cn/

[151]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

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

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

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

[155] 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.

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

[157] 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

[158] 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>

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

[160] 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).

[161] 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

[162] 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

[163]错误的拒绝无效假设，常用 α 表示。

[164]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。

[165] 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

[166] 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.

[167] 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).

[168] 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.
[169] 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.
[170] 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
[171] allowed the FDA to request NIH-sponsored testing for pediatric drug testing
[172] also called Title 21, Chapter 9 of the United States Code (21 USC 9).
[173] passes incentives which gave pharmaceutical manufacturers a six-month patent term extension on new drugs submitted with pediatric trial data
[174] 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
[175] in which the industry pays a fee for the review of the new product