TIMOTHY A. ANDERSON, MS, MBA

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PROFILE

A uniquely interdisciplined individual, melding comprehensive pharmaceutical industrial R&D, business development, QA/QC, and consultancy experiences with formal FDA-tenured regulatory credentials.

A recognized professional with demonstrable successes in the guidance and preparation for final review of regulatory filings, and the rendering of strategic advisories, bearing upon domestic and international regulatory and business affairs.

EXPERIENCE

1996-Present **THE AQUAMARINE GROUP, INC.** **Redding, CT**

Principal Consultant

For 27 years, as a retained consultant, clients have been furnished services in the areas of global regulatory filing review, writing, Agency negotiation, strategic advisories, contracted management services, and executive search.

Filing services include review/writing of Chemistry and Manufacturing Controls (CMC) sections for NDA, ANDA, IND, BLA (biologics and new chemical entities), 505(b)(2), DMF, 510(k), Type I & II, MAAs/CTX and International filings; cGMP (QC/QA), technical due-diligence, mock pre-approval inspections, R&D portfolio, and Business Analysis services.

Consultative projects have included the following:

- **Sr. Regulatory Affairs (RA) CMC Subject Matter Expert (SME)** for AMNEAL **ANDA approved, Naloxone HCl 4mg metered nasal spray (2024)**
- **Sr. RA-CMC SME** for <<confidential>> (Kazuń Nowy, POLAND) **Falkieri** (Esketamine HCl) drug/device inhaler, breakthrough indication priority review IND submission
- **Sr. RA-CMC SME** for SEAGEN site change strategy **ADCETRIS®** (Brentuximab vedotin)
- **Sr. RA-CMC SME** for JAZZ, HF strategy **Xywav™** (Oxybate) **NDA Approved July 2020;** developing CMC regulatory strategy and writing of Modules 2 and 3 for drug-device IND and CTA for IV and Sub-Q injectable product line extensions for **Defitelio®** (Defibrotide), Type C Meeting prep.
- **Sr. RA-CMC SME,** AVEXIS (Novartis), application integrity assessment, **Zolgensma®**
- **Sr. RA-CMC SME** DEBIOPHARM (Basel, SWITZERLAND) convert IMPD to IND format for PIND meeting
- **Sr. RA-CMC SME** OTSUKA PHARMACEUTICALS on filing strategies related to their ingested event monitor (IEM) & app, **MIND1®** for **Abilify MyCite® NDA approved, October, 2017**
- **Sr. RA-CMC SME,** NUPATHE **Zecuity®** sumatriptan dual reservoir patch **NDA approved, January, 2013**
- **Sr. RA-CMC SME**, INTELLIJECT/SANOFI **Auvi-Q®** epinephrine injector; **NDA approved, August, 2012**
- **Sr. RA-CMC SME**, MILLENNIUM; Module 2 & 3 eCTD services to IND stage BLA oncology (**MEPACT®**)
- **Sr. RA-CMC SME** MEDTRONIC AVE; **Endeavor®** Zotarolimus stent, IDE, CTA, PMA; **PMA approved 2008.**
- **Sr. cGMP RA-CMC SME**, PATAGONIA pre-IND submission and meeting with FDA for a topical Orphan Drug
- **Sr. RA-CMC SME**, ALLERGAN; supplemental US/European (EU) eCTD filings. Site change control
- **Sr. RA-CMC SME**, GENZYME; supplemental US/European (EU) eCTD filings. Site change control
- **Sr. RA-CMC SME**, BMS; supplement US/European (EU) eCTD filings. Site change control
- **Sr. cGMP Compliance SME** mock-PAI DNA vector Phase 1 gene-therapy cGMP firm VGXI.
- **Sr. cGMP Compliance SME** mock-PAI for M&A DNA vector Phase 3 gene-therapy cGMP UNIQURE.
- **Sr. cGMP Compliance SME** SYNTHETIC GENOMICS Advise set up for Phase 1 cGMP suite for DNA vector manufacturing as complement to the firm's BioXp™ DNA "printing" technology
- **Sr. cGMP Compliance SME** Biologics M&A due diligence at CYTOVANCE (Oklahoma City, OK)
- **Sr. cGMP Compliance SME**, LONZA BIOLOGICS; Q7 mock-inspection, **Warning Letter** remediation
- **Sr. Clinical/pre-Clinical Supplies cGMP Quality Systems SME**, BOEHRINGER INGELHEIM; mock-PAI.
- **Sr. cGMP RA-CMC SME**, US PHARMACOPOEIA; USAID/WHO-funded *Promoting the Quality of Medicines*
- **Sr. cGMP Compliance SME**, CORPAK MEDSYSTEMS; **Warning Letter** resolution; medical device
- **Sr. cGMP Compliance SME** to WYETH (2000), and GSK (2006) **Consent Decree** remediation.
- **Sr. Quality Systems SME,** MEMORIAL SLOAN-KETTERING CANCER CENTER. Establishment of regulatory & cGMP compliant quality system/SOPs for 11 Clinical Investigator's and API synthesis labs. IND preparation and review (biologics, radio-labeled peptides, devices, and new chemical entities).
- **Sr. cGMP Compliance SME** Man-in-Plant supervising Astaxanthine extraction at PHASEX.

The AQUAMARINE GROUP (continued)

- **Sr. cGMP Compliance SME** CODY LABORATORIES with regard to Quality Systems and DEA-relevant production plant modifications.
- **Sr**. **cGMP RA-CMC SME**, performed on-site gap analysis and corrective action plan for PHARMATHEN (Alexandropouli, Greece) in preparation for first FDA inspection.
- **Sr. cGMP Compliance SME** pre-NSF assessment of dietary supplement manufacturer, FoodState, Inc**.**
- **Sr. cGMP Compliance SME** NATURECOM 483 response preparation and staff re-training.
- **Sr. cGMP Compliance SME** on behalf of the VC-funded firm, CARBYLAN BIOSURGERY .
- **Sr. cGMP Compliance SME** due diligence and Quality System cGMP compliance audit of private label OTC manufacturer CISPHARMA**, Inc.**
- **Sr. RA-CMC SME** CHURCH & DWIGHT with respect to topical OTC anti-viral product acquisitions, pharma development and regulatory approval paths for 505(b)(2) OTC product line extensions.
- **Sr**. **cGMP RA-CMC SME** DAESANG (Gunsan, SOUTH KOREA); regulatory compliance readiness assessment for food-to-pharma-grade actives production for submission of DMF filings.
- **Sr**. **cGMP RA-CMC SME** CR BARD/DAVOL on preparation of their latest 510(k)
- **Sr**. **cGMP RA-CMC SME** advise XIMEDICA on drug device development projects
- **Sr. RA-CMC SME** ANDA pre-submission review, US Agent for AJANTA (Aurangabad, India)(2006-2015)
- **US Agent Services** FRESENIUS-KABI, AUSTRIA liquid formulation generic manufacturer (2014-2020)
- **Sr. Quality Systems SME** ABBVIE with respect to Quality Systems continuous improvement matters in the context of currently marketed drug-device combination products
- **Sr. cGMP Compliance SME** due diligence on behalf of the VC-funded firm APICORE
- **Sr. cGMP Compliance SME** due diligence on behalf of the VC-funded firm, PCI SYNTHESIS
- **Sr. cGMP Compliance SME** Good Distribution Practices audit performed at UNIVERSITÄTSMEDIZIN Apotheke in Mainz, GERMANY
- **Sr. cGMP Compliance SME** API synthesis and Finished product assessments made at NOVAST Pharmaceuticals (Nantong, CHINA)
- **Sr. cGMP Compliance SME** API synthesis assessments made at RA-CHEM PHARMACUETICALS (Vijayawada, INDIA)
- **Sr. cGMP Compliance SME** API synthesis assessments made at APELOA PHARMACEUTICALS (Hengdian CHINA)
- **Sr. cGMP Compliance SME** API synthesis and Finished product assessments made at GLAND PHARMACEUTICALS (Hyderabad, INDIA
- **Sr. cGMP Compliance SME** API synthesis assessments made at MALLADI DRUGS AND PHARMACEUTICALS LTD. Ranipet, Tamil Nadu, INDIA.
- **Sr. cGMP Compliance SME** Generic regulatory submission and cGMP advisory for cGMP inspection readiness and training on behalf of REYOUNG PHARMACEUTICALS (Shanghai, CHINA).
- **Sr. cGMP Compliance SME** Compounding pharmacy KRS BIOTECHNOLOGY already laboring under a Warning Letter from FDA, sought assistance during FDA inspection accomplished by FDA and Florida Dept. of Health; inspection response preparation.
- **Sr. cGMP Compliance SME** HILL DERMACEUTICALS as they negotiated with FDA and the US Department of Justice with respect to their **Consent Decree** under FDA's Application Integrity Policy (AIP)(2012)

Subject Matter Expert/Expert Witness assignments have included the following:

- **CMC Subject Matter Expert Witness** on behalf of defendant, Teva, in re: Valsaratan, Losartan, and Irbesartan Products Liability Litigation, case number No. 1:19-md-2875-RBK (New Jersey district), (2021-2024)
- **CMC Subject Matter Expert Witness** on behalf of defendants, Avicolli, v. BJ's and 4E Brands, Case No. 2:21-cv-01119-MAK (Eastern District, PA), pertaining to oral consumption of product by plaintiff, recall of methanol-tainted hand sanitizer, and to regulatory labeling requirements of hand-sanitizer products. (2021)
- **CMC Subject Matter Expert** on behalf of plaintiff, Teva Pharmaceuticals USA, Inc. v. Impax Laboratories, Inc. February Term 2017, No. 3632 (Phila. Cnty. Court of Common Pleas)(2019)
- **CMC Subject Matter Expert** on behalf of plaintiff, Stayma Consulting Services v. Teligent, Inc. (American Arbitration Association) Case No. 01-07-0006-3401 (2018-2019)
- **Medical Diagnostic Device Regulatory Affairs, FDA Subject Matter Expert** engaged on behalf of the Plaintiff, as for David Freda POA for estate of Emil Freda v. Alere, Inc., and Daughters of Israel Hospital Case No. ESX-L-7592-15, Essex County, New Jersey) (Essex County, New Jersey) (2018-2019)
- **CMC Subject Matter Expert Witness** on behalf of defendant, regarding sterile labeled Bacitracin Ointment, USP for Fera Pharmaceuticals, LLC v. Akorn, Inc., et. al., and Akorn, Inc. v. Fera Pharmaceuticals, LLC, Perrigo Company, et. al., Case No. 12-cv-07694-LLS (Southern District, NY)(2017-2018)

The AQUAMARINE GROUP (continued)

- **CMC Subject Matter Expert** on behalf of plaintiff, Spiridon Spireas, PhD., Hygrosol Pharmaceutical Corporation, SigmaPharm Inc. v. King Pharmaceuticals, Inc., et.al., Nov. Term 2011, No 0213; January Term 2012, No. 1176 (Phila. Cnty. Court of Common Pleas)(2017)
- **CMC Subject Matter Expert Witness** on behalf of plaintiff, Momenta Pharmaceuticals, Inc. and Sandoz, Inc. v. Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., Watson Pharmaceuticals Inc., and Watson Pharma, Inc., Civ. Action No. 11-11681-NMG (US District, MA) (2016-2017)
- **CMC Subject Matter Expert Witness** on behalf of plaintiff, Tanja Bruestle-Kumra v. The Abbott Laboratories Case No. 1:13-cv-00144-SJD (US Southern District, NY) Doc: #113-32 (2015)
- **CMC Regulatory Affairs, Former FDA Subject Matter Expert Witness** on behalf of the Plaintiff in the case Cox v. Moore Cause No. 1316-CV26473, (Circuit Court, Jackson County, Independence, MO); testimony in deposition regarding regulatory generic labeling requirements for Metoclopramide (Reglan®).(2015)
- **CMC Regulatory Affairs Subject Matter Expert** on behalf of the End-payor Plaintiff(s) in the case United Food and Commercial Workers Union and Midwest Health Benefits Fund ("UFCW"), et. al. v. (1.) King Pharmaceuticals, and (2.) Mutual Pharmaceuticals, Case No. 1:12-cv-194 (Eastern District, Chattanooga, TN) involving the Skelaxin® anti-trust litigation brought in the context of delaying generic metaxalone. (2014)
- **CMC Subject Matter Expert Witness** on behalf of defendant in the case of Silverman v. Watson Case no 4:10-cv-1952 (Southern District, Houston, TX) being sued for alleged product contamination. (2011)

Contracted and interim-regulatory and quality management services have included the following:

- **As Vice-President of Regulatory Affairs and Quality Operations** for the "virtual" development-stage pain management firm**, ALGORX, INC.** (now, **ANESIVA**), CMC, Formulation, QA/QC, and Regulatory filing management furnished to out-sourced domestic and international development units for three products, Phases 1, 2 and 3:
  - Synthetic new chemical entity (NCE); pre-formulation studies -- proof of concept, and first in man trials.
  - **Adlea™** parenterally administered formulations of ultra-purified, and synthetic Capsaicin (now in Phase 3).
  - **Zingo™** (PowderJect® lidocaine) needle-free anesthetic. Drug-device 505(b)(2) **NDA approved, 2007.**
  - INDs, CTXs, staffing; external vendor selection, and cGMP compliance oversight, batch record review; international/domestic clinical study supplies management; regulatory strategy and Agency meetings.

- **As acting Vice-President, Regulatory Affairs and Quality, OPTINOSE, US, INC**. lead filing and licensed partnership regulatory submission management for company's first 505(b)(2) NDA **ONZETRA™ Xsail™** (partnered with Avenir; sumatriptan nasal powder) **NDA approved, January, 2016**. Outsourced due diligence, vendor selection, and development of regulatory strategies for Fluticasone Breath Powered™ Bi-Directional device **Xhance™ NDA approved, September, 2017.**

- **As acting Vice-President, Regulatory Affairs, TARO PHARMACEUTICALS, USA, INC** US, Israel, Canada regulatory functions were coordinated, toward submission of US, Canadian, and International filings. Approvals obtained for 19 ANDAs, and 2- 510(k)s, 10 original DMFs, and an MAA for UK. Accomplished senior level (i.e., Director and VP) staffing of regulatory departments for Taro in Canada and NY.

- **As Interim Director, Regulatory Affairs (Maternity coverage)**, **BOEHRINGER INGELHEIM** site-change, and co-formulation CTD Module 2 and 3 for sNDA's for **Micardis®-HCT Tablets**

- **As acting Director, QA/Regulatory GMP/GLP, OREAD, INC.** (acquired by Emisphere Technologies)**,** starting-up Oread's **Rapid Response Laboratory,** including SOP review/revision/composition, senior staff sourcing, establishment of laboratory GLP/GMP compliance systems, client support, regulatory liaison/advisory.

- **As acting Director of Regulatory Affairs** for a radio-pharmaceutical diagnostic client, **THERAGNOSTICS**, strategy development for PET diagnostic, **Galliprost®** and Technetium Tc99m Succimer for Injection (**MPI DMSA KIDNEY REAGENT**), negotiated continued importation under FDA Drug Shortage discretion (2018).

- **As acting Manager, Regulatory Affairs** Furnished contracted regulatory management services to **INDIVIOR** negotiating with Canadian authorities, preparing, and filing Canadian Product monograph for their flagship product, **Suboxone®**.

1994-1996 **SANDOZ PHARMACEUTICALS CORPORATION** **East Hanover, NJ**
Creighton Pharmaceuticals Corporation division

Senior Associate Director, and division Vice-President, Drug Registration and Regulatory Affairs

Successfully guided, educated, and project managed the domestic and international regulatory and manufacturing functions within Sandoz, toward preparation and timely submission of Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs) to the FDA for Sandoz products, which have and/or are due to come off-patent.

Set the standard for review of competing generic filings through preparation of five first-of-their-kind original ANDAs for Clozapine, Cyclosporine, and Bromocriptine dosage forms, as part of a larger strategy to promote Sandoz brand protection.

Filed landmark citizen's petition in conjunction with preparation of first-of-their-kind patient-based clinical bioequivalence studies (Clozapine) to set the industry standard for review by the Agency; similar legal and strategic advisories rendered for the other flagship products. Coordinated the activities of outside consultants.

Regulatory advisories in the areas of cGMP compliance, Chemistry and Manufacturing Control documentation and bioequivalency standards, from first-hand knowledge of FDA/OGD expectations. Business development and licensing advisories provided in the context of OTC switches, joint ventures, site changes, and new products. Promotion from Associate Director to Senior Associate Director for Drug Registration and Regulatory Affairs (DRRA) for Sandoz and awarding of the title of Vice-President of DRRA for the Creighton Pharmaceuticals generics division.

1992-1994 **UNITED STATES FOOD AND DRUG ADMINISTRATION** **Rockville, MD**

Review Chemist (ranking), Branch 4, Division 1, Office of Generic Drugs, Centers for Drug Evaluation and Research

Employed superior communication skills in drafting coherent deficiency or approval letters in the course of thorough review of chemistry and manufacturing controls sections of original and supplemental ANDAs and DMFs, resulting in fewer required review cycles for applicants. Sought and obtained expanded assignments at other FDA offices within the Centers for Drug Evaluation and Research (CDER), reviewing INDs and supplemental NDAs. Delegated with branch supervisory duties in the absence of the branch chief. Contributions to several policy-crafting CDER committees: Chemistry and Manufacturing Controls Coordinating Committees (CMCCC), prepared policy and procedure guides (PPGs) for bioequivalence evaluation of topicals.

Contributions to drug monographs performed in conjunction with preparation of FDA guidances for presentation to the International Conference on Harmonization (ICH).

Appointed to position of Program Manager for the industry visitation initiative. Serving on the Committee for Continuing Training and Educational Development, headed up favorably received visitations to 16 sites planned and scheduled on behalf of 40 OGD review staff to broaden reviewers' technological exposure and to promote industry-Agency dialog. Program slated to expand to include other CDER offices.

1987-1992 **BAYER, USA, Miles, Inc., Pharmaceuticals division** **West Haven, CT**

Associate Scientist (ranking)

Group leadership responsibilities, including the training and coordination of the assigned workloads of 8 technicians for the finished product and raw materials Quality Assurance laboratory. Recommendations implemented for equipment upgrades; delegated with laboratory supervision in the absence of managers. Increased group productivity, efficiency, and time savings by training staff in instrumentation troubleshooting techniques and maintenance toward safe and effective operation of standard equipment and automated control devices (HP-3350A).

Sharpening existing and new methods for clarity and editing / validation of analytical methods for NDA and IND submissions accomplished, conforming European (Bayer AG) methods to USP protocols.

Scheduling of analytical testing for parenterals, cremes, ointments, lotions, otic solutions, tableted products, and raw materials and timely coordination with manufacturing toward negotiated product and packaging release timetables.

1984-1987 PURDUE-FREDERICK RESEARCH CENTER **Yonkers, NY**

Scientist, Experimental Formulations

Development of stability protocols and bioassay methods and validations, employed to determine drug and metabolite levels in plasma and serum in pre-clinical animal and clinical patient studies for newly developed drug formulae (Phases I and II). Preparation and group presentations of technical reports, detailing data, which linked chemistries to critical pharmacokinetic studies; editing of test methods of European subsidiaries to conform to USP protocols. Participation in DEA and FDA audits.

Acquired comprehensive credentials in industrial pharmacy: Tableting and granulating techniques (experimental and clinical sustained release narcotic, antibiotic, and vasodilator formulations), film coating, freeze drying, Accelocoata fluid bed drying, and Glatt mixing equipment.

1982-1984 CLINTON RESEARCH CONSULTANTS, INC. **Easton, CT**

Contracted consumer products, applications research, and development services

NABISCO BRANDS, INC., Technology Center **Wilton, CT**

- **Research Technologist**, product development, surfactant, pilot plant, and sensory studies.

THE FOXBORO COMPANY, Analytical Instrumentation **Norwalk, CT**

- **Applications Scientist**, IR spectral software programming for a new product launch, the MIRAN 1-B.

SHAW MUDGE AND COMPANY, Fragrance Formulators **Stamford, CT**

- **Formulations Chemist**, fragrance product development, QA, and rabbit conjunctival irritation studies

PATENTS AWARDED AND PROVISIONAL PATENTS PENDING (Co-inventor):

Synthesis and Purification of Capsaicin (Serial No. 10/821,473), April 8, 2004
Synthesis and Purification of Capsaicin (Serial No. PCT/US04/10745) April 8, 2004
Preparation and Purification of Synthetic Capsaicin (European patent application 04749854.8-2117-US2004010745)
Capsaicinoid Gel Formulation and Uses Thereof (Serial No. 60/630,577) November 24, 2004
Capsaicinoid Gel Formulation and Uses Thereof (Serial No. 11/286,059, docket No. 900.1034US) November 23, 2005

EDUCATION

MASTER OF INTERNATIONAL BUSINESS ADMINISTRATION **UNIVERSITY OF BRIDGEPORT**
Bridgeport, CT **5/92**
GPA: 3.6/4.0

Thesis: "ECONOMIC NEW WORLD ORDER**,** Global models structured after those of the EC toward continued international economic integration: the Commonwealth approach for the emancipation of command economies and the historical and geographical bases for regional free trading zones in the furtherance of competitive interdependence."

MASTER OF SCIENCE, BIOCHEMISTRY **NEW YORK MEDICAL COLLEGE**
Valhalla, NY **5/88**
GPA: 3.4/4.0

Thesis: **"**Synergistic reduction in proliferation of the histiocytic lymphoma cell line, U-937, by the combined action of recombinant interferon beta-ser and retinoic acid, and the associated changes in 2'-5' oligoadenylate synthetase and ribonuclease L activities."

BACHELOR OF SCIENCE, CHEMISTRY **VIRGINIA COMMONWEALTH UNIVERSITY**
Richmond, VA **5/82**

BACHELOR OF SCIENCE, BIOLOGY **VIRGINIA COMMONWEALTH UNIVERSITY**
Richmond, VA **12/80**

CONTINUING EDUCATION IN BUSINESS

LEADERSHIP-4 PERFORMANCE MANAGEMENT: Charter Oak Consulting Group
COMMUNICATION AND TEAM BUILDING: Gatto Training Associates
POSITIVE POWER AND INFLUENCE: Situation Management Systems

CONTINUING EDUCATION IN SCIENCES AND REGULATORY AFFAIRS

BIOEQUIVALENCE, BIOAVAILABILITY, AND THERAPEUTIC SUBSTITUTION: Technomic Publishing
BIOTECHNOLOGY: Centers for Drug Evaluation and Research Staff College
ISO 9000/Q90 DOCUMENTATION STANDARDS: Quality Alert Institute
EDUCATIONAL DEVELOPMENT MODULES IN PHARMACEUTICS: University of Maryland

Capsule Formulation, Filling and Manufacture; Dissolution and Bioavailability; Metered Dosage Inhalers; Creams, Ointments, and Lotions Formulation; Sustained Release Formulation; Parenterals; Packaging.

PUBLICATION:

"A flow injection analysis/mass spectrometry method for the quantification of polyethylene glycol 300 in drug formulations," Zhang, J., Lin, J., Anderson, T.A., *International Journal of Pharmaceutics,* 282(1), pages 183-187 (2004)

MEMBERSHIPS

Food and Drug Administration Alumni Association
Regulatory Affairs Professional Society
American Association of Pharmaceutical Scientists
American Chemical Society

INTERESTS

Current events, Music composition, Marine aquaria, British (MG) sportscars. Sports: soccer, volleyball, baseball, chess.

KEYWORDS

Abbreviated New Drug Application, ANDA, NDA, New Drug Application, 505(b)(2), Biologic Licensing Application, BLA, cGMP, current Good Manufacturing Practice, Food and Drug Administration, FDA, Office of Generic Drugs, OGD, CDER, CDRH, quality control, QC, quality assurance, QA, Standard Operating Procedure, SOP, regulatory compliance, cGMP compliance, 510(k), 351(k), device, combination product, drug-device, diagnostic, 21 CFR 210, 211, Quality Systems Regulation, 21 CFR 820, ISO 13485, Drug Master File, DMF, Biologic Master File, BB-MF, Device Master File, MAF, Consent Decree, Warning Letter, Form 483, remediation, interim management, maternity coverage, solid oral dosage, topical, cream, ointment, solution, injectable, sterile, fill and finish, technical transfer, due diligence, labeling, black box warning, purification, formulation, pharmaceutical development, capsule, powder, sustained release, controlled release, cosmetic, food, fragrance, over the counter, OTC, Federal Register, Chemistry and Manufacturing Controls, CMC, pre-approval supplement, PAS, Information Request, IR, Complete Response Letter, CRL, patent, Complete Response Letter, CRL, Major Amendment, Minor Amendment, Nutraceutical, 21 CFR 111, generic, Investigational New Drug, IND, orphan drug, accelerated review, Manual of Policies and Procedures, MAPP, International Conference on Harmonization, ICH, Common Technical Document, CTD, Application Integrity Policy, AIP, Active Pharmaceutical Ingredient, API, Good Distribution Practice, GDP, Good Documentation Practice, Venture Capital, VC, inspection, pre-approval, Corrective and Preventative Action, CAPA, deviation, investigation, inspection, gene therapy, peptide, New Chemical Entity, NCE, Radio-label, method validation, Type I variation, Type II variation, Marketing Authorization Application, MAA, Drug shortage, proof of concept, POC, Clinical Trial Application, CTA, Device History File, DHF, CTX, vendor selection, drug eluting stent, drug eluting patch, Quality by Design, QbD, Quality based Review, QbR, Orange Book, Refuse to Receive, RTR, HPLC, High Performance Liquid Chromatography, USP, United States Pharmacopeia, Bioequivalence, BE, Refuse to File, RTF, DESI, Drug Efficacy Study Implementation, GDUFA, Generic Drug User Fee