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.

A candidate with accomplished graduate and continuing academic credentials in both science and business.

EXPERIENCE

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

Principal Consultant

As a retained consultant, clients are 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 (biologicals and new chemical entities), 505(b)(2), DMF, 510(k), Type I & II, MAAs/CTX and International filings. Other services include cGMP (QC/QA), due-diligence, mock pre-approval inspections, R&D portfolio, and Business Analysis.

Consultative projects have included the following:

- **Sr. CMC Consultant and Subject Matter Expert** (SME) MEDTRONIC AVE; Endeavor® Zotarolimus drug eluting stent, IDE, CTA, and PMA filings. **PMA approved 2008.**
- **Sr. RA-CMC Project Management Consultant** ALLERGAN; redesign of Change Control systems, RA-Mfg-Quality Change Control Review board; RA management succession plan, department work-flow re-structuring.
- **Sr. Quality Systems Consultant,** MEMORIAL SLOAN-KETTERING CANCER CENTER. Establishment of a regulatory & cGMP compliant quality system for 11 Clinical Investigator's laboratories and API synthesis labs. IND preparation and review (biologics, radio-labeled peptides, devices, and new chemical entities), SOP composition, and crafting of a management structure to administer Regulatory/Quality functions.
- **Sr. Bio-analytical SME,** MDS-PHARMA; 5-year retrospective bioequivalence review mandated by FDA.
- **Sr**. **CMC SME**, US PHARMACOPOEIA; USAID/WHO-funded *Promoting the Quality of Medicines Program*
- **Sr. CMC SME**, BOEHRINGER INGELHEIM; site-change, and co-formulation sNDA's for Micardis®-HCT
- **Sr. CMC SME**, BMS; Compliance Submissions Initiative; European (EU) filings, eCTD Type I and II variations.
- **Sr. CMC SME**, GENZYME; preparation of supplemental European (EU) eCTD filings, supporting manufacturing changes, based upon approved US submissions for Renvela®. Change control management.
- **Sr. CMC SME**, MILLENNIUM (TAKEDA); strategy and prep of US filing for acquired EU-marketed product.
- **Sr. CMC SME**, AJANTA; review advisory for first India-originated ANDA filings, advising first WHO certifications.
- **Sr. CMC SME**, JANSSEN (J&J); Drug Master File (DMF) Annual Reporting and amendment filing preparations.
- **Sr. CMC Due-diligence Consultant**, SCIELE (SHIONOGI); tech acquisition R&D assessment, vendor certs.
- **Sr. CMC Pharma Development Plan Consultant**, CARBYLAN; venture-backed start-up; sterile drug-device.
- **Sr. R&D Portfolio Analysis Consultant**, PHARMACIA; Assessment of projected portfolio sales revenues, launch dates, phase, probability of success, costs: proof of concept, R&D, promotion -- in context of NPV.
- **Sr. cGMP Compliance Consultant** to WYETH (2000), and GSK Consent Decree remediation (2006).

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 is 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.

The AQUAMARINE GROUP (continued)

- **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. Primary liaison for negotiations with Office-level regulatory bodies on bioequivalence, CMC, and Application deficiency resolution. Accomplished senior level (i.e., Director and VP) staffing of regulatory departments for Taro in Canada and NY. Pre-IND meetings and PAIs. Authored strategic plans for accomplishment of timely submission of regulatory filings. Authored product- specific ANDA Preparation Guidelines and a universally applicable Drug Master File Preparation Guideline. Amendments, supplements, annual reports. International Rx and OTC approvals

- **As acting Director, QA/Regulatory GMP/GLP, Oread, Inc.** (acquired by Emisphere Technologies, 2000)**,** 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.

Partnering with and acquisition (1998) of Clinton Research Consultants, Easton, CT

Critical analysis of new product proposals for scientific feasibility and domestic/international marketability, profiling novel formulary and therapeutic preparations. Evaluation of marketing plans and new product proposals for anti-viral, anti-thrombotic, polypeptide, enzymatic, new chemical entities, biotechnology products, and unique formulation systems as well as authored and promoted novel contraceptive, glucose metabolism, and palatable cold symptom relief therapies.

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.