ARCIEL, LLC

**Raymond C. Lamy, MS**

Pharmaceutical • Biologic • Biotechnology
Regulatory Affairs Consulting

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**Palm Springs, CA**

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## SUMMARY OF QUALIFICATIONS

- Over twenty-five years of combined pharmaceutical/biotech industry experience in Regulatory Affairs, Clinical Statistical Programming, and Nonclinical Research, focusing on the development and marketing registration of prescription drug/biotechnology products in several therapeutic areas (i.e., oncology, CNS, pain management, anti-infective). Additional experience with nutritional supplements ("nutriceuticals"), OTC monograph products (antifungals and digestive aids), biologics (blood plasma derivatives, human growth hormone), and medical devices (drug delivery).
- Extensive knowledge of US FDA regulatory requirements. Submitted and/or managed successful clinical trial applications and new drug applications worldwide. Particularly experienced with the FDA's CDER, DEA, Orphan Products, and International Affairs divisions; with additional experience with California's DHS (manufacturing facility and clinical laboratory licenses), CLIA registrations, Health Canada's TPD, the EMEA, and some Intercontinental/Pacific Rim country health authorities.
- Assisted with regulatory strategy and issue resolution, competitive product intelligence research, scientific/medical/label writing, SOP development, and determining the viability and commercial potential of products for either acquisition and/or in-house development.
- Successful electronic IND and NDA submissions, compliant with FDA regulations, including eCTDs.
- Developed various systems for expediting Regulatory Affairs work (i.e. document standards and templates, electronic regulatory file management and tracking system).
- Developed and managed successful Regulatory Affairs groups at start-up, small, and medium sized companies.
- Participated in bringing a privately held company to an initial public offering (IPO).
- Dedicated to Quality, Efficiency, and Team Work.
- Master's degree in Computer Science and Bachelor's degree in Life Sciences

**MEMBERSHIPS:** Drug Information Association (DIA), Philadelphia, PA
Regulatory Affairs Professional Society (RAPS), Rockville, MD

**COMPUTER SKILLS:** Highly competent with PC computers using MS Windows software, including advanced use of electronic publishing, word processing, internet access, and Adobe products.

**EDUCATION:**

**MS, University of New Haven**
Computer Software Applications GPA-3.4/4.0

**BS, University of Rhode Island**
Zoology/Psychology GPA-3.3/4.0

Attended a variety of professional conferences on Regulatory Affairs (US and EU), GMP Issues, Electronic Submissions, Managerial Skills, Writing Skills, and Presenting Skills.

**PUBLICATIONS:**
Soc Neurosci Abstr Fed. Proc. of American Society for Experimental Biology, 1990.
Sigma, PCP and NMDA Receptor Systems. National Institute on Drug Abuse Research Monograph. US Government Printing Office: Washington, DC.
Soc Neurosci Abstr 16:275, 1990.
Soc Neurosci Abstr 15:422, 1989.

*References Available Upon Request*

## PHARMACEUTICAL/BIOTECH INDUSTRY WORK EXPERIENCE

### Consulting

**10/99 – present** **ARCIEL, LLC**
Owner, President, Regulatory Affairs Expert
Managerial, consulting, and contract services in regulatory affairs (US and international), working both independently and for consulting firms (Pro-Ed Communications, PAREXEL Consulting, TGen Development Services-TD2). This includes "Acting Executive", regulatory submissions and strategy, labeling, drug safety reporting, patent review, SOP writing, scientific writing, as well as project management, all pertaining to drug product development. Also wrote and presented the regulatory affairs portion of a UCSD graduate course on "Validation" in the pharmaceutical/biotech industry.

### Industry Positions

**4/01 – 12/01** **Ganeden Biotech, Inc. – Cleveland, OH**
Director, Clinical and Regulatory Affairs
Maintained FDA compliance with the company's OTC and nutritional supplement ("nutriceutical") products. Evaluated potential product lines for IND development. Managed contract organizations for nonclinical and clinical development of products. This start-up company's business goal was to develop IND products for partnering opportunities.

**10/99 – 5/00** **Situs Corporation – Solana Beach, CA**
Director, Regulatory Affairs
Managed regulatory projects to support the company's product portfolio (drugs and drug delivery device) and business goals. These projects included INDs, Orphan Product Designation applications, contract research organization interactions, regulatory and clinical audits, and project timelines (MS Project). This start-up company's business goals were to obtain "approvable" first product NDAs and a successful IPO.

**9/94 – 10/99** **SkyePharma Inc. / DepoTech Corporation - San Diego, CA**
Director, Regulatory Affairs
Assumed "functional head" responsibility for Regulatory Affairs in addition to responsibilities listed below.

Associate Director, Regulatory Affairs

Continued to manage and develop the Regulatory Affairs group to support the company's business goals. In addition to the responsibilities listed below; assisted in developing and implementing worldwide regulatory strategies for the company's products.

Senior Manager, Regulatory Affairs
Created and developed the Regulatory Affairs group to support the company's business goals. This included, submitting and managing all clinical trial applications (IND, INDS, CTX); all new drug applications (NDA, NDS, MAA) for the US, Canada, and the EU; implementing administrative systems to support these functions; interpreting regulations and guidelines and their impact on product development as the Regulatory Affairs representative on project teams.

Developed an electronic system for the company's first new drug application in accordance with FDA requirements that can be applied to other NDAs and INDs, as well as be used for electronic submission to other Health Authorities. Also participated in initiating and implementing an on-line electronic documentation/data system.

**2/93 - 9/94** **Baxter Healthcare Corporation - Hyland Division - Glendale, CA**

Project Manager, Global Regulatory Affairs

Achieved global (US, EC, Intercontinental) licensing of biological/biotechnology products, and maintained or amended existing product licenses. Managed the IND for lead biologic product. Upgraded current departmental procedures, policies and technology to accommodate industry advancement, and remain competitive with the global market.

Chaired a task force with the objective to improve business practices and develop automated systems for information exchange between functional areas. Goals: cycle time reduction and computerized submissions (CAPLAs) to worldwide Health Authorities.

**5/86 - 1/93** **Bristol-Myers Squibb Company,**
**Pharmaceutical Research Institute - Wallingford, CT**

Senior Regulatory Affairs Associate - Operations

Coordinated and prepared scientific and administrative information for both US and international filings (i.e. IND/CTAs through NDA/MAAs) across all therapeutic areas. Responsible for special computer projects (i.e. Electronic Publishing System/CANDA, IND/CTA tracking system, system site integration).

Chaired an inter-company task force to select and implement Electronic Publishing capabilities at both the Wallingford and Princeton RA offices. This was part of a collective effort towards a "Worldwide Gold Standard" dossier and CANDA.

Regulatory Affairs Associate - International Liaison

Coordinated and prepared scientific information for the filing of CTAs and MAAs internationally. As liaison between the Health and Drug Authorities outside of the US and the Central Nervous System (CNS) therapeutic area within the company, updated the company on new international regulatory requirements. Actively participated in Project Development Team and Protocol Review Committee meetings.

Statistical Programmer/Analyst

Wrote programs (in SAS) and EXEC's (in REXX) to perform statistical analysis of clinical data for various drug studies in the CNS area involving a multitude of specific drug study protocols. Worked closely with both clinical monitors (CRAs) and statisticians. Also assisted in creating menu-driven programs to allow user access to CNS database.

Assistant Research Scientist I/II

Managed a CNS screening lab for research, development, and implementation of screening models for novel compounds in various CNS programs. Skilled in small animal surgery, autoradiography/receptor binding analysis, protein analysis, digital image analysis techniques, and the safety, handling and inventory of radioactive compounds.