

## Herbert G. Luther, PhD

A pharmaceutical Regulatory Affairs professional experienced in directing and developing Regulatory Affairs departments. Providing regulatory strategy and input for multidisciplinary product development teams. Experienced in the submission of drug applications in e-CTD format and resolving regulatory issues.

### **Summary:**

- Experienced Regulatory and Clinical professional with 16+ years executive supervisory experience and 20+ years direct regulatory and clinical experience.
- Proven track record of IND, NDA, ANDA, OTC, DMF and international submissions and approvals.
- Established working relationship with FDA.
- Developed Regulatory and Clinical departmental capabilities to support corporate strategies including pharmacokinetic studies as well as Phase I, II, III clinical studies.
- Responsible for submission, approval and launch of branded drug products, including FDA negotiations/meetings, DDMAC and labeling reviews, and post approval supplements.
- Experience with various drug delivery technologies resulting in NDA approvals
- Introduced an International Regulatory Affairs department. Integrated global regulatory affairs groups with coordination between groups in Israel, UK, US and Mexico.
- Participated in Due Diligence evaluations and assessments for product and company acquisitions.
- Prepared and monitored department budgets
- Knowledge and experience working with R&D, Analytical Research, Manufacturing, Quality and Project management teams

### **Experience:**

#### **Consultant (2009-present)**

- Providing strategic regulatory input, support and regulatory guidance in product development and submissions.
- Directed the preparation of documents for Pre-IND meetings and participated in Pre-IND meetings with FDA
- Directed and participated as part of team in preparation and submission of INDs (first in man Phase I)
- Providing regulatory input in product evaluations and due diligence activities.
- Providing guidance in establishment and requirements of Regulatory Affairs departments.

#### **Perrigo (Pharmaceutical), Allegan, MI & Piscataway, NJ (2007-2008)**

##### ***Vice President Global Regulatory Affairs***

- Responsible for Global Regulatory Affairs functions and coordination of product submissions, approvals, supplements and annual reports for regulatory groups in US, Israel, UK, and Mexico. Total global regulatory staff of approximately 70.
- Responsible for over 6,000 SKUs of Generic and OTC (ANDA & monograph) products
- Core member of Global Scientific Affairs team including Formulation R&D, Analytical R&D, Clinical Affairs, Project Management and Regulatory Affairs departments.
- Primary FDA contact person.
- Participated in FDA Pre-IND meetings
- Participated in evaluation of e-CTD and document management systems.
- Participated in product and company acquisition evaluations and due diligence.
- Conducted Bioequivalence (PK) studies

**KV Pharmaceutical, St Louis, MO (1996-2006)**

***Vice President Regulatory & Clinical Affairs***

- Developed Regulatory Affairs to over 25 persons. Established Domestic Submissions and Compliance, International and Labeling Regulatory functions within Regulatory Affairs Department.
- Approvals of 2 NDAs and 15 ANDAs in short approval review cycles.
- Experienced in Extended Release and Drug Delivery technologies resulting in numerous drug approvals in the US and International markets.
- Primary FDA contact person
- Responsible for identifying and interpreting current US/ICH regulatory requirements, policies and guidances to develop regulatory strategies for product development, submissions and approvals.
- Directed Regulatory, Clinical and Statistical departments to provide integrated submission capabilities.
- Initiated eCTD submissions of INDs, NDAs and ANDAs.
- Participated in FDA meetings regarding regulatory and clinical programs and requirements for product approvals.
- Directed Clinical Department to perform over 40+ Phase I (PK-BE/BA) studies per year.
- Directed bioequivalence studies with clinical endpoints.
- Directed Phase I-IV clinical studies.
- Developed internal capabilities to conduct Phase I-IV clinical studies with in-house staff.
- Expanded clinical personnel to include medical writer, clinical scientists, program managers and coordinators, CRAs and document specialists.
- Established an International Regulatory Affairs Department with filings in over 70 countries including the EU and China.
- Participated in numerous direct meetings with EU health regulatory agencies including the UK, Sweden and Spain to negotiate application requirements for review and approval.
- Directed clinical efficacy studies outside the US (Russia, and China).
- Expanded Statistics Department to provide in-house statistical analysis capabilities for Phase I-IV studies, including SAS programming and analysis for submissions.
- Budget preparation and monitoring for Regulatory, Clinical and Statistical departments.
- Participated in due diligence and evaluation of product acquisitions and joint ventures.

**Barr Laboratories, Inc., Pomona, NY (1991-1996)**

***Director Scientific Affairs***

- Responsible for regulatory submission strategies.
- Identifying US and ICH regulatory requirements, policies and guidances.
- Responsible for supervision, preparation, submission, bioequivalence studies required for approval of ANDAs.
- Prepared and filed numerous ANDAs as “first to file” ANDAs with Paragraph IV patent challenges.
- Primary FDA contact person
- Contracted and budgeted for all BE/BA studies with CROs.
- Implemented new ANDA format for tablets, capsules, liquids, suspensions and controlled release dosage forms.
- Developed an integrated Product Development Process Template System to ensure the required documentation was generated and audited prior to FDA submission.
- Assisted in creating a R&D/Product Development audit system to review documentation for submission to ensure GMP compliance.

**Superpharm Corporation, Bayshore, NY**  
**(A former division of Goldline Laboratories, an Ivax Company)**

***Director, Regulatory Affairs (1991)***

***Manager Regulatory Affairs (1990-1991)***

- Regulatory Responsibility for all approved and pending applications
- Preparation and submission of supplements, amendments and annual reports for registrations with FDA.
- Worked with international joint venture partners to convert their applications to US format for FDA submission.

**PDK Laboratories, Ronkonkoma, New York**

***Director of Quality Control and Regulatory Affairs (1988-1989)***

- Managed QC Laboratory and operations for compliance to GMPs and FDA/USP regulations for OTC drug products.
- Initiated QA program, revised SOPs and stability testing program.

**Eight in One Pet Products, Inc., Hauppauge, New York**

***Manager Quality Control (1985-1988)***

- Responsible for testing and release of raw materials, active pharmaceutical ingredients and finished products according to USP monographs and FDA requirements.

**Luther Associates, Inc., Smithtown, NY**

***Pharmaceutical Research Consultant (1982-1985)***

- Contract clinical monitor for animal health drug trials. Involved in investigator and facility selection and GCP compliance.

**University of Illinois, Urbana, Illinois**

***Post Doctoral Research Associate (1979-1981)***

- Supervised and conducted pharmacokinetic (ADME) drug studies for FDA grants and pharmaceutical industry contracts.
- Pharmacokinetic modeling and analysis

**Education:**

***PhD, University of Illinois, Pharmacology & Toxicology, 1978***

Area of Concentration: Pharmacokinetics (FDA Research Grant)

***MS, University of Illinois, Pharmacology & Toxicology, 1976***

Area of Concentration: Infectious Drug Resistance (NIH Research Grant)

***BS, Drew University, Madison, NJ 1971***

***Major: Biology***

**Memberships:**

American Association of Pharmaceutical Scientists (AAPS)

Regulatory Affairs Professional Society (RAPS)

Drug Information Association (DIA)

Food and Drug Law Institute (FDLI)

Association of Clinical Research Professionals (ACRP)

**References:**

References will be furnished upon request.