Laura J. Weston

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SUMMARY

Results driven pharmaceutical scientist with extensive experience in facilitating the development, approval, and launch of novel small molecule and biologic drug products. Expertise in preparing CMC sections of regulatory filings, method development and validation, contract facility oversight (domestic and ex-US), regulatory compliance, building teams, and formulation development. Strengths include project management, international partner relations, system development, stability data evaluation, and technical writing.

- Authored and/or edited the CMC sections of multiple NDAs and BLA's that were approved within the PDUFA timeframe, many with zero CMC comments from the FDA.
- Prevented a product back-order situation of a commercial product by discovering the root cause of a dissolution problem for a commercial tablet product. The solution to the problem also resulted in two issued US patents.
- Developed, managed, and mentored a team in a virtual company that grew from 13 employees with 1 development product to over 400 employees with 6 commercial and 6 development products.
- Numerous direct FDA interactions (including pre-IND, pre-NDA, EOP2, Type A, B, and C Meetings) resulting in positive outcomes, including prevention of back-order situations and dozens of approved prior approval supplements (PAS).

PROFESSIONAL EXPERIENCE

DERMATA THERAPEUTICS, LLC. **2015 – Present**

Vice President, Pharmaceutical Technology *(2017 – Present)*

Provide strategic direction, key decision making and oversight for the development and commercialization of novel pharmaceutical drug products, including analytical development, process development and scale-up, and clinical supplies production and distribution.

- Oversight for the development of a novel fresh-water sponge product for the treatment of acne.

Executive Director, Pharmaceutical Technology *(2015 – 2017)*

Provide technical direction, strategic planning, and leadership for the development and commercialization of novel pharmaceutical drug products. Provide oversight for all CMC activities, including analytical development, process development and scale-up, and production of clinical supplies.

- Selected and managed CMOs for synthesis of novel drug substance and production of drug products.
- Coordinated the production of supplies for non-clinical and clinical studies for dermatology indications.

THE WINDSHIRE GROUP, LLC. **2015 – Present**

Chief Stability Scientist for Stabilityshire Service

Provide technical leadership for Stabilityshire(SM), a drug stability and shelf-life data analysis, assessment, reporting, and management service. The Stabilityshire service evaluates stability data to determine the appropriate shelf-life for new drugs and to monitor ongoing stability performance utilizing SLIMStat software.

- Produce stability reports, including trend analysis, and provide authorship of the stability sections of regulatory submissions -- such as INDs, IMPDs, and NDAs.
- Assess cGMP and ICH compliance for client current or ongoing stability programs.
- Performed implementation and validation of SLIMStat software.

LONE PINE CMC CONSULTING, INC. **2014 – Present**

Founder and Principal Consultant

Established a consulting firm focused on assisting the biopharmaceutical industry with their CMC regulatory, analytical chemistry and product development outsourcing needs.

- Authored CMC sections for multiple regulatory filings (IND, NDA, BLA, IMPD, etc)
- Performed gap analyses of regulatory submissions and corporate stability programs
- Performed due diligence and prepared development plans for several small molecule projects
- Provided technical expertise to trouble-shoot and improve several release test methods
- Created templates and processes for stability reports and FDA compliant data tables
- Sourced and managed CMOs to take a small molecule from discovery to first in human clinical trials

SANTARUS, INC. **2002 – 2014**

Senior Director, Pharmaceutical Technology *(2009 – 2014)*

Provide technical direction, strategic planning, and leadership for the group responsible for supporting the development and commercialization of small molecule and biologic products. Conducted strategic due diligence analysis, participated in audits, and made specific recommendations relating to new product acquisitions, mergers, and partnerships.

- Lead a cross-functional, international team for a delayed release rifamycin SV product from IND submission through completion of an overwhelming positive Phase 3 clinical trial.
- Drafted and Negotiated Services and Supply agreement with Biogen for a new Phase 1 anti-VLA1 monoclonal antibody drug product (Covella).

Director, Pharmaceutical Technology *(2006 – 2009)*

Developed formulations and manufacturing processes for new and established pharmaceutical products. Directed analytical development, process scale-up, and production of clinical supplies and initial commercial launch materials. Represented product development and analytical functions with all external contacts, including suppliers, contract manufacturing organizations, the FDA and other regulatory bodies.

- Led and managed formulated and development activities associated with 2nd generation Zegerid products, including Zegerid Tablets which gained FDA approval in 2009.
- Led and managed the development of a novel extended release product from concept to Phase 1 clinical trials with minimal resources.
- Voting member on cross-company Development Subcommittee responsible for facilitating communication, coordination, and review between the corporate partners of matters relating to development and manufacture of Licensed Products and regulatory affairs. Ultimately resulted in the launch of Zegerid OTC to market.

Director, Analytical Chemistry *(2004 – 2006)*

Provided technical direction and leadership for the analytical chemistry group responsible for all QC and analytical development activities associated with the formulation and production of products for use in clinical studies and commercial sales. Coordinated the preparation and submission of analytical sections of all IND, NDA and other regulatory filings.

- Successfully identified the primary stability degradant in Zegerid® products, complete with structure and degradation pathway, which allowed for wider release and stability specifications.
- Coordinated the CMC sections of 4 approved NDAs in less than 2 years, two of which were submitted to the FDA within 4 weeks of each other.

Senior Manager, Quality and Analytical Development *(2002 – 2004)*
Managed and mentored a team of chemists/project leaders responsible for stability, method development, method validation, and analytical support from Phase 1 through commercialization.

- PAI Team Leader for the Zegerid Suspension project, resulting in Zero 483 observations at our international drug substance and drug product contract facilities.
- Supported the Zegerid Capsules product, which included the manufacture and release of 13 different Phase 1 CTM formulations in less than 6 weeks.

Manager, Quality and Analytical Development *(2001 – 2002)*
Managed all quality assurance and analytical development activities. Established stability programs, quality systems, and product release documentation required to achieve product approval by the FDA.

ELAN PHARMACEUTICALS (FORMERLY DURA PHARMACEUTICALS) 1995 – 2001

Laboratory Manager – Special Project, Gainesville, GA *(2001)*
Replaced commercial QC laboratory manager of who was terminated due to impending FDA consent decree. Responsible for release and stability testing of raw material, in-process timed release beads and finished capsules for Verelan SR and Verelan PM marketed product.

- Implemented and improved upon laboratory systems for OOS investigations, reference standards, balances, and laboratory purified water system to bring into compliance.

Laboratory Supervisor *(1999 – 2001)*

- Developed a scheduling technique that improved laboratory efficiency by over 100%.

Senior Research Associate *(1997 – 1999)*

- Developed and implemented a streamlined stability data system that resulted in a 50% improvement in laboratory cycle times.

Research Associate *(1995 – 1997)*
Stability study director for over 20 stability studies of dry powder inhalation formulations. Developed and validated methods (HPLC, GC, particle sizing, etc.) for product release and stability testing.

MOLECULAR BIOSYSTEMS 1992 – 1995

Research Associate *(1992 – 1995)*
Developed and validated analytical methods to support Optison®, a parenteral biologic device.

EDUCATION & TRAINING

Executive MBA – University of Southern California – Graduated with Honors
BS, Chemistry – University of California, Davis

Numerous professional courses and seminars in biotechnology, regulatory affairs, pharmaceutical quality, GMPs, CMC, intellectual property, and management/leadership (complete list available upon request)

PATENTS, PUBLICATIONS, AND PRESENTATIONS

Several issued US patents and multiple published US patent applications.

Two presentations related to paper published in Journal of Solid State Chemistry.

Additional details for patents, publications, and presentations are available upon request.