Laura J. Weston

PROFESSIONAL SUMMARY:

Pharmaceutical scientist with extensive experience in the development, approval, and launch of novel small molecule and biologic drug products.

Authored and/or edited the CMC sections of multiple NDAs that were all approved within the established PDUFA timeframe.

Expertise in method development and validation, contract facility oversight (domestic and ex-US), CMC regulatory compliance, building teams, and product development.

PROFESSIONAL EXPERIENCE:

Dermata Therapeutics, LLC	Vice President, Pharmaceutical Technology	2017-Present
	Executive Director, Pharmaceutical Technology	2015-2017
Lone Pine CMC Consulting	President and Principal Consultant	2014-Present
Santarus, Inc	Director & Sr. Director, Pharma Technology	2006-2014
	Director, Analytical Chemistry	2004-2006
	Manager & Sr. Manager, Quality & Analytical Dev.	2001-2004
Elan/Dura Pharmaceuticals	Laboratory Supervisor and Manager	1999-2001
	Research Associate & Sr. Research Associate	1995-1997
Molecular Biosystems	Research Associate	1992-1995

Masters of Business Administration – University of Southern California
Bachelors of Science in Chemistry – University of California, Davis

PROVEN TRACK RECORD:

- Developed novel dermatology products for the treatment of Rosacea, Atopic Dermatitis and Acne.
- Prevented a product back-order situation for Cycloset® by discovering the root cause of dissolution OOT/OOS. The solution resulted in several issued patents.
- Rifamycin SV Delayed Release Tablet Team Leader – IND through Phase 3 clinical trials.
- Led and managed formulated and development activities associated with FDA approved products
- Supported the manufacture & release of 13 different CTM formulations in less than 6 weeks.
- Numerous direct FDA interactions (pre-IND, pre-NDA, EOP2, Type A, B, and C Meetings).
- Coordinated the CMC sections of 4 approved NDAs in less than 2 years.
- Authored multiple PAS for Cycloset, Glumetza, Uceris, and Zegerid – all approved by the FDA.

Key Takeaways

- Broad experience base with multiple dosage forms (topicals, immediate/delayed/extended release tablets, capsules, suspensions, chewable tablets, injectables, inhaled dry powders).
- Strong regulatory background – IND-Launch, Submissions and direct FDA
- Collaborative style with a can-do attitude.

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