Pyrenees Pharmaceutical CMC Consulting, LLC

"NAVIGATING CMC PHARMACEUTICAL DEVELOPMENT CHALLENGES, DELIVERING EXCELLENCE"

PYRENEES PHARMACEUTICAL
CMC CONSULTING

VISION: REDEFINING PHARMACEUTICAL DEVELOPMENT FOR SMALL-TO-MIDSIZE COMPANIES

OVERVIEW

Pyrenees Pharmaceutical CMC Consulting LLC provides comprehensive consulting services for Pharmaceutical Development in analytical development, preformulation, formulation and technical writing tailored to small-to-midsize pharmaceutical companies and government agencies such as the NIH.

KEY AREAS OF EXPERTISE

1. Analytical Method Development and Validation
   - Design and validation of fit-for-purpose methods for actives, impurities, residual solvents, and degradation products
   - Dissolution method development to establish in vitro–in vivo correlations
   - Specifications setting for Raw Materials, API and Finished Products.
2. Preformulation Studies
   - Solubility profiling, forced degradation, physical characterization, and excipient compatibility
   - Solid-state analysis to identify polymorphs and critical material attributes
3. Formulation Development
   - Design of Experiments for formulation and process optimization
   - Lipid-based dosage forms and solid dispersions to enhance bioavailability from preclinical through commercialization
   - Long-acting injectables, ophthalmic solutions, and nasal spray formulations
4. Due Diligence and Technical Writing
   - Module 3 CTD authoring for INDs, NDAs, ANDAs, and NADA submissions
   - Data review and regulatory support documents
5. IP and Legal Support
   - Patent strategy development and freedom-to-operate analyses for formulations
6. Technical Project Management
   - Multidisciplinary team and CRO/CDMO leadership, timeline and budget management, and risk mitigation using industry-standard PM tools

KEY ACCOMPLISHMENTS

- Authored Module 3 analytical and formulation sections for multiple INDs, 2 NDAs, 2 ANDAs, and 1 NADA
- Developed analytical methods and formulations for NCEs, 505(b)(2) products, and generics across solid oral, liquid oral, injectable, and nasal spray formats
- Established and directed the Gattefossé North American Technical Center of Excellence Application Laboratory, supporting lipid-based formulation R&D and client seminars
- Recruited, trained, and mentored laboratory teams to deliver high-quality analytical and formulation services

ACADEMIC APPOINTMENTS

- Adjunct Professor, University of Wisconsin–Madison PHM SCI 762: Drug Development from Discovery to IND
- Adjunct Professor, Saint Thomas Aquinas College CHEM 301: Quantitative Analytical Chemistry

LEADERSHIP PROFILE

Dr. Jason LePree holds a B.S. in Pharmacy from Rutgers University and M.S./Ph.D. degrees in Pharmaceutics from the University of Wisconsin–Madison. He maintains an active pharmacist license in New Jersey and brings over 25 years of combined academic and industry experience.

Jason has taught as an Assistant Professor of Pharmaceutics and served as Program Director for an M.S. Pharmaceutics program while leading analytical and formulation efforts at companies such as Boehringer Ingelheim, Hoffmann-La Roche, Novartis, Ferring, Oyster Point, Abon, Elite, and Gattefossé USA. His servant-leadership approach and deep technical expertise help guide clients through every phase of CMC development.

VISION

To redefine pharmaceutical development for small-to-midsize companies by delivering science-driven, phase-appropriate, quality-by-design CMC solutions that accelerate timelines and ensure robust submission packages.

MISSION

Empowering emerging pharmaceutical innovators with tailored CMC strategies, regulatory expertise, and servant leadership to navigate development challenges and bring therapies to market to enhance patient lives.

CONTACT

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Empowering your project with science-driven CMC excellence