



Pyrenees Pharmaceutical CMC Consulting, LLC

CAPABILITY STATEMENT

Summary: Pyrenees Pharmaceutical CMC Consulting LLC provides comprehensive consulting services in: method development, validation, and preformulation characterization of drug substances and products; drug product formulation and development for NCEs and generic products; Analytical method and formulation development following a quality-by-design approach; risk identification and mitigation to anticipate, avoid, and minimize delays in development; CDMO and CRO management for analytical services, preformulation, and manufacturing

CORE COMPETENCIES:

- **Regulatory Documentation:** Authoring Module 3 sections for IND, ANDA, and NDA submissions
- **Analytical Method Development:** Fit-for-purpose method development and validation for drug substances and products
- **Formulation Design:** Phase-appropriate formulation design for small molecules and peptides for oral, topical, nasal, ophthalmic and injectable routes of administration
- **Quality & Compliance:** Analytical method and formulation development by QbD approach, risk assessments, and remediation support
- **Technical Staff Training:** Over 25 years of teaching experience, offering courses in thermoanalytical techniques, dissolution, HPLC method development
- **Analytical Strategy:** Stability study design and protocol development, Specification setting
- **CRO and CDMO management:** Over 10 years' experience in CRO and CDMO management including analytical method development, transfer and validation, formulation development, and oral and injectable drug product manufacture

COMPANY DATA

- DUNS: 132618808
- NAICS: 541690, 541714, 541713, 541715
- UEI: TTYLRXV7DAW8
- CAGE: 140B5

CONTACT:

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EXPERTISE:

- Over 12 years' experience in CMC analytical services
- Over 12 years' experience in oral formulation development for small molecules and peptides with low bioavailability
- Over 6 years' experience in long acting injectable, ophthalmic, and nasal formulation
- Over 10 years' experience in application of Design of Experiments for analytical method development, formulation development, and critical material attribute and processing parameter identification

Certifications:

- Registered Pharmacist, State of NJ
- NJ SBE Certified: A0610-10

DIFFERENTIATORS:

- **Servant Leadership Model:** Client-centric approach prioritizing long-term partnerships over transactional engagements
- **Niche Expertise:** Education and current hands-on laboratory experience and know how in analytical sciences, preformulation and formulation.
- **Small company/startup and government agency support:** Drove development in small companies.

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