James Klancke

Senior Analytical Development Consultant

Core Competencies

- Stability Testing
- Experimental Design/DOE
- Phase I - Phase IV
- Characterization
- Method Development
- Validation
- Buccal Absorption
- Pediatric Formulation

Products

- Lorabid ®
- Gemzar ®
- Fentora ®
- Lexapro ®
- Clarinex RediTabs ®
- Zyrtec ®

Professional Summary

Mr. Klancke is an Analytical Executive with over 30 years of industry expertise in analytical method development and validation, analysis, and stability of pharmaceuticals in a GMP environment. He has expertise in all phases from drug concept through commercialization and has demonstrated leadership and management of large laboratory and technical teams. He also has experience in the development and validation of dissolution methods.

Jim has a proven ability to work effectively and meet or exceed expectations of internal and external customers leading to the launch of numerous products.

He applies a high level of proficiency in experimental design, data assessments, specification development, and risk assessment and mitigation in facilitating successful product development.

Education

M.S.	Analytical Chemistry	University of South Dakota
B.S.	Chemistry	St. Cloud State University

Professional Experience

DSI & Independent Consulting **2017 - Present**

Senior Analytical Development Consultant

Provide CMC support to multiple start-up pharmaceutical and biotechnology companies developing specialized dosage forms and drug-device combination products.

- Provide strategic planning and execution of analytical development programs for clients,
- Advise clients on specifications and control strategies for starting materials, raw materials/excipients, intermediates, drug substance and drug products,
- Evaluate test methods, stability and method validation protocols and reports, quality control systems, SOPs and specifications to ensure that they are development phase-appropriate and meet regulatory requirements.

CIMA Labs, Inc. (Teva Pharmaceuticals and Cephalon, Inc.) **1994 - 2017**

Sr. Director, Analytical Development (2003)

Technical and administrative leadership and direction of development and validation; tech transfer; stability programs with SLIM Stat; Quality Control teams in full GMP environment and alignment with ICH guidelines.

- Drug delivery combination concepts with dosage form expertise in abuse deterrent, orally disintegrating, buccal, and conventional solid oral dose development for innovator and generic drugs in partnership with formulation development, all of which reached commercialization phase; API, drug intermediate, and raw material characterization,
- Utilized experience in full regulatory complement including approvals for 30+ IND, NDA, ANDA, MAA, and JNDA submissions, resulting in limited and manageable CMC deficiency letters,
- Developed systems emphasizing GMP and CFR 211 quality focus from product conception through commercialization (SOPs, OOS//OOT deviations management, CAPA, quality metrics, cleaning verification) resulting in strong GMP posture and successful audit record,
- Proven ability to work effectively and meet or exceed expectations of internal and external customers (large and small pharma client contracts), leading to launch of numerous products.

Director, Analytical Development (1999)

Developed and validated chromatographic (HPLC, UPLC, GC) and non-chromatographic methods for drug product, intermediates, and raw materials vendor qualification enabling commercialization of multiple orally disintegrating tablet (ODT) products; extensive USP dissolution and drug release experience.

- Wrote analytical CMC modules and led lab function through successful pre-approval inspections,
- Launched first Rx product for the company in dual role as scientist and project manager,
- Developed and validated innovative method to measure liberation of CO2 from effervescent,
- ODTs using gas-phase FTIR which provided better characterization of the technology.

Eli Lilly and Company Research Labs, Lafayette, IN **1989 – 1994**

Associate Scientist and Group Leader Associate Scientist

- Supervisory and project team responsibilities,
- Methods development and analysis for New Chemical Entities (API), pivotal intermediates, and new raw materials in support of chemical process development and pilot plant operations,
- HPLC, GC, process FTIR, ion chromatography, size exclusion, extractions, impurity analysis, and Karl Fischer applied for comprehensive material characterization.