Dennis H. Roberts

Senior Project Management Consultant

Core Competencies

- CMC Development Teams
- Regulatory Compliance
- Global Health Authority Inspections
- Investigations and OOS Resolution
- Laboratory Management
- Project Management
- Drug Development
- PAI Inspection Lead

Professional Summary

Mr. Roberts is a Pharmaceutical Development leader with proven proficiency gained through 30+ years' experience guiding teams to successfully bring products to USP/EP/JP markets and maintain them. He has extensive experience with international GMP regulations for development, testing, manufacturing and commercialization, API, sterile injectable (liquid and lyophilized) and solid oral product development, testing and manufacturing. Coordinates with internal/external teams and vendors as well as negotiates with global regulatory bodies. He serves as a key client contact for assigned project responsibilities, establishing working relationships with client project teams which result in client satisfaction and operational excellence.

- Analytical Laboratory Management
- Drug Product Development
- Regulatory and Industry Compliance

Before joining DSI, Mr. Roberts served as Executive Director, Product Development at Xeris Pharmaceuticals. He holds a degree in Chemistry from Washington State University.

Education

B.S.	Chemistry	Washington State University

Professional Experience

DS InPharmatics **2019 - Present**

Consultant

As Project Manager, he compiles and drives documentation for the project, ensuring the accuracy and quality of regulatory data. Maintains lead core project team and facilitates teams' ability to ensure effective cross-functional teamwork among project team members, including both internal and external client and CMO. Monitors project scope, schedule and costs to ensure all remain on track, including milestones and financial performance targets.

Xeris Pharmaceuticals **2015 - 2019**

Executive Director, Product Development

Manage formulation/process and analytical methods development for product development for Xeris's proprietary glucagon formulation/injector system in support of PIII clinical trials and NDA submission. Develop control strategy and processes for compliance with US FDA regulations and guidance documents. Qualify and manage Contract Testing Laboratories for method development, validation and registration stability testing. Develop technology transfer process to Contract Manufacturing Organizations for process development, manufacturing and analytical testing**.**

- Led the successful resolution of a severe drug product stability problem,
- Developed an Extractables and Leachable (E&L) program to support clinical and NDA requirements,
- Author and contributor to pharmaceutical development, analytical validation, methods for NDA module 3.

CTI Biopharma, Inc. **2009 - 2013**

Vice President, Quality

Managed team of Quality professionals responsible for the quality assurance and control functions of the company including GMP and GCP compliance, API and product testing, stability program and product release. Created and implemented processes to align pharmaceutical manufacturing operations with industry standards and FDA and EMA regulatory requirements to include developing and executing SOPs and Quality Agreements for manufacturing and testing, regulatory submissions, and vendor selection/relations. Oversaw Quality Assurance/Control for GMP compliance of contractors (API, finished dosage) and internal systems.

- Minimized potential for negative observations by thoroughly preparing for FDA PAI inspections,
- Adeptly resolved critical FDA inspector identified analytical testing issue at contract manufacturing site,
- Primary liaison responding to analytical testing, quality, stability and specifications questions from FDA and EMA questions for pixantrone dimaleate injection.

Cell Therapeutics **2001 - 2009**

Senior Director, Quality Operations

Supervised and managed team of four Quality Control Specialists and a Manager, as well as two Document Control Specialists, while handling complete management functions for the Quality Group to include QC operations and document control. Created and managed budgets.

- Oversaw external CMO and contract testing lab operations and teams,
- Handled processes for product releases including chemical/microbiological methods and testing, stability program management and reporting,
- Managed batch records, change control, SOPs, and specifications for regulatory compliance,
- Participated on CMC teams as both a leader and individual contributor,
- Authored and reviewed CMC (Module 3) regulatory filing (IND, IMPD, NDA, MAA),

- Authored, reviewed and proved validation, investigation or development reports for chemistry and microbiological quality,
- Optimized global team relationships through developing strong vendor and staff partnerships,
- Served as leader during pre-MAA negotiation meetings with Dutch and German Rapporteurs for Paclitaxel Poliglumex as the CMC expert.

Akorn, Inc. **1992 - 2001**

Director, Product Development

Managed team of 15+ professionals responsible for internal development of NDA/ANDA products which included reverse engineering/formulation development, manufacturing process development (compounding, sterilization etc.), packaging, analytical testing, stability and commercial validation. The development program resulted in numerous successful product launches. The team also provided development services for external companies as part of Akorn's contract services.

- Built a cGMP compliant analytical laboratory from ground up with capabilities of stability indicating methods development, method validation, API and product release testing and stability monitoring,
- Adeptly resolved critical FDA inspector identified analytical testing issue at contract manufacturing site,
- Represented company in areas of CMC function on behalf of contract clients for FDA meetings,
- Served as point of contact for FDA and EMA PAI and inspections for development and analytical areas.