Anil Raghani, Ph.D.

Senior Analytical Development Consultant

Core Competencies

- Analytical Strategy
- Method Review
- Method Authoring
- Method Validation
- Design of Experiments
- CMO Selection
- Tech Transfer
- Small and Large Molecule
- Process Scale-up

Professional Summary

Dr. Raghani is a seasoned pharmaceutical professional with over 23 years expertise in analytical chemistry related to Chemistry, Manufacturing, Controls (CMC), Module 3/Quality, technical writing for regulatory submissions, analytical method development, validation, technology transfer and control strategy development

He is an accomplished Consultant with an in-depth understanding of manufacturing process development of small molecule therapeutics, as well as biologics, formulation development, raw material control, regulatory requirements, and ICH guidelines.

Dr. Raghani is highly experienced in reviewing scientific information from laboratory data, technical reports, and quality and manufacturing documents to assess technical merits and suitability of scientific rationale, in order to ensure information presented in the regulatory submission is presented clearly and conclusions are supported by the scientific data.

Education

Ph.D.	Analytical Chemistry	University of Florida
M.S.	Analytical Chemistry	Florida Atlantic University

Professional Experience

Design Space Inpharmatics, LLC **2018 - Present**

Senior Analytical Development Consultant

- Execution of gap analysis in CMC, developing risk mitigation plan for regulatory approval,
- Analytical characterization of pharmaceutical products to support elucidation of structure for regulatory submissions,
- Extensive experience in troubleshooting analytical issues arising at the method development, validation, technology transfer stage,
- Developing experimental plans and test protocols for reference standard characterization, force degradation and product stability.

Coherus BioSciences **2016-2017**

Director, CMC Strategy

- Develop quality target product profile (QTPP) for biosimilar products using sound scientific principles and current regulatory expectations,
- Conduct gap analysis and risk assessment in analytical CMC,
- Collaborate with process development, quality, analytical and regulatory affairs teams to meet project milestones,
- Author analytical sections of BLA, MAA,
- Review and provide technical input on cross-functional sections (Quality, Manufacturing and Analytical) of regulatory submissions,
- Provide directions and bring alignment in analytical methods used for specification testing, product characterization, process development and stability,
- Work with contract labs to design analytical experiments for product quality understanding,
- Review and approve technical reports and test protocols (comparability, similarity, reference standard, etc.),
- Influence cross-functional teams to achieve target product quality,
- Develop contingency plan in case of additional regulatory requests.

Amgen **2003-2014**

Group Leader/Principal Scientist

- Identified several critical quality attributes encountered during cell line development, process development and formulation development and consulted the project teams for their control strategy,
- Assisted process development teams to devise control strategies to eliminate impurities during future development using Quality by Design principles,
- Formulated a department-wide guideline to streamline the approach to qualification of analytical methods. The guideline significantly reduced the qualification time,
- Authored numerous CMC sections for IND applications and amendments aligned with regulatory expectations to minimize any regulatory questions on the submissions and prevent delays in entering clinical trials,
- Increased operational efficiency in the department by reducing the number of tests that were less value-added,
- Compiled briefing books, responses to regulatory questions and negotiated with health authorities on analytical commitments to enable clinical trials meet schedule,
- Presented analytical updates to senior management to receive their input and endorsement on proposed solutions to analytical challenges,
- Effectively managed analytical resources and successfully delivered to tight timelines across multiple clinical pipeline projects without sacrificing the quality of analytical data,
- Developed several analytical methods with universal set of analytical conditions that provided a unified approach for the implementation of such methods across multiple products, saving the method development time.

Pfizer/Pharmacia **1997-2003**

Team Leader/Principal Research Scientist

- Directly responsible for management of analytical needs across various projects,
- Provided coaching to direct reports on the selection of appropriate analytical technology,
- Analytical representation on cross-functional project teams,
- Provided feedback to the project teams on setting specifications and process control strategy,
- Ensured direct reports satisfy the requirements for their position including safety, quality, productivity, communication, documentation, and professional development,
- Performed yearly review of the direct reports,
- Investigated and implemented new technologies within the analytical group to enhance productivity and trouble-shooting.