Maria Arakil

Quality Assurance Consultant

Core Competencies

- Product Disposition
- QMS/eQMS Design
- SOP Design
- Change Management
- QA CMO Audits
- Stability Management
- PAI Readiness
- Quality Person Interactions
- Small Molecules
- Biologics
- Antibody-Drug Conjugates

Products

- Thyrogen ®
- Fabrazyme ®
- Cerezyme ®

Professional Summary

Ms. Arakil has expertise in phase-appropriate quality oversight for biologics and small molecules with experience in API/drug substance, drug product, and fill/finish operations from early phase development to commercial manufacturing. She has served as process owner and trainer for change control, deviations, CAPAs, material review board and product complaints (eQMS). She has also provided quality support to quality control, supply chain, clinical operations and facilities.

Education

B.S.	Healthcare Management	Northeastern University

Professional Experience

DSI & Independent Consulting **2020 - Present**

Quality Assurance Consultant

Provide QA support for internal/external manufacturing, testing, audits and SOP development in the areas of oral/solid small molecule, sterile injectable biologics including highly potent compounds such as ADCs.

- Supply Quality Management,
- Quality Systems Development,
- Phase Appropriate Controls,
- Change Management,
- IND/IMPD/NDA/BLA review.

Enanta Pharmaceuticals **2019 - 2020**

Quality Assurance Manager, CMC

- Approval of Master Batch Records, specifications, deviations, CAPAs, investigations, MRB and change controls,
- Manage stability program, approve stability documentation and expiry extensions,

- Creating a comprehensive quality management system by drafting new SOPs and reducing system gaps,
- Review IND/IMPD CMC sections for regulatory filings/updates,
- Provide quality support to clinical operations and supply chain.

ImmunoGen, Inc. **2014 - 2019**

Quality Product Steward/Manager (2018)

- Manage end-to-end product quality for Antibody Drug Conjugates (ADC) manufactured at CMOs,
- Batch disposition for small molecules and biologics, API, conjugates and DP,
- Approval of CMO master batch records, specifications and test methods,
- Review and approval for internal/external deviations, CAPAs, investigations and change controls,
- Served as subject matter expert for the eQMS (Deviation, CAPA, MRB & change control processes),
- Standard operating procedures (SOPs) revision and generation,
- Review IND/IMPD CMC sections for regulatory filings/updates; assist in drafting BLA.

Quality Assurance Operations, Lead Specialist

- Served as the small molecule quality representative managing external vendors,
- Served as the quality representative to external partners for on-site DS manufacturing and testing,
- Internal/external audit support & back room management,
- Review and approval of internal/CMO master/executed batch records, deviations, CAPAs, investigations and change controls,
- Design and administer new hire, QMS, and annual GMP refresher training.

Genzyme, a Sanofi Company **2010 - 2013**

Training & Development Specialist (2013)

- Facilitated new hire orientation classroom training supporting 400+ employees,
- Designed QA training workshops and on the job training (OJT) procedures for all departments,
- FDA and foreign agencies audit support for training.

QA Compliance Specialist, Biologics

- Worked under FDA consent decree to improve processes and procedures,
- Antibody, purification, buffers/media executed batch record review for GMP commercial product,
- Reviewed and composed standard operating procedures (SOP),
- Provided quality oversight for manufacturing and facilities.