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PROFESSIONAL OBJECTIVE

To identify and secure a position in a regulatory, quality discipline within the pharmaceutical/biopharmaceutical industry. I have direct experience in aspects of API, vendor management, training and cGMPs with increasing levels of responsibility from data/report release, manufacturing release, FDA/EMA inspections, and management of quality systems. My most recent experience is as Director, Global Supplier Quality and Compliance.

KEY STRENGTHS:

- Direct experience with Health Authority communications. Setting up, completing, and responding to inspections.
- Excellent communicator and team player. Management style/strategy is inclusive and realistic; focused on meeting objectives.
- Extensive direct experience in contract manufacturing/testing and cGMP compliance. Including Quality Agreements, hosting client and regulatory inspections, and managing vendor program.
- API, Drug Product, and Sterile Manufacturing Quality Systems.
- Front-line department responsibility for building Quality Systems.
- Strong technical writing skills -departmental and/or inter-departmental and in crafting FDA deficiency letter responses.
- Managerial experience with up to twenty total reports, four direct reports.
- Direct experience with product/process validation requirements for computer systems, equipment and methods.
- Experience with Pharmacovigilance, Clinical Educators, Adverse Event and Product Quality Complaint reporting, and applicable regulations.
- Root Cause Analysis, Investigations, and Risk Analysis

EMPLOYMENT EXPERIENCE:

CURIA GLOBAL, INC (FORMALLY AMRI) **September 2020 – Present**
Albany, NY (remote)
Director, Global Supplier Quality and Compliance

- Lead inspection preparation for high risk sites to ensure successful inspections. Work directly with high risk sites through mock inspections, coaching/training, development of storyboards, and inspection support.
- Lead, organize, and complete compliance program including internal audits and regulatory inspection preparation.
- Serve as supplier quality expert for API, drug product, drug development, and R&D business units.
- Coordinate and oversee supplier quality activities at the global GMP sites.
- Coordinate/perform periodic audits, risk assessments, supplier qualification, and scorecards of Curia suppliers, to maintain quality of Curia manufactured products.
- Coordinate/perform corporate audits of global Curia sites.

- Develop and review corporate quality standards, policies, and procedures and support/monitor their implementation at the global GMP sites (e.g., Organization and Personnel, Management Responsibility, and Supplier Qualification).
- Develop Auditor Program to certify (internally) employees to perform corporate, internal, and supplier audits. Train employees through the program.
- Coordinate and facilitate the implementation of the Global Shared Services – Supplier Quality Group (GSS). Transition site processes to include GSS in supplier qualifications.

ASHFIELD HEALTHCARE **September 2018 – September 2020**
Ft. Washington, PA
Director, Quality and Compliance

- Responsible for the Quality and Compliance systems at the Fort Washington, PA site.
- Responsible for ensuring compliance with Pharmacovigilance, HIPAA, OIG guidance, and applicable state regulations.
- Responsible for the Computer System Validation group and the validation of regulated computer systems.
- Ensure maintenance and continuous improvement of Quality Systems to comply with regulations, guidelines, and industry best practices.
- Provide direction and assistance to business units regarding Quality and Compliance strategy and day to day activities by acting as first point of contact and Quality subject matter expert.
- Management of QMS, including but not limited to CAPA, Deviation, Change Control, Computer System Validation, Investigations.
- Conduct internal investigations of compliance issues.
- Prepare and report metrics to Senior Management and external regulatory bodies, as appropriate.
- Provide Quality and Compliance trainings.
- Participate in support and completion of supplier and internal audits
- Previous responsibility for the Cary, NC site (divested in JAN2020)

MERCK **May2017-September2018**
MANUFACTURING DIVISION, WEST Point, PA.
Senior Specialist, Quality Assurance

- Manage site inspections; communicating Health Authorities to set up inspection, preparation and hosting inspections, and inspection response for large scale biologic DP (vaccine) site
- Pre-inspection request fulfillment
- Lead and participate in internal and client site audits
- Manage and provide GMP documentation to regulatory agencies for license renewal
- Participate in support and completion of supplier and internal audits

CHARLES RIVER **May 2013-May2017**
BIOLOGIC TESTING SOLUTIONS, MALVERN and King of Prussia, PA.

Senior Manager, Regulatory Compliance

- Manage Auditing and Document Control staff (20 employees, 4 direct reports)
- Host regulatory inspections (FDA, EMA)
- Complete vendor assessment and Manage site Vendor Assessment Program
- Site regulatory point person for Computer system validation (CFR Part 11)
- Lead and implement globally harmonized programs
- Implement TrackWise and Laboratory Execution Systems at Malvern site
- Provide Quality Systems training to global sites (e.g., risk assessment, root cause analysis)
- Oversee testing transfer from client to Charles River and within Charles River

CHARLES RIVER
BIOLOGIC TESTING SOLUTIONS, **July 2011 – May 2013**
Malvern and King of Prussia, PA.
Director, Regulatory Compliance

- Manage Auditing and Document Control staff (15 employees, 3 direct reports)
- Manage deviation and investigation program
- Review equipment qualifications
- Release of manufacturing projects and testing reports
- Identify and implement solutions for quality risks
- Participate and lead global initiatives.
- Vendor program participation
- Coordinate and implement Corrective and Preventive Actions

CHARLES RIVER
BIOLOGIC TESTING SOLUTIONS, **2008 - 2011**
Malvern and King of Prussia, PA
Senior Quality Assurance Auditor, Supervisor

- Quality Assurance representative and reviewer of Change Controls
- Implemented Quality Laboratory System (internal quality tracking software)
- Implement and complete internal audit program
- Deviation and investigation review
- Participate in and respond to regulatory inspections
- Vendor program harmonization and management

CHARLES RIVER
BIOLOGIC TESTING SOLUTIONS, **2005 - 2008**
Malvern and King of Prussia, PA
Quality Assurance Auditor II

- Review of documents (e.g., equipment forms, cleaning logs)
- Equipment calibration and qualification review
- Maintain general equipment files
- Review of testing reports
- Review of vendor qualification documentation

CHARLES RIVER, Malvern, PA **2001 - 2005**
Cell Culture Team Leader

- Perform several procedures in the laboratory using GMP and aseptic technique
- Maintenance of approximately 40 cell lines
- ELISA

EDUCATION:

- BS - Biology – Delaware Valley College, Doylestown, PA

SYSTEM and REGULATORY EXPERIENCE:

- API
- TrackWise
- Laboratory Execution System
- Technical Transfer of Testing
- Computer System Validation
- Equipment Validation
- Process Validation
- Regulatory Inspections
- Vendor Audits
- Internal Audits
- GMP
- GLP