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Highlights of Qualifications:

A highly-focused Quality GxP (GCP, GMP, GLP) professional committed to working with development and commercial teams to create and maintain the highest possible quality standards for investigational products. Considerable technical expertise in both small molecules and biologics coupled with a firm but highly collaborative working style maximizing team's efforts to accelerate early development timelines and commercial technology transfer without compromising global quality compliance. Extensive experience with GxP compliance and CMO management for production of biologics, gene therapy, (AAV) and small molecule from early development – labeling, packaging, supply chain and the clinical trial setting.

Education: Master of Management, University of Phoenix.
BS; Biomedical Laboratory and Clinical Sciences, Boston University, Metropolitan College

Awards: Eisai Outstanding Innovation Achievement Award; Rewards innovative science as well as innovative improvements to processes or operations in Product Creation for a program produced in Asia.

Business/Professional Experience:

L. Reed Global QA, Inc. Owner and Principal Consultant 01/14 to present
Recent Successes: Retained to work with a phase I-II gene therapy AAV CMO as QA Consultant to assess, plan and implement necessary systems to create a robust phase 3 – commercial GMP facility.

Sole Quality Assurance support from November 2015 – November 2018 for Potenza Therapeutics, successfully stage quality programs for partner buy out. Completed December 2018.

Head of Quality (GxP) for Cambridge small molecule start up, creating and implementing Quality Systems that support GMP and GCP compliance.

Work as QA Support for Gene Therapy AAV product to treat CHM, an inherited retinal disease caused by mutations in the CHM gene on the X chromosome. Client purchased by Biogen March 2019.

Actively engaged with the following client industry efforts:

- Senior Consultant, Global GxP and Business Partner of The Conjugate Group; providing QA support and resource management across multiple clients. Manage QA programs for virtual / early stage product development and commercial release of drug product.
- Audit CMO Vendors in behalf of clients to ensure GMP, GLP or GCP vendor qualification.
- Work with a consultant-based CMC team to manage client development efforts providing QA support to create, implement and direct compliance programs that ensure FDA PAI GMP and GCP audit readiness state for oncology product produced in EU and USA working within CMO locations.
- In behalf of client, participate in a CMC third party (Shanghai, China, USA) cross functional group responsible for assistance with launch of commercial product providing QA GMP over-sight of manufacturing compliance and disposition of commercial product.
- Provide quality assurance services for development and commercial products produced in USA, UK, and Germany for commercial release to the US market. Participate and complete serialization of commercial product.
- Perform Client audits in USA, EU and China CMO and CTL sites to ensure both GMP (Part 210 and 211) and GLP (Part 58) compliance.
- Significant experience with FDA, ICH, EU Directives, QP Certification and international auditing.

Senior QA Consultant Additional Activities 11/2014 to present

- GMP and GLP audits in behalf of client supplier approval programs.
- Liaison between client and CMO organizations to ensure adherence to GMP compliance for all stages of development, clinical trial supply.
- QA Lead for due diligence assessment of manufacturing facilities located in South America.
- Create client-based document repository and document change control within Share-point system. Ensure client documents are appropriately stored, secure and manage change control.

EISAI, Inc. Andover, MA 01/05-12/13

Director, Global Development Quality Assurance, and Validation Eisai Americas (North and South America)

- Global Director of GxP compliance for Eisai Americas development API, clinical trial material and biotechnology drug substance and drug product programs, (5 direct reports)
- Responsible, through delegation of 5 staff members, for cGMP compliance and validation of a multi-product small molecule development pharmaceutical manufacturing site.
- Ensured GxP compliance for product in the development phase through commercialization. Including starting material, API, drug substance, drug product, labeling and packaging for products produced at Eisai small molecule manufacturing site and global biologics Contract Manufacturing Operations, (CMO) including EU and Asia.
- Direct responsibilities for ensuring GCP adherence including, labeling, packaging, shipping, deviations in the clinical setting and CRO assessment.
- Responsible for GMP auditing program at CMO sites in North America, Europe and Asia commencing with starting material through product stored and used in the clinical setting.
- Chair and responsible for the North America internal change control committee
- Responsible for local and global document control using both Pilgrim and Share Point software. Create and implement electronic document control and electronic training modules.
- Responsible for compliance of product in the clinical setting to ensure the integrity of the product(s) are maintained through out the clinical trial cycle. Create and implement a program to ensure deviations and investigations of product in the clinical setting are appropriately conducted.
- Provided comments for FDA guidance's for bio similar and quality agreements.

Director, DQA (Development QA) (MGI Pharma, Inc. - Purchased by Eisai, Inc. January 2008), 11/05 – 12/07

- Development of quality assurance systems to ensure compliance with global regulations and standard operating procedures related to GxP.
- Work independently in a cross-functional CMC team to represent and implement DQA GxP requirements for MGI CMO North American and European locations. Responsible for GxP compliance for CMO process development operations.
- Responsible for clinical quality assurance (GCP).
- Responsibility for budget development and adherence for DQA project management.
- Participated in the development of technology utilizing custom design SKID for encapsulated pDNA drug substance and drug product processes to ensure availability of clinical trial supplies.
- Responsible for GLP auditing, close out of reports and storage of tissue samples.
- Participated in the development, validation and technology transfer for a unique micro-encapsulation pDNA SKID.
- Responsible for auditing US and EU CMO sites.

SHIRE PHARMACEUTICALS GROUP / TRANSKARYOTIC THERAPIES. INC. (TKT)

Site Director, Quality Assurance 05/02-11/05

- QA site Director of commercial drug substance manufacturing for release of product to EU.
- Received EU and FDA commercial site approval. Prepare and participate in European PAI inspection for TKT drug substance manufacturing site, Japanese and contract manufacturing partner site audits.
- Implemented and ensured all aspects of day to day GMP compliance for release of protein based drug substance in a multi product development/commercial manufacturing site to ensure enough supply for TKT commercial and clinical needs for lysosome disorder (LSD) products.
- Provided direction to 7 staff members to manage QA systems such as CAPA, change control, deviations, investigations, lot release, employee training, batch and lot number issuance and environmental programs.
- Participated as team member representing QA compliance for the renovation of a manufacturing site to create a validated multi-product licensed drug substance facility.
- Created and implemented product-to-product change over procedure for multi product drug substance manufacturing facility.
- Created and implemented a labeling and reconciliation procedure for labeling drug substance containers.
- Participated in team meetings to review status of Manufacturing, QC, Facility, Validation, and Engineering departments to ensure GMP compliance of technology transfer for drug substance development.

ALTAREX, INC. 01/01-05/02

Director, Quality Assurance

- Responsible, through management of contract sites, for QA and QC GMP compliance of manufacturing, testing and labeling of lyophilized MAb oncology therapeutic.
- Responsible for GLP and GMP qualification, compliance, and auditing of contract testing laboratories.

- Participate with contract sites to ensure contractor SOPs and Batch Record development reflects the approved manufacturing process and QC testing program. Responsible for QC Out of Specification program as it applied to Contract Testing Laboratories.

REPROGENESIS/CURIS 05/96-12/00

Manager, Quality Assurance / Senior Manager, Quality Assurance

- Responsible for creating, implementing, and managing GMP compliance programs for autologous tissue engineered products from pre-clinical through Phase III pivotal trials.
- Created, implemented, and managed a document control system which included creating a SOP format, sop/document numbering system, revision, approval, and issuance of controlled SOPs to SOP manuals.
- Created and managed a system for documenting and investigating planned departures and deviations of approved processes and procedures. Responsible for creating and initiating a procedure for product labeling and reconciliation.
- Involved in the validation of equipment and HVAC system for control of a class 10,000 clean room.
- Created and implemented GLP laboratory notebook auditing procedure. Conduct internal, GLP and GLP vendor audits as necessary.

Additional Work Experience includes

IMMUNOGEN, Inc. **Quality Assurance Supervisor/ Quality Assurance Specialist III**

CHARLES RIVER LABS **Animal Technician / Quality Control Associate / Quality Assurance Specialist**