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Highlights of Qualifications:

A highly focused Quality GxP (Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices) (GLP, GMP, GCP) professional committed to working with development and commercial teams to create and maintain the highest possible quality standards for investigational or commercial 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, and small molecules from early development through labeling, packaging, supply chain and clinical trial setting. Recent experience includes participation as a Senior Leadership Team member at Snapdragon Chemistry, A Cambrex Company.

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

Business/Professional Experience:

L. Reed Global QA, Inc. President & Principal Consultant **01/2014 to Present**
Activities Include:
Head of Quality Consultant **01-2014 – Present**

- Acting Head of Quality Assurance (GXP) Consultant (Werewolf Therapeutics) **01/2020 – 09/2025**
  - Create, implement, and manage fit for purpose GXP compliance programs based on Client clinical phase.
  - Manage Client CDMO and External Partners operations ensuring appropriate disposition of CTM product.
  - Significant expertise with document management including Part 11 software validation and implementation. Decision maker for purchase and implementation of eQMS software to transition from a paper-based system to an electronic QMS used for Document Control, Training, Equipment tracking and calibration.
  - Manage Quality Person (QP) declaration for DP release in EU.
- Other Client Work,
  - Work involves QA support for a commercial small molecule company. Product was primarily produced in EU and USA. Manage all aspects of GMP vendor qualification, quality agreements, DP disposition, deviations, investigations, complaints, serialization of commercial product and storage of released product at 3PL location.
  - QA GCP Consultant for small molecule company multi-site clinical programs. Audits of CRO QA systems.
  - Sole Quality Assurance support from November 2015 – November 2018 for Potenza Therapeutics. Successfully, working with CMC team, stage 3 biologics programs from initiation of manufacturing through phase 2 trials (GLP/GMP). Worked with CMO sites to ensure management of product including creating necessary quality systems for partner (Astellas) buyout. Successfully completed December 2018.
  - 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.
  - Senior QA 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 products.
  - Worked for the Bill & Melinda Gates Foundation, QA oversite for development of malaria product. Assessed manufacturing CDMO in Brotas Brazil.
  - Senior QA Consultant Live Oak Pharmaceutical Consulting, Inc.
  - Audit CMO Vendors on behalf of clients to ensure GMP, GLP or GCP vendor qualification.
  - On 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 & GCP over-sight of manufacturing compliance and disposition 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.

Snapdragon Chemistry, Inc. **09/2020 to April 2025**
Head of Quality CDMO; Part of Senior Leadership Team, (SLT)

- Member of the SLT to drive site management decisions. Participate as a team member in management of Snapdragon Chemistry.

- Created the Snapdragon Chemistry QMS from no QA systems to fully compliant fit for purpose QMS resulting with 100% Client site approval for the manufacturing of API/DS. (21 CFR part 211, ICH Q7, Q9 & Q10)
- Responsible for working with Analytical / QC team to create GMP compliant QC testing laboratory.
- Client GMP QMS support from process development to clinical PI-III GMP systems.
- Decision maker for purchase and implementation of eQMS software to transition from a paper-based system to an electronic QMS used for Document Control, Training, Equipment tracking and calibration. Ensure validation for agreement with Part 11 regulations.
- Work with CEO to complete buildout of a 51,000 sq ft GMP manufacturing facility.
- Create and implement cGMP requirements for facility systems validation including HVAC, USP RO/DI, MiliQ water system, set up of temperature and Rh% facility tracking/trending and software validation.
- Technology Transfer and implementation of cGMP systems for First in Human (FIH) lots for client development programs.
- Participate in Cambrex buyout of Snapdragon Chemistry, February 2023.
- Transition to global QA function within Cambrex to create Development Clinical QA QMS.

Syndax Pharmaceutical, Inc. **04/2020 to 05/2021**
Senior Director GxP Quality Assurance

- Support Syndax multi-site/country GCP clinical programs.
- Responsible for all aspects of GXP and GPV compliance for both small and large molecule clinical phase programs. Ensure through delegation of staff management of GXP activities:
- Manage review, approve and oversite of GLP studies. Ensure, through auditing, appropriate staging of non-human studies.
- Management, through delegation of staff, of all GMP activities for on time disposition of product from starting material through to labeled final drug product. Support of CMC development teams to ensure robust supply chain that is submission and audit ready.
- Create and maintain robust document repository to ensure electronic audit ready documentation. Responsible for document control.

EISAI, Inc. Andover, MA **01/2005-12/2013**

Global Development Quality Assurance (DQA) Sr Director/Director, 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 + 1 person located in Japan and 1 person located in NC USA)
- Responsible, through delegation of 5 staff members, for cGMP compliance and validation of a multi-product small molecule development 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 throughout 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 for bio-similar and quality agreements.

Director, DQA (Development QA) (MGI Pharma, Inc. - Purchased by Eisai, Inc. (January 2008), **11/2005 – 12/2007**

- 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 **05/2002-11/2005**

- 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. **01/2001-05/2002**
Director, Quality Assurance

- Responsible, through management of contract sites, for QA and QC GMP compliance of manufacturing, testing and labeling of lyophilized 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 **05/1996-12/2000**
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**

Listed in Marquis's Who's Who 2025.
https://www.24-7pressrelease.com/press-release/524003/marquis-whos-who-honors-lisa-reed-ms-for-expertise-in-biotechnology-research