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QUALITY AND OPERATIONS MANAGEMENT: PHARMACEUTICAL PRODUCTION

Experienced, results driven engineering, quality assurance, and operations professional with extensive knowledge in pharmaceutical and biotech processing. Skilled leader including start-up, process improvement, safety and regulatory compliance in both the pharmaceutical and biotech markets. Demonstrated ability to set strategy and improve performance measures within operations, technical support, and quality assurance areas including efficiency, safety, and compliance enhancements. Proficient problem solver with proven ability to direct the resolution of compliance gaps and process excursions in an expeditious manner.

PROFESSIONAL EXPERIENCE

EXELEAD, INDIANAPOLIS, IN• JUNE 2020 TO JULY 2022

Exelead focuses on the development and manufacturing of liposomal products, other unique formulations and sterile drug product filling for pharmaceutical clients as a contract manufacturer.

Vice President, Manufacturing (February 2022 – July 2022)
Set direction and lead a manufacturing organization of ~70 personnel. Overall responsibilities include ensuring equipment and facilities are maintained and upgraded as necessary and staff is trained and qualified to produce lipid nanoparticle and other drug products safely, efficiently, within specifications and requirements, and per client required schedule.

Key Accomplishments:
- Reorganized personnel and implemented processes, goals and tracking systems to improve execution in manufacturing and batch documentation review
- Established process for technical support to provide hands on learning opportunities to operations
- Developed and delivered training to improve understanding of key requirements by all personnel who enter manufacturing areas

Vice President, Quality Operations (April 2021 – January 2022) /
Sr Director, Quality Operations (June 2020 – April 2021)
As Head of Quality, participated as a key member of the leadership team that sets strategy and direction for the company. Led the development and implementation of the quality strategy for the company. Provided primary quality oversight for Exelead including direct responsibility for Quality Assurance, Quality Control, and Regulatory Affairs. As a hands on leader in quality, my support included regular interactions with all parts of the organization including on-the-floor alignment discussions with manufacturing, warehouses, support areas and laboratories.

Key Accomplishments:
- Facilitated gap assessment process and then directed project with information technology and technical support to improve alignment with 21CFR Part 11 computer system requirements for the numerous computer systems utilized by the company.
- Developed and implemented improved root cause investigation and change control oversight processes and rolled out to organization.
- Led efforts and provided guidance to warehouse, manufacturing, and laboratories as they introduced processing of material with tighter exposure guidelines than previous products handled.

KBI BIOPHARMA, THE WOODLANDS, TX • SEPTEMBER 2019 TO JUNE 2020

KBI is a contract manufacturing organization. The Woodlands facility develops production processes and produces cell therapy products for early phase clinical trials.
Vice President, Quality Assurance (September 2019 – June 2020)

Served as site quality lead for The Woodlands site ensuring that quality systems were implemented and followed in all aspects of the site's operations including manufacturing, quality control testing, materials receipt and storage, facilities and equipment qualification and maintenance, change management, deviation and out of specification investigation, and corrective and preventive actions.

Key Accomplishments:
- Following a strategic gap assessment process, prioritized closing gaps with aseptic processing guidance and coordinated with manufacturing and quality control leadership to address the gaps
- Developed and implement cross-functional system for facilitating seven day turn around for batch record review and fourteen day product release to meet critical client requirements
- Identified site training gap with KBI's quality computer systems (e.g., deviation, change control, and training systems). Networked with other sites to learn systems and then trained The Woodlands personnel on how to properly utilize the quality computer systems

MAPP BIOPHARMACEUTICAL, CARMEL, IN • MARCH 2018 TO SEPTEMBER 2019
Mapp develops monoclonal antibodies to address unmet public heath needs. Mapp currently has products in non-clinical and clinical stages of development.

Director, Quality Assurance (March 2018 – September 2019)
Provided primary oversight for cGMP drug product parenteral manufacturing, testing and storage including contract manufacturer operations and final drug product release. Developed, directed and deployed quality and regulatory strategy within Mapp and ensured alignment at contract manufacturer, testing, and storage companies. Served as point of contact for regulatory authorities regarding quality-related issues at the parenteral drug product manufacturing sites.

Key Accomplishments:
- Provided oversight and training for contract personnel in Africa that increased understanding of requirements resulting in improved control of product, documentation and organization of records
- Implemented computer system validation requirements and applied to new and existing systems
- Successfully negotiated quality agreements with key production and storage contractors

COOK PHARMICA, BLOOMINGTON, IN • MAY 2013 TO MARCH 2018
Cook Pharmica is a biological drug substance and drug product contract manufacturer. At the time of employment, Cook Pharmica employed over 700 personnel and served over 60 clients a year.

Quality Assurance Director (November 2013 – March 2018)
Led a team of approximately 50 Quality Assurance professionals overseeing the contract manufacturing of biologic drug substances and drug products. Activities supported included developing quality performance objectives and measuring performance, identifying and directing the completion of quality and compliance improvements, interfacing with clients to ensure their quality requirements and expectations were achieved, and providing oversight for all quality systems including production, packaging and labeling, facilities and equipment, quality control laboratories, materials, and the quality systems (exception reports, change control, complaints, CAPA, etc).

Key Accomplishments:
- Improved on-time completion of quality commitments
- Provided quality direction that improved usage and accuracy of manufacturing execution system
- Aligned quality personnel to better support production operations and ensure expertise for key functions

Director Drug Substance Operations (September 2014 – March 2015)
This was a short-term assignment to cover an opening in this position. Provided operations oversight for biological drug substance manufacturing including Upstream, Downstream, and Media/Buffer Formulation operations. Activities supported included setting and communicating direction, objectives and expectations

for the division and setting the direction for to 2 operations managers, 7 supervisors and ~65 operations personnel.

Key Accomplishments:
- Reduced human performance deviations by nearly 50%
- Implemented checklists and enforced preparation according to schedule to ensure production readiness
- Enacted deviation and CAPA tracking systems that facilitated elimination of deviation and CAPA backlog

Quality Assurance Manager (May 2013 – November 2013)
Directed a team of Quality Assurance professionals providing oversight for biologic drug substance manufacturing. Responsibilities were similar to Quality Assurance Director (above) with focus on drug substance manufacturing area.

Key Accomplishments:
- Implemented a risk based approach to batch record review
- Facilitated the completion of mycoplasma contamination risk assessment
- Reorganized quality assurance personnel to improve focus on specific areas of manufacturing

ASH STEVENS, RIVERVIEW, MI • 2012 TO 2013
Ash Stevens was a contract manufacturer of chemical APIs focusing on synthetic organic chemistry process development and production of intermediates and APIs for clinical trials. At the time of employment, Ash Stevens employed approximately 70 employees and supported over 10 clients a year.

Quality Assurance Director (2012 – 2013)
Improved quality systems at the company and ensured ongoing compliance with ICH and regulatory requirements. Specific focus in improving cleaning, contamination control, supplier oversight, deviation and root cause investigations, and corrective and preventative actions.

Key Accomplishments:
- Developed and applied company wide contamination control processes and expectations
- Identified equipment cleaning improvements and coordinated with operations to implement
- Put a supplier quality agreement process in place and successfully executed numerous agreements
- Initiated monthly company wide quality training and expanded all employees' knowledge of GMP and regulatory expectations

EVONIK DEGUSSA CORPORATION, LAFAYETTE, IN • 2010 TO 2012
Evonik Degussa is a custom chemical production company. The facility in Lafayette focused on the contract development of processes to manufacture chemical APIs for clients to use in clinical trials and for commercial sale.

Quality Assurance Manager (2010 – 2012)
Directed a 21 person Quality Assurance department providing cGMP oversight for the manufacture of nine bulk drug substances, 16 intermediates, and numerous development products. Ensured compliance with ICH requirements through the sustainment and improvement of quality systems at the plant site. Improved operations by insisting on thorough root cause investigations for process excursions and appropriate corrective and preventative action implementation. Managed the quality aspects of changes at the plant site to maintain the safety of the drug substances produced.

Key Accomplishments:
- Facilitated ISO Certification of plant site
- Successful FDA inspection with no 483 observations
- Directed the development of a process to efficiently determine toxicity based cleaning limits
- Led risk assessments which allowed the development of cross-contamination control strategies for the plant site, improved quality assurance efficiency by reducing batch production record review time,

transfered technical oversight to engineering personnel as appropriate, and eliminated unnecessary documentation

ELI LILLY AND COMPANY, LAFAYETTE, IN • 1998 TO 2010

Eli Lilly and Company is large pharmaceutical manufacturer with clinical and commercial drug substances and drug products produced by biological and chemical processes.

Quality Assurance Manager (2008 – 2010)

The Lafayette, Indiana, plant was sold to Evonik Degussa at the beginning of 2010. Responsibilities with Eli Lilly were the same as with Evonik Degussa above.

Key Accomplishments:

- Reorganized department structure to provide for better coverage and to more effectively utilize the talents of the Quality Assurance staff
- Consolidated Quality Assurance management support into one position
- Implemented a plant-wide change management prioritization process to focus resources on the improvements most important to the site

Operations Department Head (2004 – 2008)

Provided management oversight for a 40 person operations team processing 1.8MM kg of antibiotics per year. To meet customer demands, production up-time had to be maintained above 95%. Process excursions were investigated immediately and appropriate countermeasures were implemented to prevent recurrence. Department was managed to exceed safety, environmental, quality, financial and operational performance metrics.

Key Accomplishments:

- Improved OSHA recordable rate for department to 0 and maintained this rate for over two years
- Reduced number of major quality deviations by 62%
- Managed department successfully through a voluntary exit program where 30% of the operations staff was replaced. 6-sigma principles were used to develop an expedited training program that brought new employees up to speed quickly
- Sponsored numerous 6-sigma projects. One successful project allowed for a 5% reduction in operations staff. Another project developed more efficient operating scenarios based on demand.
- Led improvements in change management and deviation investigation processes for entire production area, resulting in more thorough and complete documentation of changes and deviations

Biotech Process Engineering Department Head (2000 – 2004)

Led a 23 person process engineering group, supporting the construction and commissioning of a biotech bulk drug substance production facility. Also led another team of seven, providing process engineering support for insulin fermentation and antibiotic purification processes.

Key Accomplishments:

- Built a highly effective engineering team by bringing in talented young engineers and dividing the group into support areas that each had an experienced technical lead (mentor engineer)
- Led the development of installation and operational qualification requirements for the project
- Successfully implemented improvements in the change management process and facilitated the change management process for the project
- Benchmarked with sterilization experts to develop effective steam-in-place validation strategies

Technical Services Process Engineer (1998 – 2000)

Rapidly learned this process support role and was asked to take on leadership of an operations unit team. The technical services role was responsible for overseeing the chemistry of the process and maintaining the batch production instructions. The unit team leadership role required coordination of all functions supporting intermediate and bulk drug substance manufacturing for the unit (operations, engineering, quality assurance, safety, and environmental).

Key Accomplishments:
- Effectively scaled up three bulk drug substance processes to produce materials for clinical trials
- While supporting the first designated safety critical production operation at the plant site, developed the processes for technical review and management oversight for the most hazardous operations at the site
- Led the unit team in the successful execution of 4 cleaning validations

THE DOW CHEMICAL COMPANY, MIDLAND, MI • 1995 TO 1998

The Dow Chemical Company is large manufacturer of chemical products. At the time of employment, Dow's Specialty Chemicals division had a pharmaceutical contract manufacturing facility that focused on the development and execution of chemical processes to manufacture chemical APIs and intermediates for clients.

Pharmaceutical Development Engineer (1996 - 1998)

Organized the scale-up of intermediate pharmaceutical processes from the laboratory to a GMP pilot plant. Material was produced to support clinical trials of drug substances.

Key Accomplishments:
- Safely and efficiently implemented the production of eight intermediates at the pilot plant scale
- Completed mass balance and waste calculations to prove compliance with environmental requirements
- Successfully developed and scaled up a process to produce ionically pure semi-conductor monomers

Research Engineer (1995 – 1996)

Participated in a rotating assignments program. Completed assignments in four different areas of the company.

Key Accomplishments:
- Coordinated a chlorine scrubber research project that developed recommendations to improve the operation of scrubbers used in thermal oxidizers
- Scaled-up a synthetic organic chemistry pharmaceutical process step from the lab to the pilot plant
- Facilitated a laboratory research program that developed a recovery method for a byproduct of a monomer production process
- Directed the installation of two new chiller units to support the production in a styrenics pilot plant

EDUCATION & CREDENTIALS

Bachelor of Science – Chemical Engineering
Rose-Hulman Institute of Technology, Terre Haute, IN