Shelli L. Connelly

Senior Drug Product Consultant

Core Competencies

- Sterile Fill/Finish
- Product Scale-Up
- Filter Validation
- Liquids
- Tech Transfer
- Parenterals
- Single Use Technology
- Suspensions
- Process/Cleaning Validation
- Containment

Professional Summary

Ms. Connelly is a pharmaceutical professional with over 20 years of long- term success in the pharmaceutical/medical device manufacturing industry. She has expertise in pharmaceutical/medical device transfer/process validation (product, cleaning, and equipment), business development activities, strategic planning, process improvements/project management activities, risk assessment, quality assurance, quality audits, cGMP (Current Good Manufacturing Practices)/manufacturing support, regulatory submission support and technical writing.

She's well versed in parental process equipment: tanks, single use mixers, microfluidizer, milling equipment, ophthalmic fillers, syringe fillers, vial fillers, , and isolator filling lines,. She is able to effectively handle multiple projects simultaneously, and understands customers needs and how best to meet them.

Education

M.S.	Management	Walsh College
B.S.	Biotechnology	Ferris State University

Professional Experience

Design Space InPharmatics, LLC **2020 - Present**

Senior Drug Product Consultant

- Formulate, develop, launch, and optimize parenteral drug products,
- Work directly with client project leaders and CMO's as the technical SME to develop parenteral products,
- Propose phase appropriate solutions and recommendations on an ongoing basis during Drug Product development,
- Proactively inform clients when their development program falls short of industry standards, current regulations, or would benefit from study/risk mitigation.

Bryllan **2017 - 2020**

Manager Business Development
Manager Process Development

- Provide leadership for the site management team with expertise and direction to reporting departments (Project Management and Process Development). This includes but is not limited to: Building/leading cross functional teams, and managing overall performance. Lead Site team to DEA approval for the facility,
- Drive and promote customer focus project teams to support the technical transfer of sterile parenteral manufacturing activities from development to clinical/commercial manufacturing utilizing isolator based technology (including vials, syringes, cartridges, dual chamber bags, IV bags and autoinjectors). This includes collaboration on manufacturing process development, batch records, protocols/reports, oversight of manufacturing activities and regulatory filing support,
- Responsible for site technical transfer operations and project deliverables,
- Lead DEA team to DEA site approval to manufacture Schedule III & IV controlled substance drug products.
- Developed and authored Containment Master Plan is support of manufacturing activities for cytotoxic, potent, hormone and biological based sterile drug products.
- Formulate contingency plans & risk management strategies for high value projects by maintaining strategic alliance with external CMOs & aligning internal teams with overall project target strategy,
- Build customer relationships and product pipelines for business development opportunities, reviewing RFI/RFPs or SOW from customers and providing cost estimates/proposals to customers while viewed as an SME for pharmaceutical manufacturing processes,
- Instrumental in developing initiatives for new projects together with product development team.
- Involved with customer site visits, company presentations and product kick off meetings.

PAR Sterile Products **2010 - 2017**

Process Engineer III

- Responsible for technical transfer of generic/customer sterile parenteral products (developmental, clinical and commercial which includes solutions, suspensions, lyophilized products, and ointments). Including determination of required resources, process/equipment requirements, risk assessments, process improvements and documentation,
- Created and initiated the first SUT (Single Use Technology)/Disposable items used at the facility. Responsible for creating/developing material specifications, inventory control and usage of the SUT items,
- Technical writing and review of numerous activities: SOPs, engineering studies (DOE, QbD), risk assessments, regulatory affairs support documentation(CMC), material specifications, process flow charts, batch records, deviations, change controls, CAPA, effectiveness plans and planned process modifications,
- Work closely with Business Development and Project Management to provide cost estimates and established appropriate project timelines.

VTS Consultants **2008 - 2010**

Senior Validation Engineer

- Involved with technical transfer of sterile parenteral products which include working with supporting departments and customer representatives. Facilitating and finalizing project timelines, scale-up, bulk compounding and filling, release testing and packaging activities,
- Responsible for technical writing of documents (Process engineering studies, batch records and change controls).

Pfizer **2006 - 2007**

Senior Associate Scientist

- Initiated and executed IQ, OQ and PQ validation protocols on equipment used in clinical manufacturing for tablets and capsules. Prepared final reports for validation qualifications,
- Established good working partnerships with numerous departments for support of validation activities,
- Capable of set up and tear down of change parts for validation activities of the MG Futura Capsule Filling machines,
- Responsible for writing and updating equipment SOPs and delivery of training of employees,
- Led validation deviations that determined and documented root cause of failures and recommended corrective and preventative actions,
- Perform periodic reviews of validated equipment to ensure equipment remains in a validated state.

VTS Consultants **2002 - 2006**

Validation Engineer

- Initiated, executed, and finalized IQ, OQ and PQ validation protocols and reports (including computer validation) on equipment used in clinical manufacturing for tablets and capsules. Trending/tracking performed on deviations/change controls to determine any quality issues,
- Conducted and documented quality assurance vendor audits for solid dosage clinical products and prepared final reports for Pfizer Quality Assurance Department. Evaluated vendors to ensure compliance with Pfizer's safety and quality standards set fourth by FDA and Pfizer's guidelines for solid dosage clinical pharmaceuticals,
- Attended Quality Assurance meetings regularly in order to improve overall quality of procedures and products.

Ferndale Laboratories **2005 - 2005**

Process Validation Engineer

- Established and maintained entire process validation activities associated with Ferndale's topical products and medical devices,
- Activities included: protocol and final report writing, investigations, technical support of manufacturing activities, small scale/experimental studies deliverables and timelines.

Parkedale Pharmaceuticals **1997 - 2002**

Manager/Pharmaceutical Technology
Senior Scientist/Pharmaceutical Technology
Scientist/Pharmaceutical Technology

- Led a team of scientists that support clinical and commercial pharmaceutical manufacturing,
- Responsible for technical writing and reviewing documents (Product validation master plan, SOPs, validation reports, batch records, change controls, deviations). Streamlined project planning and technical support of manufacturing,
- Established and maintained filter validation, cleaning validation, product validation (liquids, suspensions and lyophilized products), and technical support for manufacturing of sterile parenteral products,
- Organizational skills used to oversee batch and fill processing and planning of material flow,
- Responsible for technical writing of documents (Product validation master plan, SOPs, validation reports, batch records, change controls). Involved with internal and external (FDA and customer) quality audits,
- Function as primary contact with third party customers (Supergen, Ortho-Biotech, QLT, Centacor and Hoffman-La Roche) to manufacture material for clinical trials and commercial production,
- Collaborated with manufacturing colleagues and third party customer representatives constructing, facilitating and finalizing design of experiment activities, scale-up, bulk compounding and filling, release testing and packaging activities.