Nicholas M. Cardoso

Summary

Nicholas is an accomplished scientist and manager with over 18 years of experience in the pharmaceutical industry and proficient in all phases of pharmaceutical drug product development and manufacturing. Nicholas has extensive experience in managing and troubleshooting manufacturing products/processes from Phase 1 – Commercial, Solid oral dose and aseptic manufacturing. Nicholas is a technical expert in: spray drying, wet/dry granulation, compression, coating, continuous manufacturing, early phase formulations, microparticulate processing for parenteral injection, and aseptic fill/finish. Nicholas is quality focused with extensive knowledge of cGMP's and compliance, including but not limited to; writing and reviewing: SOPs, batch records, IOQs, processing/cleaning validation, deviations, change controls, and technical GMP documentation. Nicholas has also been involved in designing labs and manufacturing suites with a focus on streamlining the drug product formulation and manufacturing process including assisting in the execution of one of the first continuous pharmaceutical commercial manufacturing rigs in North America.

Experience

Senior Director of CMC, Epizyme Pharmaceuticals 2020-2023

- Managed all drug product development and clinical/commercial manufacturing
- Authored and reviewed regulatory documents for the drug development and manufacturing sections
- Lead CMC working teams for commercial and clinical projects including pediatric formulations

Associate Director CMC, Flexion Therapeutics 2015-2020

- Oversaw the scale-up and technology transfer of a specialized manufacturing process for a parenteral combination product
- Managed the expansion of a commercial site (doubling capabilities) in anticipation of future demand
- Supported a successful MHRA and FDA audit of commercial manufacturing sites

Scientist, Vertex Pharmaceuticals 2008-2015

- Designed and executed experimental programs using QBD to develop phase I, II, and III clinical and commercial formulations
- Lead the design and assisted in the coordination of building a clinical manufacturing annex; with capabilities of Phase I through commercial including continuous manufacturing
- Formulated and tech transferred clinical suspensions for early phase projects

Philosophy

Streamlining efforts with a good foundation in quality habits allows for an expedited path to support patients. I am here to assist in any way possible to achieve the ultimate goal of helping patients.

Achievements

Innovation – Finding novel ways through science to streamline processes

Communication – Using networks to expedite drug development and manufacturing

Mentoring– Providing companies different paths to success

Strengths

- Problem solving
- Cgmps
- Leader
- Experimental design
- Spray drying
- Granulation
- Tableting
- Energetic
- Optimistic
- Outside the box th

Education

BSc Biological Sciences

2001-2005

University of Rhode Island