RESEARCH SCIENTIST

Professional Profile

A Research Scientist in Pharmaceutical Industry having BS - Pharmacy + MS in Pharmaceutical Manufacturing with 5 years of Formulation & Process development experience with Tech transfer, QbD approach and scale up, in the Solid Dosage Pharmaceutical Manufacturing.
Design and develop the product master formula and perform the evaluation of critical formulation factors by using Design of Experiments Reviewing patents, papers, and experimental data and writing reports.
Preformulation physical-chemical characterization studies, and formulation development studies Executing DOE plans and preparation of formulations for ANDA products including FTF.
Help and develop the process of the plant and assist in evaluating new equipment Formulate and modify existing formulas to meet regulatory guidelines, cost parameters and claims.
Think creatively in prototype preparation and in problem solving Source, develop and work with outside laboratories and manufacturing facilities to identify and support innovative products and delivery methods.
In-depth knowledge of various dosage forms of pharmaceutical drugs and pharmacokinetics.
Remarkable knowledge of cGMP and GLP processes, FDA guidelines and other government regulations Experience with troubleshooting in scale-up process of solid dosage manufacturing operations like granulation, wurster coating, film and functional coating on tablets, tableting, encapsulation etc. Extensive experience with technical documentation for sampling & validation protocols, batch recording, Design Of Experiments and training manuals 2 years with CMO company (Norwich Pharmaceuticals).
Excellent customer service attitude, used to interface directly with external customers for complete project life cycle.
Excellent team player. Works well with business development, contract manufacturing, R/D, product development / formulations, tech services, analytical development, etc.
Enjoy working in a fast paced medium sized company environment. Legal to work in USA.
Permanent resident status - Green card holder Local NJ person, commutable to Tri-state area.
Willing to Relocate and overnight travel up to 30%.

Qualifications

- Research and Analysis
- Design of experiments
- CMC
- Time Management
- Plan experiments
- Effective Multitasking
- Proofreading/Editing

Experience

Research Scientist

January 2013 to Current Verizon Media (Former Oath) - Sunnyvale , CA

- 4 years with the same parent company, worked at 2 locations - Plant and corporate.
- Lead projects focus on development of oral solid dosage forms (including Modified Release Oral Solid Dosage forms) during clinical batch production and commercial scale up Filed two ANDA products successfully to the FDA including modified release products Design and develop the product master formula and perform the critical formulation factors Use of QbD and Lifecycle approach for drug product development and continuous improvement Evaluate and interpret analytical results to make data based decisions during development activities Document BMRs and Protocols for registration, clinical and validation batches Prepare product development reports by using QbD approach for the ANDA filing to FDA Provide technical and engineering support for Supply Chain, Quality Assurance (QA) and Regulatory Affairs Departments.

Research Associate

August 2010 to January 2013 David Zwirner Gallery - East Elmhurst , NY

- Contract Manufacturer for Pharmaceutical products in business for 100+ years.
- Lead role in technology transfer for the manufacturing Processes of Controlled release oral solid dosage forms Succesfully filed three ANDA first-to-file projects to the FDA Preparing the documentation for BMRs, Protocols and Product Development Reports for the ANDA filing including first to file Work closely with other functional areas such as Analytical Development, Project Management, Quality and Commercial manufacture as well as with clients to meet the timelines Experience in product development with different kinds of solid dosage forms like Tablet in tablet, pellets in capsule, mini-tabs in capsule and bi-layer tablets Experience in operation and troubleshooting of different unit operations including extrusion, spheronization, fluid bed Processing, high and low shear granulation, milling, blending, roller compaction, compression, coating (functional and non-functional) and encapsulation.

Education

PhD : Pharmaceutics , 2019 University of the Sciences at Philadelphia - City , State Pharmaceutics
Master of Science : Pharmaceutical Manufacturing , 2010 Stevens Institute of Technology - City , State GPA: GPA: 3.9/4.0 Pharmaceutical Manufacturing GPA: 3.9/4.0
Pharmacy , 2007 Maliba Pharmacy College - City , State , India Pharmacy

Affiliations

Member of American Association of Pharmaceutical Scientists (AAPS)

Skills

approach, bi, Oral, continuous improvement, clients, documentation, engineering support, filing, focus, forms, functional, GC, HPLC, manufacturing Processes, MS Office, mill, press, Product Development, Project Management, Protocols, Quality, QA, Quality Assurance, Regulatory Affairs, Supply Chain, troubleshooting, UV, validation