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Product Development Manager

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Company: SFI Health

Location: Australia

Category: other-general

Product Development Manager

USA Full time

SUMMARY:

As Manager of Product Development within Americas Region of SFI Health you will report and work closely with the Director of Product Design and Development in managing the PD team through formulating and product design for company wide projects to include; SFI Health brand, CMO/CDMO, and custom formula customers. A successful person in this role is confident, organized, and professional as this position will interact with heads of other departments and cross functional teams to achieve productivity goals.

This position is also responsible ensuring products is run effectively and efficiently on our manufacturing equipment by conducting bench work, production pilots and initiating change control process where applicable to improve formulations and process. We are seeking an A-player who doesn't fear challenge but embraces it and will be at home in an environment where new approaches are welcomed and leadership in implementing them well is rewarded.

JOB FUNCTIONS:

Essential job functions: Plan, manage, and engage team to deliver on major and minor projects with significant commercial implications by keeping stakeholders informed, engaged and on time

Product Development and Formulation Management:

Contribute to oral dosage formulation and process development, process scale up and

technology transfer to commercialization throughout the product lifecycle.

Develop, Design and/or Review Master Formulas, Product Specifications ensuring accuracy and is compliant with Regulatory, SOP, SAP, and customer requirements.

Evaluate the formulation and process to determine their effects in relation to final product specification, including evaluating equipment set points and process parameters for their impacts on final product characteristics.

Design, plan and execute prototype formulation development studies, and scale up of manufacturing processes.

Identify and execute projects to reduce product cost, improve product quality, improve yield, and reduce material usage, and collaborate with Production, Engineering, and Quality to optimize productivity, yield, product quality, and supply reliability.

Provide support to ensure Inspections, Deviations, Change Control, CAPAs and Regulatory commitments are met on time with the highest standards of quality.

Establish and upgrade programs, practices, and processes to drive a high-performance culture and engaged workforce across Safety, Quality, Delivery and Cost.

Lead project teams in developing project strategy for both new product development and tech transfers, including process validation, and associated regulatory filings as required.

Collaborate with cross functional and cross organizational partners, both on site and off site to establish project plan timeline with appropriate milestones.

Provide process technology training, SOP writing, technical reports and Validations, as well as providing training and support to Product Development personnel during the development and scale up of formulations on cGMP equipment.

Must stay current with relevant technologies and forward thinking to identify new approaches.

QUALIFICATIONS:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill,

and/or ability required.

Education:

A minimum of BS degree in Pharmaceutical Science, Pharmaceutics, Pharmacy, Industrial Physical Pharmacy, Chemistry, Pharmaceutical Engineering, Chemical Engineering, Biology, Chemistry, Nutrition or an equivalent foreign degree.

Experience with Quality management systems, SAP software project management software desired, Quality by Design

Experience:

A minimum of 8 years of experience for BS or 6 years of experience for MS in Solid dosage formulation and/or pharmaceutical/ nutraceutical manufacturing areas.

Technical/Functional Skills:

Must be proficient and have hands on experience with manufacturing processes such as blending, encapsulation, compression, milling, roller compaction, tablet coating and other related solid dosage form manufacturing unit operations.

Ability and eagerness to learn new manufacturing technologies.

Good understanding on quality and regulatory requirements of nutraceutical and/or pharmaceutical industry.

Ability to train fellow scientists, lead project teams on new product development and technology transfer activities.

Serves as an effective subject matter expert to cross-functional teams

Computer skills:

Microsoft Office Suite and analytic tools

Document and Change Control, Qualityze or other EQMS

Database management

Total Quality Management

OTHER INFORMATION

Supervisory Responsibilities:

This position supervises the following positions:

Product Development Specialist – I and II

Product Development Scientist – I and II

Work Environment: **On site at Reno, NV offices**

Physical Demands: Working outside of normal business hours when keeping the project running smoothly requires it.

Career Path (Optional): Opportunity for growth into Sr. Director or VP at the regional or potentially global level

Who to Contact:

Send your applications to:

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