

Engineer II, Process Engineering (Filling MSAT) (12 month Contractor position)

Job ID: 201909-126227

Job Function

Production Engineering

Location

Hillsboro
Oregon
United States of America

Schedule

Full time

Job type

Contractor

Company/Division

Pharmaceuticals

Job Level

Individual contributor

The Position

Main Purpose of the Position:

This position is in Manufacturing Science and Technology (Fill MSAT), supporting Commercial Drug Product Operations and Validation in Hillsboro. In this position, you will need to work effectively as part of a team responsible for ensuring successful and efficient Drug Product operations.

Responsibilities:

- Utilize Lean Production System elements and methods to continuously improve Drug Product Operations and Process Engineering processes and procedures.
- Prepare development, characterization, validation & change control documentation, including protocols, summary reports, etc., for development and validation activities.
- Support Investigations and atypical events, as well as resulting corrective or preventive action implementation
- Owns activities of moderate scope & complexity (ex. Owns change records, responsible for CAPA actions, executes small scale/validation studies, performs troubleshooting, & monitors operations).
- Provide troubleshooting and issue resolution support for the Drug Product operations to decrease time of recovery from process and or equipment malfunctions
- Participate in the identification, evaluation, and implementation of new process technologies in alignment with business objectives or regulatory requirements
- Support the change management system for validated equipment, utilities and facilities.
- Foster an environment that encourages continuous learning. Maintain expertise as necessary to stay abreast of technical and industry advancements.
- On a regular basis analyze processes, make suggestions for improvement to management, & provide input to improving systems/processes.

- Frequent use & application of basic Engineering/Scientific/GMP theories, principles & techniques.
- Demonstrated capability of applying a broad scope of regulatory policies, guidelines & requirements applicable to assigned area and suggesting improvements.
- Ability to support internal & external Health Authority inspections.
- Represents group on cross functional teams or projects of limited scope

Qualifications / Requirements:

- BS/MS in engineering, or related field/experience, with a minimum of 8 - 10 years experience in Process Development, Engineering, Manufacturing, or Technical Services is required.
- Working knowledge of formulation and filling processes and equipment in a regulated environment is preferred.
- Knowledge of cGMPs or equivalent regulations.
- Working knowledge of formulation, filling, packaging and equipment/process characterization and qualification in a regulated environment is required.
- Demonstrated understanding of project management and validation skills.
- Ability to work with internal teams, partners, suppliers and customers.
- Professional level written and oral communication skills.
- Key to this position is the demonstrated ability to provide technical input and teamwork in a cGMP environment across functional and organizational boundaries

Who We Are

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