Genentech
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Date: 09/09/19

Senior Engineer, Process Engineering (Filling & Validation) (Contractor)

Job ID: 201909-126228

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

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page.