Genentech
A Member of the Roche Group

Date: 10/18/19

Medical Device / Combination Product Process Engineer

Job ID: 201908-124827

Job Function
Production Engineering

Location
South San Francisco
California
United States of America

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Individual contributor

The Position

Executive Summary

The Senior Process Engineer will be responsible for providing drug delivery device production innovation support to project teams developing combination drug delivery devices for parenteral pharmaceutical therapeutics at Genentech.
The candidate has in depth experience in high volume manufacturing processes and methodologies and leads process development to support clinical and commercial production activities within Genentech's device development programs, including internal engineering partners and external design/development partners and component suppliers.
The Senior Process Engineer will be assigned responsibilities to engineering areas and will initiate projects, define critical steps and resources, and develop practical and thorough solutions to complex problems.
The candidate will work with limited direction and may provide guidance and coordinate work activities of other personnel.
The work is reviewed with a focus on long-term perspectives, as the candidate establishes his/her own work priorities and timelines.

Job Responsibilities

Quality Systems Compliance:

- Understand, implement and maintain Roche Pharma Quality Policy and Pharma Quality System (PQS) in the department.
- Use (and create and implement, if necessary) local PTDU-D procedures and templates ensuring alignment with current versions of PQS documents and best practices.
- Assist with resolving issues arisen from internal quality assessments/audits, regulatory inspections and notified body interactions, and aid in driving closure of inspection issues by preparing appropriate responses and corrective action resolutions.

- Create and review discrepancy, change and risk management documents for PTDU-D and Devices Teams, as appropriate.
- Ensure compliance of training to PQS and job-related requirements.

Design Control:

- Draft, review and/or approve design control documents (i.e. DHF documents) to support device development deliverables using available templates, such as protocols and reports, design verification, design validation, failure modes effects and analysis, risk management plans, change management plans and design review meeting minutes.
- Employ good document practices (GDP) when recording data, maintaining archives and drafting and reviewing documents.
- Participate in hazards analyses and design assessments and reviews.
- Utilize electronic document archive system and collaborate with Document Control team to ensure document compliance with PQS standards and DHF regulations.

The incumbent in this position will be responsible for supporting activities within Device Development department and facilitating product development towards the goal of commercialization. This objective will be accomplished by executing activities in the areas of:

Process Engineering:

- Use of state-of-the-art technology to lead process development to enable clinical and commercial production in our netowrk worldwide.
- Create leading-edge mechanical drug delivery devices and architects their high-throughput assembly
- Regularly interact at a detailed technical level with design engineers, equipment and production engineers.
- Provide engineering tetchnical leadership to internal cross functional team and external development partners and component suppliers.

Qualifications

Education and Industry Experience

- B.S, M.S, or advanced degree in Engineering, with preference for Mechanical Engineering, or the equivalent.
- At least 8 years of experience in the industry and/or academia (including advanced studies) after receiving their Bachelors degree.
- In depth experience in high volume manufacturing processes and methologies, with an emphasis in plastic molding and mechanical assembly is expected.
- Demonstrated success in project planning, resource management, liaison with engineering and manufacturing resources in other countries is critical.
- Hands-on experience working with control systems to be used in production and batch release.
- Strong expertise with statistical handling and interpretation of data, technical report writing and reviewing.
- Familiarity with risk management tools; develop FMEAs of the products and ability to assess changes, non-compliances, etc., with risk assessment methods.

Technical Knowledge

Strong skills in relevant modeling and design tools, design controls and/or statistical analysis.

For example:

- Modeling: Monte Carlo Simulations, Tolerance Analysis, Finite Element Analysis.
- Device Design: CADD (Solidworks, AutoCad), Design for Manufacturability, Molding.
- Full data and statistical analysis (JMP, Minitab) and Design of Experiments, and providing detailed review of data with an emphasis on statistics.
- Design Controls for regulatory compliance & filing (ISO 13485, etc): GDP/GLP/GMP, Design History Files, User Requirement Specifications (URS), Factory/Site Acceptance Testing (FAT/SAT), test protocols, technical reports, control systems to be used in production and batch release and risk management tools (methods, FMEAs, non-compliances, etc)..
- Six Sigma (Green/Black Belt): DMAIC and DFSS

Interpersonal Skills

- Proven track record of working effectively in a matrix organization with a highly cross-functional (*e.g., validation, quality,* and program management) and collaborative environment is very desirable.

- Excellent oral and written communication skills are required.
- Able to work with external design/development and production partners is also highly desirable.
- Highly organized and detail oriented.
- Excellent leadership skills.
- Demonstrated success in project planning, resource management, and liaisoning with engineering and manufacturing resources in other countries.

Training Requirements

Core training is mandatory and must be completed within the allotted time frame beginning with on-board date. Initial training requirements are listed in this section. **(Confirm role)**

PTD DEV: Process Engineer 30

PTD DEV: Process Engineer 60

PTD DEV: Process Engineer 90

Additional training to enhance Core requirements may be assigned as elective courses. These elective courses are deemed essential to performing the job duties related to this position.

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