

Principal Technical Manager, Devices and Combination Products- PTQXF Quality Engineering - North America

Job ID: 00414152

Job Function

Quality

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

The Quality Engineering manager works independently and provides oversight of quality engineering activities during design development. Be the quality engineering subject matter expert during device development, manufacturing, technology and associated verification and validation.

Job Responsibilities:

- * Works closely with Device Development and device CMOs to assure that combination products maintain their requirements and specifications and are compliant with the Quality System
- * Liaises with technical groups to review and revise specifications based on design and/or process changes
- * Supports root cause analysis in the implementation of corrective actions
- * Responsible for continual improvement activities and liaises with experts to apply

appropriate improvement tools

- * Provides technical consultation on the development of fixtures, methods, test equipment, and tooling in order to continually improve process and products
- * Establishes quality inspection processes and supports quality activities to ensure that products and processes comply with the relevant requirements of the quality management system.
- * Supports internal/external audits and vendor qualification, including closing out audit findings and determining proper corrective and preventive actions.
- * Responsible for planning, organizing, and managing the overall testing activities of quality functions.
- * Collaborate on and /or author policies and procedures and act as a trainer / subject matter expert on applicable quality systems, standards or business processes (as required).
- * Set personal performance goals and provide input to departmental objectives and establish work priorities to meet targets and timelines. Maintain current status on all required job related training and strive to continuously improve knowledge and skills in quality, compliance and technology. Perform any other tasks as requested by Management to support Quality oversight activities
- * Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.

Who You Are

- * BS degree in an Engineering discipline, Graduate degree preferred
- * 10+ years experience in a Quality Engineering role for a pharmaceutical or medical device company
- * Quality Engineer certification (ASQ) recommended
- * Experience leading and working with internal and external teams through end-to-end projects
- * Able to educate teams and organization on Design Controls and related topics
- * Demonstrated capability of ISO13485, 21CFR820 and ISO14971
- * Demonstrated capability of applying risk management concepts and tools
- * Understanding of the biotechnology industry and specifically combination products.
- * Hands on expertise in one or more areas including secondary packaging, device development, aseptic product development, and manufacturing
- * Well developed teamwork and collaboration skills and ability to communicate clearly and professionally both verbally and in writing. Experience working in a global environment is a plus.
- * Demonstrated problem solving and decision making skills including hands on working

experience with tools Six Sigma / DMAIC is preferred

* Travel required is approximately 20 - 40%

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