

## Principal Technical Manager, Device Design Control

Job ID: 00410174

### 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 incumbent in this position will be responsible for managing Device Development Quality areas including development of Design Controls and associated documentation, documentation control system implementation, as well as coordinating educational forums for project teams. Quality System areas of accountability include Risk Management, Design History Files, and other aspects of Design Controls. With respect to Design Controls, responsibilities include participation in cross-functional initiatives to develop, influence and globally align the Design Control strategy while ensuring consistent practices are adopted and followed. The incumbent will also serve as the primary liaison / spokesperson between Quality and the Device Development Leadership team. He/she will work with Device Teams to create, oversee maintenance and continuously improve Design Control processes for teams, and drive consistency in approach and documentation content across the pipeline portfolio to streamline development. Regular interaction with Device Team Leaders is required. The position requires working with teams to develop and implement Risk Management plans and Design History Files ensure the approach is consistently applied across projects. The incumbent will support internal and external audits of the department, and is accountable for ensuring that the department is in compliance with regulatory requirements for combination products. The incumbent will regularly interface with those functions contributing to execution of the Device Strategy including but not limited to Clinical, Development, Manufacturing Collaborations, Quality and Regulatory Affairs. The incumbent will also support the continuous improvement of business processes related

to combination product development and commercialization, providing linkages between the Design Controls and device business processes. The incumbent will also serve as a departmental representative for commenting on global regulatory authority draft guidance and proposed rules.

### **Who You Are**

- B.S. degree in Life Sciences or equivalent
- At least 10 years' experience in the Pharmaceutical or Medical Device industry, with at least 3-5 years of experience in devices or combination products
- Extensive knowledge of global quality system / regulatory requirements for devices
- Working knowledge of manufacturing, quality, and regulatory areas pertaining to delivery devices and combination products
- Working in a highly matrixed environment
- Excellent interpersonal, communication, and influencing skills

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