

Senior Manager - Product Quality & Development Projects

GENEVA, SWITZERLAND

Are you passionate about the product?
With a device division that has almost tripled in size over the last 3 years, this is a global company heavily investing in R&D!
Owing to a full pipeline of groundbreaking new drug/device products within the E-Health space, we are recruiting a Quality manager, with a focus on Design and Maintenance for regulatory affairs new product development projects.
The product: a mechanical drug delivery device.
Your focus will be the mechanical device

In this new and exciting Quality Manager role, you will:

- **Lead the design control activities to ensure compliance throughout the design and development process of combination devices**
- **Work on exciting development projects with partners from both within and outside the company, on cross company collaboration projects**
- **Review and approve project deliverables, as well as training, labelling and promotional material**
- **Participate in the transition to the new MDR**
- **Represent quality interests in product development projects of combination device systems.**
- **Collaborate in multi functional teams: alongside Marketing, Development, and Regulatory to bring your new product to market**

- Supporting global regulatory submissions
- Once you have successfully marketed your device, you'll be the main contact person for the maintenance;
- Lead the CAPA and complaint handling process for drug delivery devices
- Supervise change controls
- Maintain supplier qualification

Requirements

- Are you able to influence others through excellent communication skills?
- Do you have a technical/engineering background, with a good eye for details
- Experience with design controls in a medical device context is a requirement! ISO 13485, 21 CFR 820, ISO 14971, CE marking
- The ability to take independent decisions is a must!

Contact:

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