Senior Design Control Specialist

Deadline:
31-07-2025

Contact person:
Michael Mikkelsen

Job area:
Systems Engineering & Design Control

Position type:
Full time

Join Our Team as a Senior Design Control Specialist
As our Senior Design Control Specialist, you will be at the heart of managing and conducting design control activities for both new and existing products. You will collaborate closely with engineering, regulatory, and quality assurance teams to ensure design control processes and documentation is compliant with industry standards.

Your main tasks and responsibilities:
- Develop and maintain design control documentation throughout the product lifecycle, from concept to commercialization.
- Create design history files (DHF) and ensure they meet all regulatory requirements (e.g., FDA, ISO).
- Work with engineering, regulatory, and quality assurance in project teams to ensure product designs meet all applicable standards.
- Assist in risk management activities, including system risk analyses, failure mode and effects analysis (FMEA), and implement risk mitigation strategies.
- Facilitate and follow up on design reviews and outcomes.
- Support project progression by drafting technical justifications, memos, and other necessary documentation for informed decision-making and regulatory compliance.
- Ensure all design-related changes are correctly documented, reviewed, and approved.
- Assist in preparing for regulatory submissions by providing relevant design documentation and reports.
- Stay updated on relevant regulatory requirements, such as FDA 21 CFR Part 820, ISO 13485, ISO 14971, and others.

Being a Consultant at Technolution
Our idea of a good consultant is one who takes the necessary time to listen, observe, question, and challenge our clients to ensure we fully understand and know how to best help them within the scope of our agreement. As a consultant, you will be involved in diverse projects for start-ups and industry leaders, sometimes from our office in Hørsholm, sometimes onsite with clients, and sometimes remotely, but always in close contact with your team. You will typically work on 1-2 projects and clients at the time, as well as take part in internal projects and tasks.
For this role we imagine that you thrive with the varied tasks of design control, from defining early requirements to conducting design reviews and supporting verification and validation. You will prepare detailed technical documentation, refining processes, updating templates, and ensure excellence in regulatory compliance and best practices.

Your Qualifications:
- You have solid experience in Pharma or MedTech
- MSc or BSc in Engineering (e.g., biomedical, mechanical, etc.) or similar.
- At least 3 years of experience working with Design Control.
- Knowledge of ISO 11608 and experience with design reviews, design transfer, change control, and development of design outputs is a plus but not required.
- Professional proficiency in English.

Want to Know More?
If you are intrigued and want to know more about the position, reach out to Michael Tokeskov Mikkelsen at 42 45 85 10 or Michael.mikkelsen@technolution.dk

How to Apply
Skip the formal cover letter and apply with your CV. Leave out the photo as well – we would like to see you in person when we meet.