



Design Control Specialist

Occlutech is a leading specialist provider of minimally invasive cardiac devices, with a mission to improve the quality of life for people with heart conditions. The vision is to become a global leading specialist provider in cardiac devices, addressing congenital heart defects, stroke prevention, and heart failure. Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with more than 139,000 products sold. The company markets and sells its products in circa 85 countries and has around 320 employees.

Position: Design Control Specialist (m/f/d)

Location: Istanbul, Turkey

Role and Responsibilities:

- Participating in design activities and providing guidance and support to the design team as needed in process verifications and validations and quality plans, when necessary, backup for other projects of Occlutech Group,
- Ensures that the ongoing design activities are followed according to procedures and related standards, when necessary, works on the improvement of procedures,
- Perform verification tests, when necessary,
- Providing support to R&D, QA, and RA for performing Gap analysis regarding changes/updates in regulations and standards,
- Perform other duties as assigned by the Quality Assurance/Quality Management team.
- Responsible for controlling design activities for R&D projects

We are looking for a candidate, who has

- Min. BS in Engineering or Technical discipline; or equivalent experience. MS in Engineering is a preference
- Min. 3 years in the medical device (Experience in QA role in Medical Device is preferred)
- Experience working in the medical device industry within US FDA 21 CFR 820.30 and EN ISO 13485:2016 Clause 7.3 requirements as a design engineer or a QA role is preferred.
- Ability to work autonomously and accurate in every detail
- Strong organizational, planning, and analytical skills, results-oriented.
- Excellent communication and interpersonal skills, ability to work in an international environment with cross-functional team
- Must be self-directed and able to prioritize tasks to meet the needs of multiple business units.

Occlutech Ltd.
Istanbul, Turkey
Tel +0212 465 04 97
www.occlutech.com





If you

- Excellent knowledge of MS Office
- Strong analytical and problem-solving skills
- Ability to collaborate with cross-functional teams.
- Advance level in writing, speaking, and reading English

Are you interested?

We look forward to receiving your application (cover letter, CV, including qualifications and references - all documents in one pdf file), your salary expectation, and the earliest possible date for the start of work to tugce.erdogan@occlutech.com

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