

QA & RA Specialist

Job description:

We at CathWorks, a dynamic successful and well-funded medical device startup in the field of cardiac imaging are looking for a QA & RA Specialist to join us! The candidate should be a team player as well as a strong individual contributor. The environment we are working at offers great opportunities and professional challenges.

Responsibilities

Document Control Center (DCC) – manage documents changes, approvals and release

Customer Complaints – document complaints and collaborate in complaints investigations

CAPAs/SCARs – initiate and manage CAPAs and SCARs

ECO – initiate and manage ECOs

Assist in QA projects and regulatory submissions

Job Requirements:

2 years of experience in QA&RA, preferably in DCC / CAPAs / ECOs / Complaints, from a software medical device company regulated under ISO13485

Knowledge in ISO13485, FDA QSR, and EU MDD/MDR requirements

Excellent communication skills in Hebrew and English, written and verbal

Preferable:

B.A or B.Sc. degree (advantage to Biomedical Engineering)

Experience with ISO27001 requirements

Send your CV: oded@cath.works