# ROOK QUALITY SYSTEMS

**We are a consulting firm dedicated to helping medical device companies develop and maintain effective and efficient quality systems. We provide specialized and custom consulting services for all classes of medical devices including Software as a Medical Device (SaMD).**

Watch On-Demand Webinar
**"Prepping Your QMS for EU MDR"**

Rook QS consultants complete over 20 notified body and regulatory audit days per year and are constantly applying the most current practices and knowledge to all of our clients.

Our software engineers are at the forefront of an ever-changing field. We support multiple submissions, full design verification projects, usability tests, clinical evaluations, and more for our clients each year.

## EXPERIENCE

Rook QS is composed of medical device quality experts with experience in a wide range of medical devices and technologies. We work closely and efficiently with our clients to meet their quality needs and ensure their products meet and exceed regulations and standards.

**PRE-MARKET -** Our scope of work covers initial quality system design through completion of design history files and risk management files.

**POST-MARKET** - We provide a variety of QMS related services depending on the client and size of the company.

We often support DHF remediation projects for hardware and software devices to help achieve market clearance. Our consultants can complete remediation projects in less than one month in certain situations. Rook QS has worked on multiple SaMD products with great success and is a leader in the medical device software community.

## READY TO LEARN MORE?


**WEBSITE:** rookqs.com
**EMAIL:** info@rookqs.com
**PHONE:** 770.833.0116


SCHEDULE MEETING NOW





# REVIEW OUR SERVICES

## QUALITY SYSTEM DESIGN

Rook QS creates efficient and compliant QMS packages to fit your companies size, scope, and regulations. Our QMS is audit tested and compliant with MDSAP and MDR. We created a specific SaMD QMS for agile or waterfall practices.

## QMS MANAGEMENT

Our quality engineers can maintain your QMS as a contract quality team. This includes yearly audit packages, management review, complaint handling, CAPA, and Non-conformance management.

## ONSITE AUDIT SUPPORT

Rook QS provides onsite audit support to provide another expert in the room representing our clients. We have a proven track record of success for all of our clients and are available on short notice to support you during your audit.

## SOFTWARE DOCUMENTATION

The documentation requirements for medical device software and SaMD are very detailed and prescriptive. Our software engineering team at Rook will provide support throughout the software lifecycle to help you achieve compliance for market clearance and audits.

## DESIGN CONTROL

Our approach to design control allows for companies to quickly translate their internal research and testing into a formal DHF. We provide training and coaching to complete your DHF including protocol writing, usability testing, and V&V support.

## RISK MANAGEMENT

Our consultants are experts in risk analysis and can create your Hazard Analysis or FMEA from scratch. We can also support 60601 documentation including risk management file, IFU, and label compliance.

## INTERNATIONAL COMPLIANCE

Rook QS can provide international regulatory support to help expand the reach of your device. We have helped multiple companies grow their sales international through both quality and regulatory support.

## QUALITY SYSTEM TRAINING

Rook QS provides onsite or remote training for all areas of the medical device QMS. Popular courses include Internal Auditor training, CAPA training, and validation training. Contact us for a custom training program for your company.

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**Book a Meeting Now**