# CHARLTON REGULATORY CONSULTING

Specialist Software Medical Device Consultancy

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## About

Charlton Regulatory Consulting aims to give Your Organisation the medical device, privacy and security knowledge it needs to create and manage medical device and healthcare software and services.

We provide consulting and contracting services in regulatory compliance within the SaMD and healthcare software industry. Having created and managed software and systems within this field, we have the experience necessary to help understand and overcome the unique challenges faced by SaMD and and healthcare software service companies in the combination of medical device regulations, privacy and security regulations, and the overlap of quality, risk management, security, privacy and business continuity management standards.

## Services

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| **Regulatory strategy for SaMD and healthcare software** | Consultation on regulatory pathways and finding routes to market, as well as helping to create strategies for growth and adoption of quality, privacy and security processes as businesses adapt and expand. |
| **Implementing, maintaining and improving business management systems** | Consultation and assistance in the implementation of policies and processes, staff training and internal auditing activities across quality, security, privacy and business continuity management systems. |
| **UK, EU and US medical device regulatory clearance** | Assistance planning software medical device design, clinical evaluation and filing activities as well as offering support in creating design documentation and regulatory filings. |
| **Technical planning and implementation** | Helping to plan technical solutions to quality management and software production problems and providing technical support in commissioning, integrating and customising systems such as Atlassian Confluence and Jira, the Google suite, Microsoft 365, and other off the shelf eQMS and design tools. |
| **NHS Standards** | Help with the DSPT, DCB0129 and DTAC standards required to work with NHS Trusts. |
| **Labelling and user documentation** | Advice on product labelling and instructions for use, providing regulatory review of labelling and writing user documentation if needed. |

# Skills and Experience

## Regulatory and Standards Compliance

- UK Medical Device regulation 2002, EU Medical Device Directive 93/42/EC and EU Medical Device Regulation 2017/745, EU In Vitro Diagnostic Medical Device Directive 98/79/EC and EU In Vitro Diagnostic Medical Device Regulation 2017/746
- EU AI Act 2024/1689
- U.S. Quality System Regulation (21 CFR 820)
- Creation and management of medical device technical documentation for CE and UKCA marking for SaMD
- FDA De Novo application and 510k clearance of novel SaMD
- Creation and management of ISO 13485 and 21 CFR 820 compliant quality management systems
- Medical device clinical, AI and cybersecurity risk management (ISO 14971, BS/AAMI 34971, AAMI TIR57, IEC 80001-1 and -2, ISO/TR 80002-1)
- SaMD development (IEC 62304, IEC 62366-1)
- Secure software development (IEC 81001-5-1)
- Clinical evaluation (MEDDEV 2.7/1, ISO 14155, UK REC approval, basic knowledge of IRB approval)
- Labelling and instructions for use (ISO 15223-1, ISO 20417) and eIFUs (EU regulations 207/2012 and 2021/2226)
- Creation of ISO 27001 and ISO 27701 compliant information security and privacy information management systems
- ISO 22301 based business continuity management systems
- HIPAA and HITECH compliance of security and information management systems
- SOC2 certification of security and information management systems
- UK DPA and UK/EU GDPR in a complex data controller and processor environment
- EU and UK Network and Information Systems Regulations (the NIS Directive, DSP Directive and UK NIS Regulations) and compliance with the ENISA technical guidelines for DSPs
- NHS standards compliance (NHS DCB0129 Clinical Risk Management, Data Security and Protection Toolkit, DTAC)
- Web Content Accessibility Guidelines (WCAG) and the EU web accessibility directive

## Quality Management

- ISO 13485 certification
- Creating and maintaining policies, processes and procedures
- Vigilance activities including MIR, FSCA, HHE and communicating with Competent Authorities
- Management and registration of economic operators in the UK and EU
- PMS report and PSUR writing
- Creation and management of training and competence systems and resources

## Security and Privacy Information Management

- ISO 27001 and ISO 27701 certification
- Creating and maintaining policies, processes and procedures for ISO 27001, HIPAA and SOC2 compliant systems
- Creation and management of training and competence systems and resources

## Leadership

- Establishing and growing engineering and quality assurance teams
- Establishing best practices and standards for quality, security and data protection
- Creating technical platforms and tools to support engineering teams
- Leading CE marking of novel SaMD and healthcare software
- Leading building quality, privacy and information security systems from the ground up
- Onboarding and training quality and security management leads and staff

# Past Clients

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| **April 2023 – Present:**<br>**Radley Scientific** | Supporting MDR CE clearance of bone cement removal medical device firmware. |
| **Mar 2024 – Present:**<br>**Holberg EEG** | Supporting MDR CE clearance and FDA 510k clearance of AI enabled EEG analysis medical device software.<br>Supporting improvements to software development, cybersecurity and general quality management processes. |
| **Jan 2024 – Present:**<br>**Zola Health** | Regulatory support and advice on route to market for novel decision support software. |
| **Aug 2023 – Present:**<br>**Odin Medical** | Improvements to software and cybersecurity processes and procedures.<br>Regulatory support for new AI enabled products and design changes to existing AI enabled product range.<br>Supporting FDA 510k clearance of AI enabled software products. |
| **Jun 2023 – Present:**<br>**Sonio** | Supporting SOC2 type I and type II clearance.<br>Audit and gap analysis against EU GDPR, creating compliant GDPR policies and procedures to remedy.<br>Support for 510k clearance cybersecurity documentation for AI enabled medical device software. |
| **Sep 2023 – Oct 2023:**<br>**iQ Endoscopes** | Software cybersecurity support for 510k clearance of endoscope firmware. |
| **Mar 2023 – Jul 2023:**<br>**Taika 3D** | Advising on ISO 13485 quality management system implementation. |
| **Dec 2022 – Nov 2023:**<br>**Oxehealth** | Supporting MDR and FDA 510k clearance of an AI enabled software device. |