CHARLTON REGULATORY CONSULTING

Specialist Software Medical Device Consultancy

info@charltonregulatory.com
+44(0)7843 755490

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

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.
Supporting regulatory roles	UK Responsible Person services, acting as PRRC where required, to a Manufacturer or Authorised Representative, as well as handling registration with and reporting to regulators.

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
- U.S. Quality System Regulation (21 CFR 820)
- Creation and management of medical device technical documentation for CE marking 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 and cybersecurity risk management (ISO 14971, IEC 80001-1 and -2, ISO/TR 80002-1)
- SaMD development (IEC 62304, IEC 62366-1)
- 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
- 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
- UK Cyber Essentials and Cyber Essentials Plus

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
- 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