ETHOS Service Definition

GCLOUD15

Contents

Welcome to ETHOS

We are experts in the regulatory and compliance fields that are required to enable your products to be used in health and care

Our team at ETHOS are passionate about actively contributing to good practice and effective, consistent application of safety and security standards in the sector.

We are the largest and fastest growing advisory service provider for the UK NHS and associated sectors, providing the full range of services for digital health compliance.

About Us

ETHOS is a company driven by a passion for high quality and effective digital health products and services.

The team provide a depth of expertise across the core domains needed for the safe, secure, and effective deployment of digital health focused technology at scale. Each member of the team has more than 15 years NHS & health sector experience including clinicians and senior leaders working nationally and internationally.

We proactively support our professional bodies to improve standards and influence sector workforce development. As subject matter experts we strive to contribute to the industry via our professions as part of our charter.

At ETHOS we believe in a fair rate of pay and ethical working practices to ensure we give back to our sector, supporting charity and not for profit digital offers.

You can read more about our team and find out how we might help you.

Find out more about our full services

Follow us on LinkedIn and Twitter to hear more about our latest projects and service developments.

Crown Commercial Service Supplier

SGS Consultants Connect standard

bsi Standards Maker

CPD MEMBER The CPD Certification Service

bsi ISO/IEC 27001 Lead Auditor PRACTITIONER

Register of Chartered Security Professionals

Value Proposition

ETHOS has over 20 years of experience implementing and managing, digital health services. This includes the creation of and preparation for certification to UK NHS standards and associated regulations. Our client base covers NHS health organisations, commissioners, academic innovators (spin outs to start-ups), small to medium sized and larger corporate level organisations. This demonstrates not only the provision of subject matter expertise in the regulatory domain, but an appreciation for organisation culture and values to achieve your objectives. We see regulations and standards acting as an enabler not a barrier to innovation.

All our work with clients, includes regular planning, reporting and communication within a format in which the organisation utilises or is comfortable with.

ETHOS Services Provided

ETHOS provides the full suite of services required for commissioning, developing, and supporting digital health service implementation:

- Information Governance & Cyber Security
    - Information Security Officer & DPO
- Clinical Safety (DCB 0129 & DCB 160)
    - Clinical Safety Officer
    - Clinical Safety Training
- Digital Technology Assessment Criteria – DTAC
- Medical device services for digital health technologies
    - Medical Device Regulatory Lead
    - UK Responsible person
    - EU Authorised Representative
- Research Innovation partnerships (critical friend)

Cost Model = £650 to 950 per working day, business working day from 9am to 6pm.

Resources available:

UK & EU Regulatory Lead (Medical Devices)

Clinical Safety Officer

Information Security Officer

Cyber Security Specialist

Safety Engineering Specialist

Audit / Compliance Manager

Codesign Specialist

Information Governance & Security services

Information security is a vast area of complex regulatory responsibilities, core to working safely and effectively with the NHS and wider health and care sector providers. ETHOS is an expert in the field and believes in an ethical approach to deploying a best in class solutions at a sensible price.

At ETHOS we will build your Information Security Management Systems from the bottom up including:

- documenting the necessary policies and procedure
- generating mandatory evidence records
- creating a staff handbook and guidance
- business management manual
- statement of applicability
- your information risk assessment
- other documentation necessary for the effectiveness of the information security management system.

There are no hidden charges, and we only remain engaged until you have gained your certification and your staff have the knowledge and confidence to operate and maintain the safety system unless you select our ETHOS Virtual role deployment option.

Compliance work includes:

- ISO 27001 – ISMS
- ISO 27001 – Path to certification
- ISO 27001 – Implementation Training
- ISO 27001 – Internal Audit
- Cyber Essentials / Plus certification
- Cyber Security Health Check
- Cyber and Information Security Awareness and Training
- Data Security and Protection Tool Kit (DSPT) certification
- GDPR – Compliance Training

ETHOS Virtual ISMS roles to support your organisation when it needs it most. ETHOS will assess your most immediate needs and develop a roadmap to support your compliance work requirements. The team collaborate regularly with regulatory bodies and professional standards organisations to influence best practice across the health and care sector.

Clinical Safety (DCB 0129 & DCB 0160) services

NHS Digital have published standards for clinical risk management of health IT systems that are mandatory for health and care in the UK and synergises with international standards relating to medical devices.

ETHOS provides clinical safety support to the NHS and those organisations supplying products and digital health services into the NHS. Our co-founder Stuart Harrison is the original author of the clinical safety standards and has supported NHS leadership strategically over his 20 years as clinical safety lead in the NHS and more recently into NHS England, DHSC and NHS X for responses to the pandemic - COVID app, test and trace service and the NHS X Digital Clinical Safety strategy.

ETHOS supporting Clinical Safety Officers (CSO) are all fully accredited and have more than 100 years collective experience providing clinical safety services into digital health organisations[1]. Our CSOs are all registered with their professional institute (colleges) for their relevant speciality.

Digital health interventions are increasing at pace to support health and care professionals and patients using safe and effective technology. The need for compliance with these standards has never been more important. This includes the overlap into and from MedTech and Medical Devices manufacturers.

Implementing the clinical safety standards DCB 0129 & 0160 can be daunting and complex for innovators and health organisations alike. ETHOS CEO Stuart Harrison co-authored the standards and continues to lead their next stage development internationally.

The handpicked team at ETHOS is led by the best in the field and you will be guided through the implementation of the standard in a way that respects your deep knowledge of your product development lifecycle. Our approach seeks to build confidence and competence in your workforce, your greatest asset.

ETHOS provides Clinical Safety Officers who are suitably qualified and highly experienced health care practitioners (Nurses, Doctors and AHPs). We will work with the strengths of your team, systems, and processes to ensure solutions are practical, efficient, and become part of business as usual. Culture change is a core element of successful safety systems driving efficiency and it provides reassurance to your customers and end users.

ETHOS team have carried out clinical workflow analysis for a wide range of implementations. We also have a deep understanding in the context of implementing within NHS provider organisations seeking to build capacity in clinical safety work.

Compliance work includes:

- DCB 0129 & DCB 0160 internal audit and review reporting
- Creation of Clinical Risk Management System(s)
- Creation of Clinical Risk Management Plans and Clinical Safety Case Reports

[1] Our Team - ETHOS

- Integration of the requirements of DCB 0129 into Medical Device Quality Management Systems and Technical Files
- UK NHS Compliance strategy
- NHS DTAC

ETHOS will assess your most immediate needs and develop a roadmap to support your compliance work requirements. The team collaborate regularly with regulatory bodies and professional standards organisations to influence best practice across the health and care sector.

Clinical Safety Training

Accredited Foundation CSO course

Our training will prepare the ground for your first clinical safety officer role, equipping you with the basic requirements of the DCB0129/0160 standards, clinical risk assessment and management. Once completed you will be certified as an accredited CSO.

Online: MS Teams, **Duration:** 9.30am - 3.30pm, **Cost:** £408 (including VAT) per person

Who is this aimed at?

The standards state that the Clinical Safety Officer (CSO) must be a registered health professional and have some understanding of technology and risk assessment processes. As a registered health professional, you will need the very best grounding to ensure you are confident and competent to lead others through this risk management process effectively. Our trainers are all highly experienced Clinical Safety Officers who are registered practitioners from a range of backgrounds from Nursing to Physio and Pharmacy.

Aims of the day:

- To gain a clear understanding of the scope and scale of the requirements
- To differentiate between these standards and medical devices regulation
- To get hands-on with hazard identification and evaluation
- To understand risk control and measurements
- To understand the safety reports and the review process

General information

- Content will be tailored to learner needs and preferences wherever possible
- Different learning styles will be accommodated where feasible and negotiated with other participants
- Materials will be available free of charge after the session, via email
- Interactive and creative activities using Miro and Office formats
- Space for discussion and questions is woven into the day
- Regular breaks are negotiated with participants
- Some preparatory work and/or follow up reading may be needed, where appropriate
- Clear, paced information – let us know if you need a particular format
- Session evaluations and quality management are carried out at the end of every session.

eLearning - Digital Health Software: Safety and Risk Management

ETHOS has developed this online eLearning, the learning is CPD accredited and provides a broad foundation of understanding. This course provides introductions into clinical risk management, quality, safety engineering and clinical or medical safety officer practices, that are equivalent to many aspects of the medical devices regulations.

Digital Technology Assessment Criteria (DTAC) services

ETHOS knows that building safety and human-centred design early in the product life cycle is going to ease regulatory and other compliance requirements when it is deployed. This approach seeks to support early stage thinking about safety systems and ensuring that users' needs, and requirements are sought using robust engagement methodologies. ETHOS will work with your team to create well defined hazard identification and user feedback, using a range of tools, to evaluate potential deployment issues and risks. We know an effective digital solution is one that clinicians can evaluate as safe, secure, and effective.

Digital effectiveness also aims to support commissioners in decision making processes, guiding developers and health innovators, and ensuring effective procurement practices. Equalities considerations, Data Collection, Reliable Information, Quality & Safeguarding, Credibility with UK health and care professionals and relevance to current care pathways are some of the measures for effectiveness we promote. The ETHOS team are experienced in a range of methods such as NHS England Large Scale Change, NASSS framework, audit, and service improvement methodologies. We use critical appraisal of research and data insights to inform our work and can support you to create a fit for deployment, safe and effective product. The Digital Technology Assessment Criteria[2] for health and social care (DTAC) gives staff, patients, and citizens confidence that the digital health tools they use meet our clinical safety, data protection, technical security, interoperability and usability and accessibility standards. The DTAC brings together legislation and good practice in these areas. It is the national baseline criteria for digital health technologies entering and already used in the NHS and social care.

The Digital Technology Assessment Criteria for health and social care (DTAC) aims to give staff, patients, and citizens confidence that the digital health tools they use meet clinical safety, data protection, technical security, interoperability and usability and accessibility standards. DTAC is administered by NHS England. DTAC is the new national baseline criteria for digital health technologies into the NHS required to gain a listing on the NHS Apps Library from January 2021. It is designed to be used by suppliers to build technology and healthcare organisations to build and to buy technologies that meet a minimum baseline standard. The assessment criteria are focused on 5 core areas. Sections 1-4 below, form the assessed criteria, with a separate conformity rating provided around usability and accessibility:

1. Clinical safety: assessed to ensure that baseline clinical safety measures are in place and that organisations undertake clinical risk management activities to manage this risk.
2. Data protection: assessed to ensure that data protection and privacy is 'by design' and the rights of individuals are protected.
3. Technical assurance: assessed to ensure that products are secure and stable.
4. Interoperability: assessed to ensure that data is communicated accurately and quickly whilst staying safe and secure.
5. Usability and accessibility: products are allocated a conformity rating having been benchmarked against good practice and the NHS service standard.

[2] Digital Technology Assessment Criteria (DTAC) - Key tools and information - NHS Transformation Directorate (england.nhs.uk)

Medical Device Services

ETHOS has many years' experience with providing regulatory support to organisations wishing to place medical device products on the market in the US (FDA), EU & UK.

Our approach is aligned to international and regional regulatory body best practise, regulatory requirements, and standards for notified body certification. The International Medical Device Regulators Forum provides the internationally common forum from which all emerging principles for regulating medical devices emerge, i.e., Software as a Medical Device (SaMD) and Artificial Intelligence (AI) enables devices and modelling tools for clinical investigation or trials. These requirements are communicated to the any regional (e.g., EU) and country regulatory markets (e.g., US & UK). From that point, regulatory bodies will interpret the requirements for certification to that country or region. This includes the requirements for those organisations that certify medical device products on behalf of the regulator (e.g., BSI or SGS as notified bodies on behalf of the UK MHRA).

We are specialists in simplifying regulatory compliance for small and medium-sized enterprises, our services also include regulatory strategy should you be looking to certify your device in other countries.

Compliance work includes:

- Technical Files, Quality and Risk Management Systems, Clinical Evaluation Reports
- Person Responsible for Regulatory Compliance & UK Responsible Person
- Integration with DCB 0129 (UK NHS) Clinical Safety standard
- Compliance Strategy
- Remediating audit findings
- Device development and CE marking
- Recalls and Adverse Event management, Post Market Vigilance and CAPA
- Other markets – EU MDR, US FDA and more
- Global Regulatory Strategy
- Harmonised Standards & State of the art management – ISO 13485, ISO 62304, ISO 14971, ISO 82304, EN 60601, EN 62366

Our experience within the medical device industry and from working for Notified Bodies, enables us to provide solutions that work for you and your business that are compliant with the regulators, first time. Our medical device regulatory team is qualified to act as 'Qualified Persons' in line with the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

ETHOS will assess your most immediate needs and develop a roadmap to support your compliance work requirements. The team collaborate regularly with regulatory bodies and professional standards organisations to influence best practice across the health and care sector.

Other countries/markets

Other countries/markets such as Australia, Saudi Arabia, Brazil etc, have an approach to regulating medical devices based upon a claim of equivalence. Equivalence means that

evidence of approval and certification from US, EU or UK provides a substantial if not equivalent body of evidence to support placing a product on the market. Most countries utilise local organisations as agencies to support product safety and certification activities.

Therefore, placing a medical device product in any other country or region other than the EU, UK, or US; is relatively straightforward with a series of application forms, timescales, effort and supporting evidence to provide.

These regulatory requirements can be provided if required and is publicly available via various industry forums and regulatory bodies.