



G-Cloud 15 Service Definition

**Digital Health Compliance and Regulatory
Services**

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 **accenture**

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1.0 Scope of our services

Accenture offers a complete range of compliance services specifically designed for the healthcare sector. These services, including clinical risk management, regulatory affairs, quality management, data protection, security, and accessibility, are aimed at making your compliance management process easier and more efficient. Whether you require expert advice or a fully managed service, we can scale to meet your specific requirements, both in the UK and globally. Our fully integrated approach to compliance management is designed to free you up from the complexities of compliance, allowing you to focus on innovation and business growth.

Service Summary

Clinical Risk Management

DCB0129 and DCB0160 are clinical risk management standards mandated by the Health and Social Care Act 2012 for the NHS in England. They primarily aim to ensure the safety and effectiveness of Health Information Technology (HIT) systems deployed in health and care settings. These standards collectively establish a comprehensive framework for risk assessment, risk management, and documentation. This framework is designed to ensure that HIT systems are implemented and utilised in a manner that maximises their benefits while minimising potential risks to patients.

Suppliers who want to develop their products for use in the NHS, either directly or through competitive procurement frameworks, must provide evidence of compliance with the requirements of DCB0129. NHS organisations must assess compliance during procurement using the NHS England Digital Technology Assessment Criteria (DTAC) framework. NHS organisations in England using HIT systems that have the potential to negatively impact patient care must comply with DCB0160.

Each standard necessitates the creation of a Hazard Log, Clinical Safety Case Report, and Clinical Risk Management Plan, with clinical risk management being a continuous process throughout the HIT system lifecycle. Accenture can assist you in attaining and maintaining compliance, whether you require an expert to generate the necessary compliance documentation, oversee it in live service, or act as an external reviewer to provide an impartial evaluation of your Clinical Safety Case.

Service Components

- **Clinical Risk Assessment and Management:** We can conduct clinical risk assessments and develop robust management strategies to ensure compliance with relevant clinical risk management standards.
- **Clinical Safety Documentation and Management System Oversight:** Create and maintain clinical safety documentation and develop and oversee your clinical risk management system.
- **Comprehensive Consultancy Services:** We offer consultancy on all aspects of clinical risk management, including establishing your Clinical Risk Management System, advising on compliance, patient safety best practices, and risk mitigation strategies.
- **System Audit and Gap Identification:** We can audit your Clinical Risk Management System, identify gaps, and assist in addressing them.
- **Clinical Safety Officer Support:** Whether a supplier or NHS provider, we can provide you with a Clinical Safety Officer to support your clinical risk management activities.

- **Specialised Training Programs:** We can provide training on DCB0129 and DCB0160, as well as the ISO 14971 Risk Management Standard for medical devices.

2. Security and information governance

In today's digital landscape, the necessity for robust cyber security cannot be understated. Our comprehensive suite of security services is designed to safeguard organisations against the evolving spectrum of cyber threats while aligning with your organisational goals and regulatory mandates. Our offerings include bespoke risk management services, expert cybersecurity consultancy, and security compliance. We will help you define your security requirements, carry out Security by Design, and conduct extensive security testing to assess and enhance system resilience. Our proactive incident management and ongoing security governance ensure that your organisation maintains a solid security posture. With our specialised audit services and support for Information Governance, including impact assessments and consent management, we are committed to elevating the security standards within your organisation, ensuring compliance, and protecting your critical assets. Accenture can also provide other related services such as Supplier Risk Management.

Service Components

- **Tailored Security Strategies:** We provide tailored security strategies to align with organisational goals and regulatory requirements, ensuring a robust defence against cyber threats.
- **Security Risk Management Services:** Our security risk management services identify, assess, and mitigate risks associated with security vulnerabilities that are aligned with your business objectives.
- **Seamless Security Frameworks:** We design security frameworks that integrate seamlessly with existing infrastructure, optimising protection and functionality, including Security by Design.
- **Expert Consultancy:** Expert consultancy services are available to guide organisations through the complex landscape of cybersecurity threats and solutions, including those specific to digital health and MedTech (Figure 1).
- **Security and Information Governance Requirements:** Create requirements for Security and Information Governance for your product and service.
- **Secure Software Development:** Create software that is securely built and tested for secure operational working for on-device and back-end aspects like Cloud computing, and complies with Accessibility laws.
- **Comprehensive Testing Services:** This includes comprehensive testing services for both in-house and third-party suppliers, such as Penetration Testing (Dynamic Analysis Security Tooling), Security Environment and Code Scanning (Static Analysis Security Testing), and Performance Testing. These services are designed to evaluate the resilience of systems against attacks and assess performance under various conditions, providing appropriate remediation strategies.
- **Rapid Response Solutions:** We offer rapid response solutions for managing and mitigating the impacts of security incidents.

- **Governance Leads:** We can provide Security Governance and Information Governance leads to help ensure alignment with your agreed Security Posture.
- **Information Governance Assistance:** Information Governance Assistance for Data Processing Impact Assessments, User Consent forms, Compliance to Users Rights etc.
- **Security Audit Services:** Our security audit services can thoroughly assess your security practices and protocols to ensure compliance with UK and international standards.
- **Suppliers Cyber Security Risk Assessment:** We offer services to evaluate your suppliers' cyber security risks and ensure compliance with DTACs and the Data Security Protection Toolkit (DSPT).

Certification and Expertise

Accenture has ISO27001, ISO27701 Privacy Certifications, Cyber Security Essentials and Cyber Security Essentials Plus certifications. Our team comprises certified professionals accredited by CREST and CHECK for penetration testing. Each member possesses certifications relevant to their specific roles within the team, e.g., Certified Cloud Security Professional.

- Software and Infrastructure optimised for your Security posture.
- Cost-effective collection, use, and deletion of data that is aligned with your service needs.
- Clients are aware of their data collection and how it is being used for their benefit with their consent.
- Ongoing Security and Information Governance alignment for the creation and ongoing service.
- Spending the minimum required money to meet security needs which having a known maintained security posture.

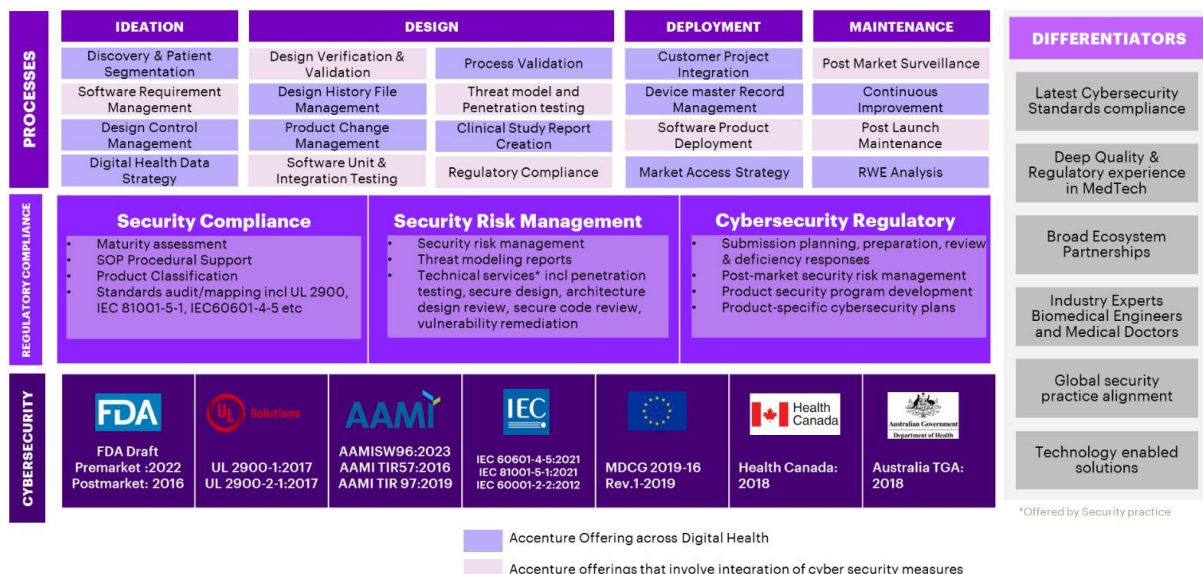


Figure 1 Cybersecurity in Digital Health and MedTech

2.0 Regulatory and quality management

The Accenture Quality Management and Regulatory team has a wealth of experience that spans over two decades. Our compliance support expertise extends across the globe, serving a diverse range of clients including the NHS, leading pharmaceutical and health tech companies, and emerging health tech startups. Demonstrating our extensive global presence, we have managed regulatory submissions in over 100 countries, with a particular focus on the UK, US, and EU markets.

Our capabilities are diverse and comprehensive, including Certified Quality Management Systems (QMS ISO 13485), alongside Consultancy in Quality and Regulatory. We also offer Quality Operation Services, Regulatory Operation Services, and Regulatory Affairs services. Particularly notable is our involvement in MedTech and Software as a Medical Device (SaMD) regulatory activities, where our services extend across the health sector and the broader Life Sciences industry.

Accenture's team comprises over 200 regulatory professionals who are currently managing in excess of 350 client projects. This extensive team reflects our broad reach and deep expertise in the field. Furthermore, we have end-to-end capabilities to execute the SaMD Lifecycle as per IEC 62304. This flexibility allows us to operate either under the client's QMS or under our own Accenture QMS, catering to a wide range of client needs and preferences.

Our Quality Management System (QMS) services stand out in the industry. We offer quality consultancy, which includes formulating quality strategies, providing audit and inspection support, setting up a QMS, conducting assessments, and performing remediations. Our software development processes and methodologies are particularly tailored to comply with SaMD and SiMD regulatory standards. These include but are not limited to the development lifecycle (IEC62304), usability (IEC62366), product cybersecurity (ISO80001), and medical device risk management (ISO14971).

- **Consulting on Quality Expertise at Global Scale:** Our consulting service provides expertise in Quality Management Systems (QMS), regulatory compliance for medical devices, and post-merger integrations, ensuring global standards and seamless transitions.
- **Consulting on Regulatory Expertise at Global Scale:** Our consulting service offers regulatory strategies, considerations, and implications tailored for medical devices on a global scale, ensuring compliance and facilitating market access.
- **Quality Assurance for Outsourcing Services:** Our Quality Assurance service ensures that outsourced functions meet predefined quality standards, encompassing partner vetting, requirement definition, metric establishment, audit execution, and corrective action implementation.
- **Regulatory Submission Management and Operations:** Our Regulatory Submission Management service coordinates the submission process to regulatory agencies, managing documentation completeness, accuracy, timelines, agency communication, and overall submission oversight.
- **Clinical Evaluation, Study, and Reporting Processes:** Our Clinical Evaluation service oversees systematic assessment of safety and efficacy, including study design, participant recruitment, data analysis, and regulatory-compliant report preparation to inform clinical decision-making.



Figure 2 - Core Services

UK Regulatory Landscape

Accenture ensures that all services are tailored not only to meet but also to exceed the requirements set forth by UK government standards and expectations. This could involve more detailed consultations on navigating the NHS's regulatory landscape, especially with new digital health technologies.

- **Regulatory Strategy and Compliance:** Offering strategic guidance on navigating the updated MHRA Medical Device Regulations, ensuring that all medical devices and SaMD products comply with the latest regulatory requirements.
- **Quality Management Systems:** Implementing and maintaining ISO13485 certified Quality Management Systems tailored specifically to meet MHRA standards, ensuring continuous compliance and operational excellence.
- **Documentation and Submission Support:** Assisting in preparing and managing all necessary documentation and submissions to the MHR A, including Clinical Evaluation Reports , Technical Files, and Design Dossiers, aligned with the new regulatory framework.
- **Post Market Surveillance and Vigilance:** Providing support for ongoing post-market surveillance activities, including incident reporting and corrective actions to meet MHRA vigilance requirements.
- **Risk Management:** Integrating ISO14971 risk management practices into product development and lifecycle management, focusing on risk assessment and mitigation strategies required by the MHRA, where the medical device software is integrated with HIT, we will ensure your compliance with DCB0129.
- **Audit and Inspection Preparation:** Offering expert consultancy and support during MHRA audits and inspections, including mock audits and staff training to ensure preparedness and compliance.
- **MHRA -Specific Training:** We deliver targeted training sessions to client teams on MHRA regulatory processes, updates, and compliance strategies , ensuring they remain informed and compliant.

- Advisory on Regulatory Updates: We keep clients updated with the latest MHRA guidelines and regulatory changes and provide consultancy on adapting business and compliance strategies accordingly.

3.0 Pricing

Please refer to the associated pricing document/ rate card relevant for this service.

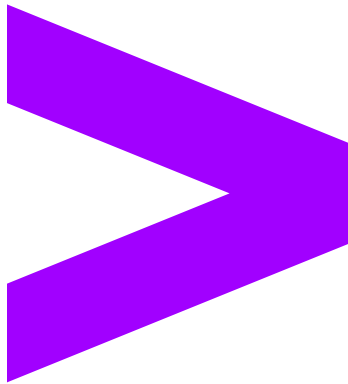
4.0 **Contacts**

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5.0 About Accenture

Accenture is a leading global professional services company that helps the world's leading businesses, governments and other organisations build their digital core, optimise their operations, accelerate revenue growth and enhance citizen services—creating tangible value at speed and scale. We are a talent- and innovation-led company with approximately 799,420 people serving clients in more than 120 countries. Technology is at the core of change today, and we are one of the world's leaders in helping drive that change, with strong ecosystem relationships. We combine our strength in technology and leadership in cloud, data and AI with unmatched industry experience, functional expertise and global delivery capability. We are uniquely able to deliver tangible outcomes because of our broad range of services, solutions and assets across Strategy & Consulting, Technology, Operations, Industry X and Song. These capabilities, together with our culture of shared success and commitment to creating 360° value, enable us to help our clients reinvent and build trusted, lasting relationships. We measure our success by the 360° value we create for our clients, each other, our shareholders, partners and communities



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