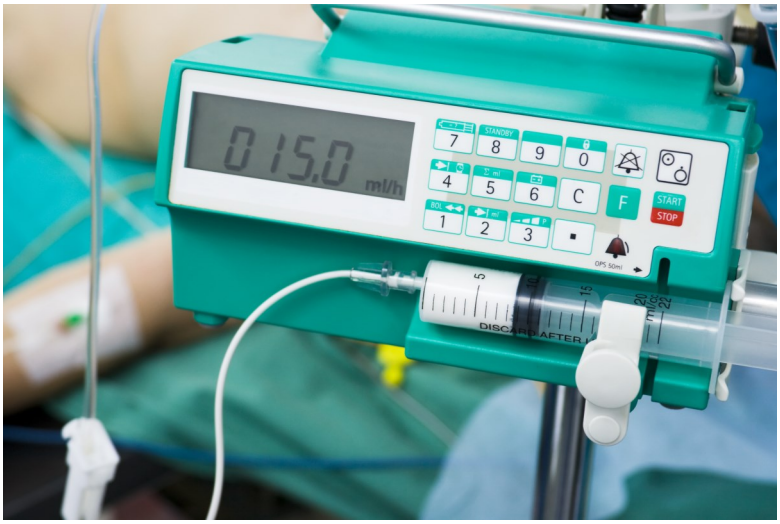
Medical devices



A track record of success

- Development of safety assurance cases for 510(k) submission
- Review and development of risk management files for DCB0129
- Providing expert advice on medical device software assessment to MHRA
- Client application of key standards including ISO 14971:2019 and IEC 60601
- Training in safety assurance case creation

ASCE, safety assurance case and 510(k) submission

New infusion pumps require a safety assurance case as part of the FDA's 510(k) submission process.

Adelard has been instrumental in providing manufacturers of infusion pumps with training, consultancy and the ASCE software tool to develop a safety assurance case and achieve a successful 510(k) submission.

Programs commence with a comprehensive training session on assurance cases for medical devices and the use of Adelard's assurance case tool, ASCE. The training introduces participants to the structured argument using notations such as CAE or GSN and the process of evidence incorporation.

To help manage the process of 510(k) submission Adelard has developed a technical file schema for use with ASCE. Use of the schema allows for rigour and repeatability in the development and management of safety assurance cases. The schema comprises:

- *Regulatory compliance:* A clause-by-clause compliance management tool showing the status of compliance.
- *Technical file:* Used to manage the hierarchy of documents that make up the technical file, so that the evolution of documents can be tracked and recorded.
- *Assurance case:* A typical Claims-Arguments-Evidence notation is included in cases where the manufacturer is required to, or wishes to produce an assurance case for their device.
- *Project management:* Aspects of the schema to identify task/component owner, review status etc.

ADELARD

Adelard LLP is an independent product and services company, founded in 1987, which supports its clients in the areas of safety, dependability, security and risk management. We add value by enabling our clients across industry sectors to:

- Efficiently develop, communicate and maintain safety and assurance cases. This process is supported by our ASCE software solution.
- Have confidence in the status of safety and related compliance evidence.
- Respond to regulatory change and manage reputational risk.

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Medical devices, NHS Digital and DCB0129

Following the release of the medical devices regulation EU 2017/745 in May 2017, which requires that medical devices with software need a clinical risk assessment with supporting evidence, NHS Digital have extended the scope of DCB0129 to all medical devices. Medical devices now have to conform to the NHS Digital Clinical Safety Standards specified in both DCB0129 and DCB0160. Under DCB0129 medical devices require risk management files for regulatory approval and evidential documentation to share with customers.

We have assisted several clients in the review of risk management files for correctness and completeness, and in the development of risk management files to comply with DCB0129.

Risk management files include :

- Risk management plan
- Hazard log
- Safety case
- Safety case report

Achieving regulatory compliance

Adelard's specialists are expert in software analysis, risk management, human factors analysis, and safety assurance cases, and we work within the FDA, EU and UK regulatory frameworks for medical devices.

We specialise in the application of all key standards for medical devices, including:

- ISO 14971:2019 – Risk management
- ISO 13845 – Quality management
- IEC 62304 – Software development
- IEC 60601 – Medical Electrical Equipment

Mobile apps, software and medical devices

The European Commission under MEDDEV 2.1/6 states that standalone software which has a medical purpose is considered to be an active medical device. Many 'apps' now fall into this category, for example, apps that provide triage and wellness monitoring systems on mobile devices.

Adelard has supported many of our customers by performing static code analysis and the assessment of the quality of software development. We also help provide justification for the use of COTS operating systems such as Microsoft Windows.

We have provided expert advice on medical device software assessment to the UK regulator of medical devices, the Medicines and Healthcare products Regulatory Agency (MHRA).

Cybersecurity

The FDA encourages medical device manufacturers to address cybersecurity risks to keep patients safe and better protect public health. For devices with cybersecurity risk, FDA draft guidance includes cybersecurity device design, labeling, and documentation for premarket submission. Adelard has consulted with many clients on including cybersecurity risk analysis within their safety assurance cases.

Training, assurance cases for medical devices

Adelard offers a 2-day training course on the development of safety assurance cases, covering the fundamental concepts, regulatory requirements, methodologies and best practice in the industry.
The training course is delivered by assurance case practitioners with experience in developing assurance cases for infusion pumps and also from other industries.

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