In this sector brief we highlight:
> The IEC 62304 software standard, which specifies life cycle requirements for the development of medical software and software within medical devices.
> The FDA guidance document that outlines validation principles for medical device software.
> How Cantata and AdaTEST 95 support project certification

IEC 62304

IEC 62304, *Medical device software - Software life cycle processes*, is a harmonised standard that is used as a benchmark to comply with regulatory requirements in both the European Union and the United States.

**Standard Requirements**

Cantata’s functionality specifically addresses the following sections of the IEC 62304 standard:

- Clause 5 Software Development Process
- Clause 6 Software Maintenance Process
- Clause 8 Software Configuration Management Process
- Clause 9 Software Problem Resolution Process

FDA

The guidance document, *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, outlines general validation principles applicable to the development of medical device software.

**Standard Requirements**

Cantata specifically addresses the following sections of the guidance document:

- Section 3 Context for Software Validation
- Section 4 Principles of Software Validation
- Section 5 Activities and Tasks
- Section 6 Validation of Automated Process Equipment and Quality System Software
> The Safety Manual provides guidance for how to use Cantata in a safety-related context, and to meet the requirements of independent tool certification

> The Standard Briefing papers are intended to serve as a reference to show how Cantata can be used to satisfy requirements of the IEC 62304 standard and FDA guidance document respectively.

> The Certification of Cantata was undertaken by SGS-TÜV GmbH, an independent third party certification body for functional safety, accredited by Deutsche Akkreditierungsstelle GmbH (DAkkS) [accreditation ID: D-PL-12088-01-01]

**Customer Case Studies**

Our Customer Case Studies provide more information on how Cantata and AdaTEST 95 were successfully used by various companies worldwide.

“Cantata testing had a positive impact on the way we write the code - reducing coupling between objects and making isolation testing easier!”
- GE Healthcare

**Quicklinks**

> Customer Case Study: GE Healthcare
> Customer Case Study: Hamilton Medical

All Customer Case Studies are available upon request