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Meet Requirements of IEC 62304

If your medical device has software that regulates its functionality in a way that contributes to Basic Safety or Essential Performance, then you will need to comply with IEC 62304, and we can help!

It's true: Software Development Life Cycle activities generate a great deal of documentation that can be difficult to keep organized and readily available when needed. InfoStrength's solutions, combined with the regulatory expertise of our consultants, structure SDLC management documentation for easier compliance, faster validation, and better process management – so you maintain your regulatory obligations more efficiently and meet your commercialization goals sooner.

InfoStrength provides a central web-based repository to store and organize documents. Reporting capabilities track each document from origin to obsolescence, giving your team complete visibility into the system and satisfying the demands of even the most rigorous auditor. InfoStrength can also track software incidents, assign their resolution to a developer, and trace their resolution to your SDLC processes*.

The Benefits Are Clear

Dramatically Reduce Costs

Time is money. Avoid costly mistakes by keeping documents and records in order.

Secure Environment

Allow the Notified Body to retrieve documents and tables securely.

Increase Oversight

Rely on incident management tools from identification to resolution validation.

Collaboration & Controls

Collaborate securely with both internal and external personnel.

About InfoStrength

InfoStrength Smart Enterprise Suite (SES) is a leading quality and regulatory solution designed specifically for regulated businesses. The powerful, scalable and easy to use solution, combined with the benefits of On-Call Quality Support and experienced consultants help make FDA compliance, business process management and business communication manageable and efficient for life science companies. Businesses worldwide rely on InfoStrength to support their products in the commercialization process.

*Only available with specific implementations of the software.

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Requirements

IEC 62304, when prescribed by Clause 14 of 60601-1 3rd Edition Amendment 1, may require the following:

- Full quality management system compliant with 21 CFR Part 820, ISO 13485 or both (depending on market)
- Software development processes and plans, including:
  - The processes to be used in the development of the software system
  - The required verification tasks for each life cycle activity
  - Software maintenance processes and plans
  - Software risk management procedures and processes compliant with ISO 14971
  - Product risk assessments
  - And MORE!
- Additional software documentation:
  - Title, name or naming convention
  - Purpose
  - Intended audience for the document
  - Procedures and responsibilities for development, review, approval and modification
- Software configuration management, such as:
  - The classes, types, categories or lists of items to be controlled
  - The software configuration management activities and tasks
  - When the items are to be placed under configuration control
  - When the problem resolution process is to be used
  - And MORE!

Get compliant and stay compliant with InfoStrength's unique combination of document management software and regulatory consultants who help you navigate IEC 62304 and other difficult requirements. Call us today to learn more!

Looking to be competitive in a global marketplace?

Because it has been harmonized with the Medical Device Directive in the EU and Recognized as a Consensus Standard by the FDA in the US, IEC 62304 can be used as a benchmark to comply with regulatory requirements in both markets. To date, this standard has been recognized in most countries that use compliance standards to fulfill regulatory requirements. **InfoStrength will help you meet IEC 62304 requirements with:**

- Easy yet controlled access to your most current relevant SDLC and other GMP procedures
- Incident and bug management from identification to resolution validation
- A secure collaborative environment between quality, regulatory and software development personnel with the appropriate document management and version controls to enable a smooth work process