Software Validation Service for Medical Devices

Provided by Ginsbourg.co.il (since 2008)

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About The Service

Software validation for medical devices is a requirement that applies to software that is used as a component of medical devices, or software that is by itself a medical device, and software used in the production of medical devices, or used in the implementation of the medical device manufacturer's quality system. In addition, any software used to automate any part of a medical device production process or any part of its quality system must also be validated for its intended use. Moreover, computer systems that create, modify, and maintain medical and pharmaceutical electronic records, or manage electronic signatures for medical and pharmaceutical records are also subject to validation requirements. Those systems and software applications must be validated in order to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

The ultimate goal of Ginsbourg.co.il is to deliver a powerful and reliable service suite for building confidence in your medical software's safety and effectiveness. The validation activities for each phase of the medical software development lifecycle are carefully planned, reviewed, and executed. Deliverable documents are printed in order to confirm the validation process and, in time, to present them to the regulatory authorities and appropriate notified bodies for accepting worldwide marketing approvals.

Software validation for medical devices includes consistent imperative tasks, e.g., performing a risk analysis, determining a level of concern, producing a comprehensive software documentation dossier (including a software requirements specification, a software design specification, a crosswise traceability analysis, etc.), execution and logging the validation and verification tests, Part 11 validation, and more. All the above activities and their branches are cordially provided as part of the full service.

With software validation service, you assure attaining CE marks, FDA approvals, and worldwide marketing certificates for your medical devices, innovations, and technology.

Key Features

- ✓ **Risk Analysis –** Identifying hazards, evaluating risks, developing, implementing, and monitoring risk control measures.
- ✓ **Level of Concern** – Estimating the severity of injury that a device could permit or inflict as a result of failures.
- ✓ **Software Description** – Composing a summary overview of the features and software operating environment.
- ✓ **Software Requirements Specification** – Constituting the software functional requirements.
- ✓ **Software Design Specification** – Describing the implementation of the above requirements for the software.
- ✓ **Architecture Design Chart** – Depicting the functional units and software modules by state diagrams and flow charts.
- ✓ **Validation and Verification Testing (VV&T)** – Planning, conducting, and reporting all test protocols.
- ✓ **Traceability Analysis** – Trailing among requirements, specifications, tests, identified hazards and mitigations.
- ✓ **Unresolved Anomalies Resolution** – Listing and annotating them with their impact on safety or effectiveness.

Key Benefits

- ✓ **For your customers** – Software validation for medical devices assures superior end-user experience.
- ✓ **For your R&D** – Software validation for medical devices guarantees the quality of the developments and products.
- ✓ **For your management** – Software validation for medical devices is the key for achieving CE marks and FDA approvals.

Contact and Order

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