Medical Device Software Software Life Cycle Processes

Medical software

global IEC 62304 standard on the software life cycle processes of medical device software states it is a "software system that has been developed for

Medical software is any software item or system used within a medical context. This can include:

Standalone software used for diagnostic or therapeutic purposes.

Software used by health care providers to reduce paperwork and offer digital services to patients, e.g., a patient portal.

Software embedded in a medical device (often referred to as "medical device software").

Software that drives a medical device or determines how it is used.

Software that acts as an accessory to a medical device.

Software used in the design, production, and testing of a medical device (or)

Software that provides quality control management of a medical device.

IEC 62304

IEC 62304 – medical device software – software life cycle processes is an international standard published by the International Electrotechnical Commission

IEC 62304 – medical device software – software life cycle processes is an international standard published by the International Electrotechnical Commission (IEC). The standard specifies life cycle requirements for the development of medical software and software within medical devices. It has been adopted as national standards and therefore can be used as a benchmark to comply with regulatory requirements.

V-model (software development)

stable software products. Lately, it is being adopted by the medical device industry. Product lifecycle management Systems development life cycle Clarus

In software development, the V-model represents a development process that may be considered an extension of the waterfall model and is an example of the more general V-model. Instead of moving down linearly, the process steps are bent upwards after the coding phase, to form the typical V shape. The V-Model demonstrates the relationships between each phase of the development life cycle and its associated phase of testing. The horizontal and vertical axes represent time or project completeness (left-to-right) and level of abstraction (coarsest-grain abstraction uppermost), respectively.

Software safety

published as ED-109A by Eurocae). IEC (2006). Medical device software — Software life cycle processes. International Electrotechnical Commission. IEC

Software safety (sometimes called software system safety) is an engineering discipline that aims to ensure that software, which is used in safety-related systems (i.e. safety-related software), does not contribute to any hazards such a system might pose.

There are numerous standards that govern the way how safety-related software should be developed and assured in various domains. Most of them classify software according to their criticality and propose techniques and measures that should be employed during the development and assurance:

Software for generic electronic safety-related systems: IEC 61508 (part 3 of the standard)

Automotive software: ISO 26262 (part 6 of the standard)

Railway software: EN 50716

Airborne software: DO-178C/ED-12C)

Air traffic management software: DO-278A/ED-109A...

Medical device

medical device is any device intended to be used for medical purposes. Significant potential for hazards are inherent when using a device for medical

A medical device is any device intended to be used for medical purposes. Significant potential for hazards are inherent when using a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country. As a general rule, as the associated risk of the device increases the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase.

Discovery of what would be considered a medical device by modern standards dates as far back as c. 7000 BC in Baluchistan where Neolithic dentists used flint-tipped drills and bowstrings. Study of archeology and Roman medical literature...

Outline of software engineering

Scrum Heavyweight Cleanroom ISO/IEC 12207 — software life cycle processes ISO 9000 and ISO 9001 Process Models CMM and CMMI/SCAMPI ISO 15504 (SPICE)

The following outline is provided as an overview of and topical guide to software engineering:

Software engineering – application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is the application of engineering to software.

The ACM Computing Classification system is a poly-hierarchical ontology that organizes the topics of the field and can be used in semantic web applications and as a de facto standard classification system for the field. The major section "Software and its Engineering" provides an outline and ontology for software engineering.

Agile software development

teams trying to optimize their development processes and ensure consistency in the software development life cycle. By not having sponsor support, teams may

Agile software development is an umbrella term for approaches to developing software that reflect the values and principles agreed upon by The Agile Alliance, a group of 17 software practitioners, in 2001. As documented in their Manifesto for Agile Software Development the practitioners value:

Individuals and interactions over processes and tools

Working software over comprehensive documentation

Customer collaboration over contract negotiation

Responding to change over following a plan

The practitioners cite inspiration from new practices at the time including extreme programming, scrum, dynamic systems development method, adaptive software development, and being sympathetic to the need for an alternative to documentation-driven, heavyweight software development processes.

Many software development...

Commercial off-the-shelf

are complied with. The standard IEC 62304:2006 "Medical device software – Software life cycle processes" outlines specific practices to ensure that SOUP

Commercial-off-the-shelf or commercially available off-the-shelf (COTS) products are packaged or canned (ready-made) hardware or software, which are adapted aftermarket to the needs of the purchasing organization, rather than the commissioning of custom-made, or bespoke, solutions. A related term, Mil-COTS, refers to COTS products for use by the U.S. and Canadian militaries.

In the context of the U.S. government, the Federal Acquisition Regulation (FAR) has defined "COTS" as a formal term for commercial items, including services, available in the commercial marketplace that can be bought and used under government contract. For example, Microsoft is a COTS software provider. Goods and construction materials may qualify as COTS but bulk cargo does not. Services associated with the commercial...

Outline of software

of a data processing system. The term was coined to contrast to the term hardware, meaning physical devices. In contrast to hardware, software "cannot be

The following outline is provided as an overview of and topical guide to software:

Software – collection of computer programs and related data that provides the information for the functioning of a computer. It is held in various forms of memory of the computer. It comprises procedures, algorithms, and documentation concerned with the operation of a data processing system. The term was coined to contrast to the term hardware, meaning physical devices. In contrast to hardware, software "cannot be touched". Software is also sometimes used in a more narrow sense, meaning application software only. Sometimes the term includes data that has not traditionally been associated with computers, such as film, tapes, and records.

Software verification and validation

In software project management, software testing, and software engineering, verification and validation is the process of checking that a software system

In software project management, software testing, and software engineering, verification and validation is the process of checking that a software system meets specifications and requirements so that it fulfills its intended purpose. It may also be referred to as software quality control. It is normally the responsibility of software testers as part of the software development lifecycle. In simple terms, software verification is: "Assuming we should build X, does our software achieve its goals without any bugs or gaps?" On the other hand, software validation is: "Was X what we should have built? Does X meet the high-level requirements?"