Electronics Design-for-eXcellence Guideline

EDM-D-202
Design of Electronic Medical Devices

V2.0
September 2023

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The Electronics Design and Manufacturing Guidelines principles

The Electronics Design-for-eXcellence (DfX) Guidelines are designed to provide all electronic supply chain actors involved in the design, qualification, industrialization and production of Electronics practical guidelines to master the multi-disciplinary hardware aspects of electronic module realization and operation in a cost-effective way. The Electronics DfX guidelines provide the system designer the boundary conditions of industrial electronic manufacturing technology and guidelines to achieve quality, operational reliability and regulatory compliancy. It is intended to support the development of cost-effective, reliable electronics with a short time-to-market requiring a minimum number of design iterations.
Some of the characteristics of the Electronics DfX Guidelines are:

- The Electronics DfX Guidelines are oriented towards the overall optimization of the physical design of the electronic product.
- The guidelines refer to the relevant industry standards that are predominantly used in the international electronics industry such as those published by organizations as IPC and JEDEC. The guidelines do not replace industrial standards but define or recommend what options in the standards to use and will fill-in gaps if necessary. They provide the basis on which a company/product/product-line or application specific approach for design, industrialization and/or realization can be defined.
- Scientific argumentation and physical models form the basis of a large part of the guidelines and of the associated tools. This allows the use of the guidelines beyond the boundary of the users' experience domain. Therefore, it provides a powerful product and process innovation aid.
- The Electronics DfX Guidelines will not specify, recommend or exclude specific brands of materials, components, suppliers or products. They will put forward minimal requirements on quality, physical and chemical properties and testing.
- The Electronics DfX Guidelines are based on verifiable physical models, standards and empirical data.

Electronics DfX Guideline Scope

- This guideline supports the design of electronics in active medical devices and their parts.

Acknowledgement

Funding organizations

Agentschap Ondernemen is acknowledged for funding the project GENEESS that provided the basis for the EDM-X-202 guidelines on electronics for medical applications.

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1. Applicable Documents

This Electronics DfX Guideline refers to the most recent version including amendments and addendums of the following documents:

93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. (MDD)
2007/47/EC	Amendment to 93/42/EEC, 98/79/EC and 98/8/EC.
2017/745/EU	Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices. Amendments, corrigenda and implementing measures: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en.
93/68/EEC	CE certification directive
21 U.S.C.	Title 21 of the United States Code: Federal Food Drug & Cosmetic Act (FD&C).
21 CFR Ch. I	Title 21 of the Code of Federal Regulations, Chapter I: Food and Drug Administration. (US)
21 CFR part 820	U.S. Food and Drug Administration, Quality System Regulation, Part 820
EN ISO 13485	Medical Devices Quality Management Systems
EN ISO 14971	Medical Devices – Application of risk management to medical devices
IEC 60601	Medical Electrical Equipment basic safety and essential performance series. Identical to EN 60601 (EU) en CSA 60601 (Can). Consensus standard per FDA.
EN 60601	Medical Electrical Equipment basic safety and essential performance series. Harmonized standard.
IEC 62304	Medical Device Software – Software Life Cycle Processes. Identical to EN 62304. Consensus standard per FDA.
EN 62304:2006	Medical Device Software – Software Life Cycle Processes. Harmonized standard.
EDM-P-202	Product Life Cycle Management of Medical Devices
EDM-Q-202	Certification of Medical Electronics

2. Applicability of the Electronics DfX Guideline EDM-D-202

- This guideline focuses on devices for medical application that contain electronics or are electronic products.
- The recommendations given in the guideline are intended to help the user in designing electronics for medical applications.
- This guideline provides a high-level, introductory guide towards medical device design per EU or US-FDA regulations.
- Details of the requirements and the methodology can be found in the applicable EU-CE and US-FDA regulations and standards.
- EDM-P-202 on Product Life Cycle Management of Medical Electronics provides essential information for the application of this guideline and shall be used in conjunction with this guideline.

3. Definitions

See section 3 of EDM-P-202.

4. All Markets

4.1. Medical Device Design

4.1.1. The design shall preferably be executed per EN ISO 13485 design procedures.

4.1.2. Medical device software shall be designed per EU harmonized standard EN 62304 which is identical to IEC 62304, a consensus standard per FDA.

4.1.3. Electronics design and design verification and validation shall be per EU harmonized standard EN 60601 to ensure safety and effectiveness requirements of medical electrical equipment. EN 60601 is identical to IEC 60601 which is a consensus standard per FDA.

4.1.4. Risk assessment in the design phase shall preferably be per EN ISO 14971, see also 2017/745, Annex I(3).

4.1.5. Design history, audit and CAPA reports from previous or similar medical devices shall be investigated for relevant data on safety risks and other product risks. Lessons learned as well reported misuse and accidents shall be anticipated on.

4.1.6. A first risk analysis shall be conducted to evaluate safety and medical effectiveness.

4.1.7. Throughout the development cycle risk management shall be conducted per ISO 14971. For all non-acceptable risks, solutions must be found to reduce the risk, by avoiding the failure occurrence, and/or reducing the severity of the consequences as identified per Failure Mode and Effect Analysis. The manufacturer must provide evidence of the right compromise.

4.1.8. The design risk management focuses on the design quality of the medical device by questioning the design impact on quality in all relevant domains such as:

- Quality and reproducibility of raw materials, components, etc.
- The quality of goods and services delivered by third parties, i.e., the supply chain
- The quality of processes, facility and equipment control.
- The quality of the software development.

4.2. Design-for-eXcellence of Medical Devices

4.2.1. Quality is essential in medical device design and manufacturing. Therefore, one shall set high Design-for-Manufacturing standards. Use the EDM Design-for-Manufacturing guidelines with IPC class 3 requirements for the electronics.

4.2.2. Reliability is a second crucial property of a medical device. The highest level of reliability insurance shall be applied. Use the EDM Design-for-Reliability and Qualification guidelines with IPC class 3 requirements for the electronics.