Electronics Design-for-eXcellence Guideline

EDM-D-202
Design of Electronic Medical Devices

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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 the electronics in active medical devices and their parts.

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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.
MEDDEV 2. 4/1	Guidelines relating to the application of the council directive 93/42/EEC on medical devices.
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
ISO 13485	Medical Devices Quality Management Systems
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 referenced 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.