Product Life Cycle Management Guideline

EDM-P-202
Product Life Cycle Management of
Electronic Medical Devices
V2.0

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The Product Life Cycle Management Guideline

The Product Life Cycle Management (PLCM) Guidelines intend to provide guidelines for the overall management of the life cycle of stand-alone or embedded electronics, with focus on the design, manufacturing, operation, reliability, and end-of-life aspects. Marketing and business development lie outside the scope of these guidelines.

- The recommendations given in the guidelines are intended to help the user in the Product Life Cycle Management of electronics and products with embedded electronics.
- The PLCM guidelines promote the use of scientific methods such as physical modelling, physics-of-failure based accelerated testing, simulation, virtual prototyping, etc., over experience-based guidelines and extensive product testing. Physical models extend the capability of predicting the designed product's properties and behaviour beyond experience. This provides a cutting-edge innovation advantage over an experience-based development approach.
- Physical models reduce the development cost and time by reducing product testing and, especially, the number of design iterations.

Product Life Cycle Stages and Phases

The following Product Life Cycle stages and phases are distinguished.

Innovation Stage New Product Exploration

1. **Problem Research**
   Evaluation of the product idea by experts and stakeholders on its technological feasibility, its viability of providing a solution to a user problem and its business potential. Brainstorming, expert consultancy and literature study form the basis of a low-cost evaluation methodology in this phase. It delivers a product research plan with a rationale and a budget proposal for more in-depth evaluation of product options, priorities, and opportunities.
2. **Product Research**
   Evaluation of most viable product options using functional software and hardware evaluation kits or test models, product mock-ups, etc. The output of this phase is a Proof-of-Concept called a Product Concept Demonstrator, demonstrating the key features of the product solution.

Innovation Stage New Product Planning

3. **Product Specification**
   Based on the Proof Concept Demonstrator and Product Research results the requirements for the product that will be marketed are created. The output of the Specification phase is a high-level description of the product to be designed: the Product Requirements Document (PRD)
4. **Product Planning**
   The planning phase creates a business, operations and product development plan for the product. It contains the main targets and their critical milestones and timing specified in a comprehensive New Product Introduction (NPI) plan.

Innovation Stage New Product Introduction

5. **Architecture**
   Based on the PRD the product's architecture is defined, the Detailed Product Specification and the detailed NPI project plan are created.
6. **Design**
   Execution of the detailed design based on the output of the Architecture phase, evaluation of engineering solutions using simulations and engineering prototypes. Specification of the new product including manufacturing instructions for the product prototypes.
7. **Prototyping**
   Design evaluation and product qualification on product prototypes.
8. **Industrialization**

Preparation of the regular production of the product and hand-over to operations.

Product-to-customer Stage

9. **Production**
   Product manufacturing including quality management throughout the operational lifetime of the product.
10. **Distribution**
    Distribution of products from the production warehouse(s) to the customer(s).

Product-at-customer Stage

11. **Installation**
    Installation and start-up of the product at the customer's site.
12. **Product Operation**
    Product operation including aspects like reliability and maintenance throughout the operational lifetime of the product.

Retirement Stage

13. **Decommissioning**
    Actions taken to end the product's use.
14. **The End**
    Re-use, recycling and/or waste handling of products that have been decommissioned.

Product Life Cycle related and supporting activities

The following related activities are identified:

1. Technology Development (product independent)
2. Component Development (product dependent)

The following supporting activities applicable to a class of products are identified (not limiting):

1. Technology qualification program
2. Design methods and guidelines
3. Product verification, validation and certification
4. Qualified supply chain
5. New Product Introduction Program
6. Product Change Program
7. Quality Control Program
8. Maintenance Program
9. Decommissioning Program
10. Re-use, recycling and waste handling

EDM-P-200 describes a physics-based approach to Product Life Cycle Management
EDM-Q-200 describes a physics-based "White Box" approach to technology qualification.

PLCM Guideline Scope

- This guideline supports the product life cycle management aspects of electronic medical devices and the electronics in medical devices and their parts. It provides a high-level, introductory guide towards medical device management per EU-CE or US-FDA regulations.
- Details of the requirements and the methodology can be found in the referenced EU and US regulations and standards.

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Table of Contents

1. Applicable Documents

This Product Life Cycle Management Guideline refers the most recent version including amendments and addendums of the following documents:

GHTF/SG1/N15	Global Harmonization Taskforce: Study Group 1 final document GHTF/SG1/N15: 2006: The principles of Medical Device Classification.
2001/83/EC	Directive 2001/83/EC on the community code related to medicinal products for human use.
2004/726/EC	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. (MDD) *Replaced by Regulation 2017/745/EU on medical devices*.
2007/47/EC	Amendment to 93/42/EEC, 98/79/EC and 98/8/EC.
90/385/EEC	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. (AIMDD) *Replaced by Regulation 2017/745/EU on medical devices*.
98/79/EC	Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices. (IVDD) *Replaced by Regulation 2017/745/EU on in vitro diagnostic medical devices.*
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
2017/746/EU	Regulation (EU) 2017/746 of the European Parliament and the Council of 5 April 2017 on in vitro diagnostic medical devices. Amendments, corrigenda and implementing measures: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en.
MDCG-Y-No-Rev	Medical Device Coordination Group (MDCG) endorsed guidance documents https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
93/68/EEC	CE certification directive.
1012/2012	Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation.
85/374/EEC	Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.
21 U.S.C.	Title 21 of the United States Code: Federal Food Drug & Cosmetic Act (FD&C).
42 U.S.C.	Title 42 of the United States Code: Public Health Service Act (PHSA).
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. (QMS)
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.