

Product Life Cycle Management Guideline

EDM-P-202
Product Life Cycle Management of
Electronic Medical Devices
V1.1
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Contact

Geert Willems

Phone: +32 16 288962
Mobile: +32 498 91 94 64
Geert.Willems@imec.be
IMEC
Kapeldreef 75
B3001 Heverlee

Verantwoordelijke uitgevers

Luc Van den Hove - IMEC

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The Product Life Cycle Management 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 electronics and of the electronics' aspects of products containing electronics with focus on the design, manufacturing, operation, reliability and end-of-life aspects. Marketing and business development aspects lie outside the scope of the guidelines.

- The recommendations given in the guidelines are intended to help the user in the Product Life Cycle Management of electronics and products with integrated electronics.
- The PLCM guidelines promotes the use of scientific methods such as physical modeling, 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 behavior 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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imec contributors

Filip Ponsaerts
Maaïke Op de Beeck, Ph.D.
Geert Willems, Ph.D.

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