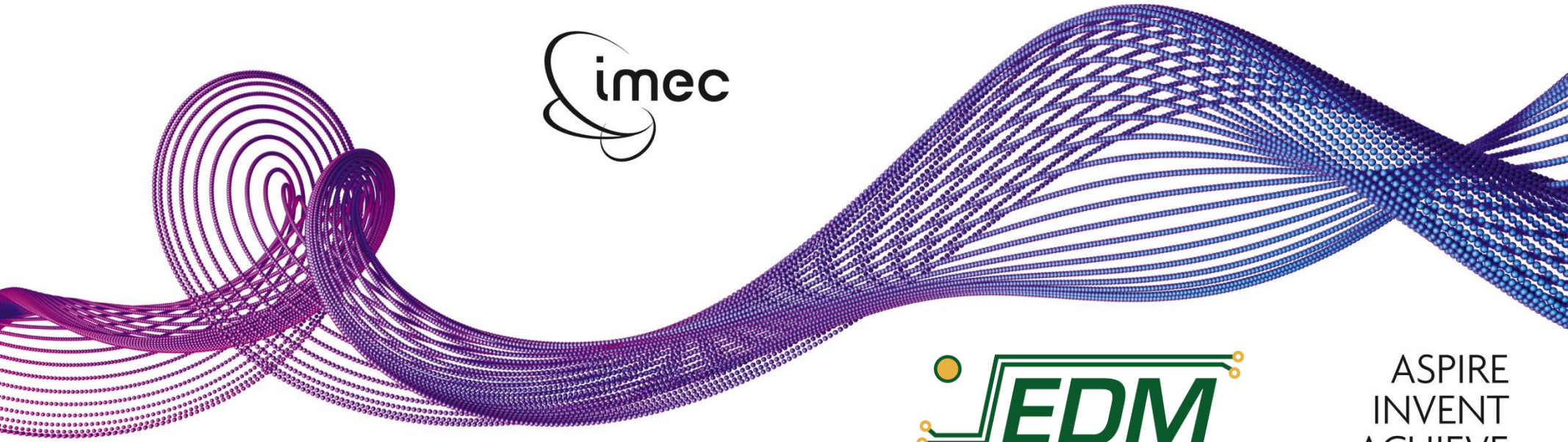
GUIDE FOR THE DEVELOPMENT OF MEDICAL TECHNOLOGY

BEST PRACTICES GUIDELINE, TOOLKIT AND ISO13485

CENTER FOR ELECTRONICS DESIGN & MANUFACTURING

IMEC – ICLINK - EA



imec

EDM
Electronics Design & Manufacturing

ASPIRE
INVENT
ACHIEVE

CEDM WITHIN THE IMEC COMMUNITY

World-leading research in nano-electronics

- Founded in 1984; HQ: Leuven, Belgium
- > 2200 employees

Value chain aggregator (VCA): support companies, universities and research institutes to layout, prototype, fabricate, test and qualify their electronic products

- Design and manufacturing services (IC, package, board)
- Access to foundries (TSMC, UMC, ...) for various IC technologies
- Prototyping to low-volume

Industry support in the development of high quality, reliable and cost-effective electronic modules (PBA)

- DfX Guidelines - Consultancy – Training
- PBA Design-f-X supporting tools:
  X: Manufacturability, Test, Reliability, etc.
- Hardware failure root cause analysis

CEDM MISSION

To support industry

in the development of

high quality, reliable and cost-effective

electronic modules (PBA)

by means of

knowledge creation and sharing,

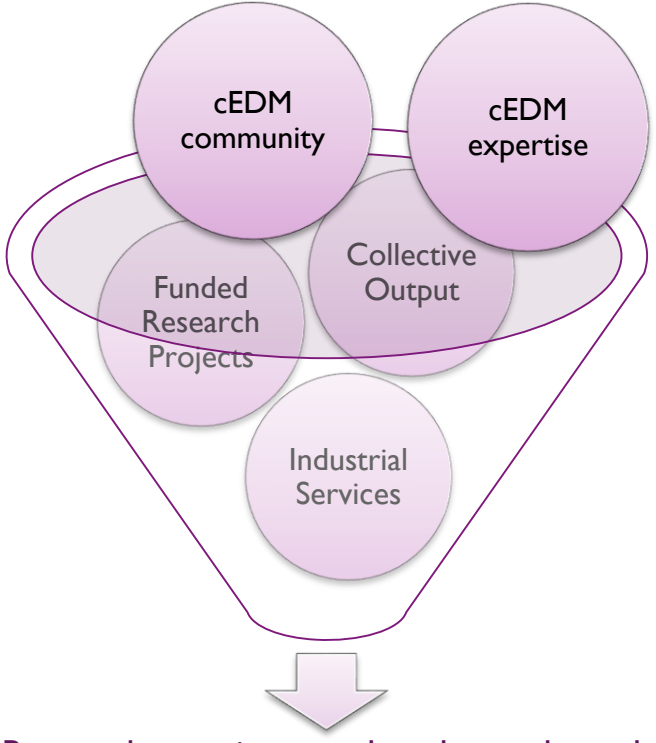
scientifically sound methodologies

and

collaboration

throughout

the electronic supply chain.



Better electronics at reduced cost through

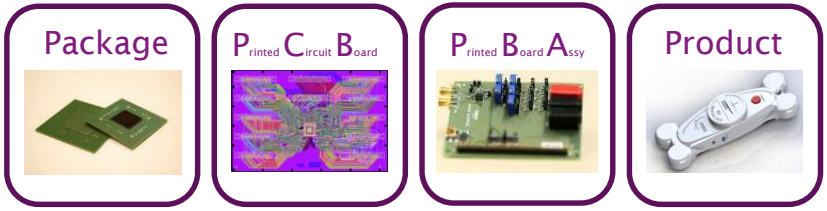
science based design & production methodologies

CEDM EXPERTISE

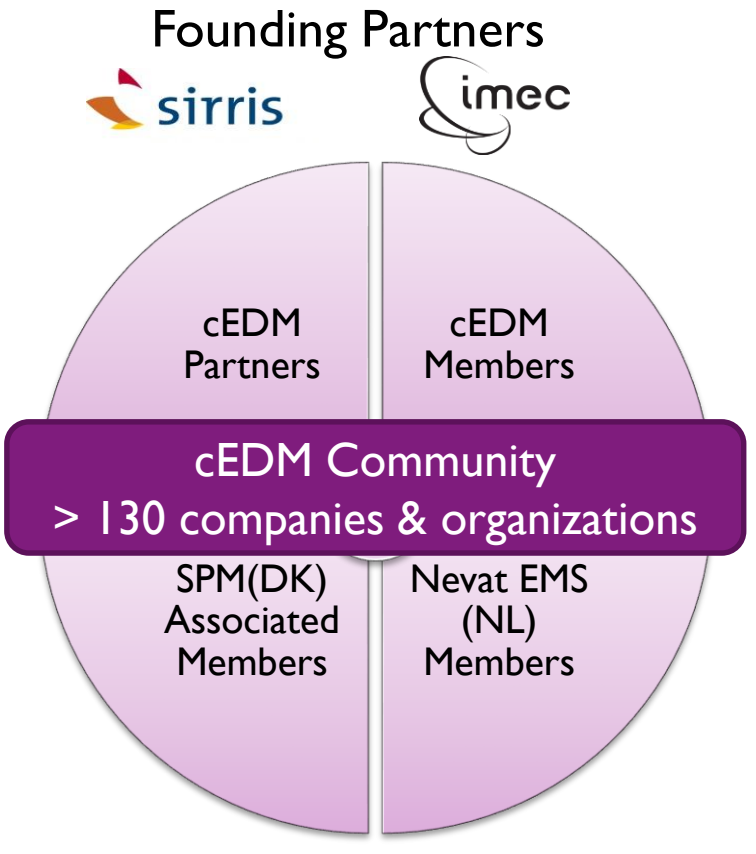
- **P4** : IC **P**ackage – **P**CB – **P**BA – **P**roduct technology & reliability
- Design-for-X:

  Manufacturability, Reliability, Test, Cost,...
- cEDM team: >100 years of electronics industry practice

  Design – Industrialization – Production – Quality



THE CEDM COMMUNITY



GENEESS GUIDELINE

BEST PRACTICES FOR ELECTRONICS IN MEDICAL DEVICES

- Version 1: May 2015
- Version 2: May 2016
- Content:
  - Basic elements of regulatory requirements for medical devices.
  - The realization of medical devices containing electronics.
  - Basic elements of project management for medical devices.
  - Basic elements of Design-for-X: Design-for-Test, Design-for-Reliability, Design-for-RoHS, etc.
  - Basic overview of biocompatibility for medical devices.
  - Design & testing
- Authors:
  - Maaike Op de Beeck - imec
  - Filip Ponsaerts - imec
  - Frederik Horemans - DSP Valley

GENEESS GUIDELINE

APPROVAL FDA (US) AND CE MARKING (EU)

- Pre-approval in US
  - FDA (Center for Devices and Radiological Health)
    - Class I: very low to low risk
    - Class II: moderate risk
    - Class III: high risk (all implants are class III)
  - Quality System Regulation
- Approval in EU
  - Medical Devices Directive (MDD): 93/42/EEC & 2007/47/CE
    - Class I, Is, Im
    - Class IIa
    - Class IIb
    - Class III: highest risk (such as implants)
  - Notified Bodies (NB) assess whether a product meets the MDD (CE marking)
  - Quality Management System
  - IEC 60601-1

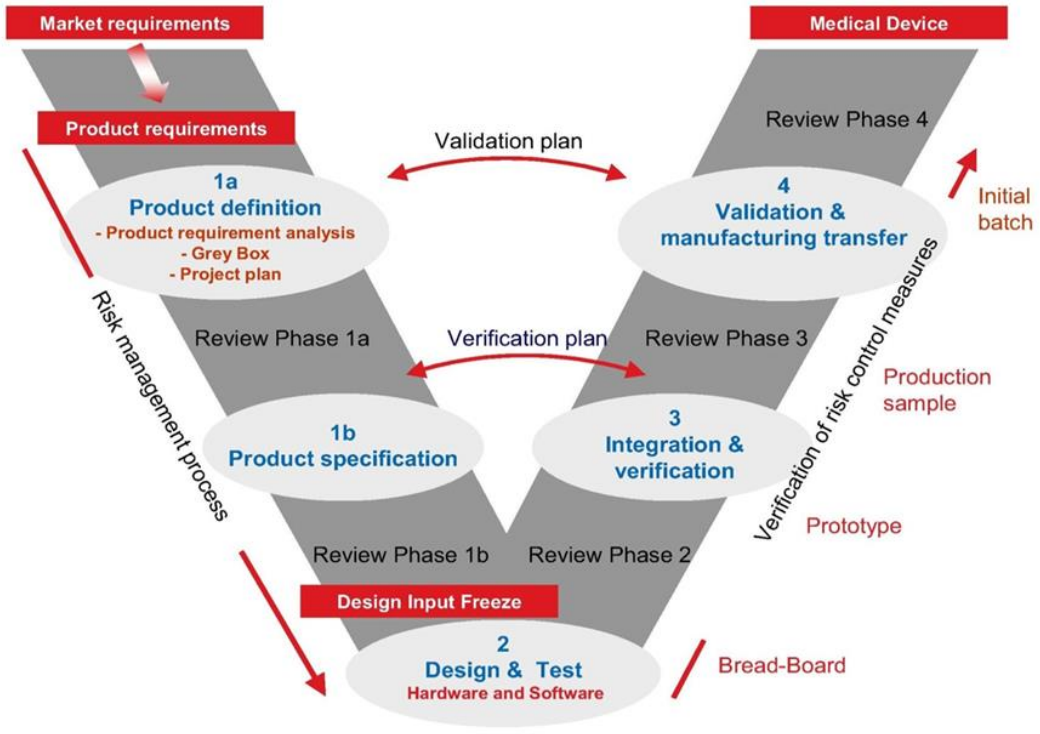
GENEESS GUIDELINE

PROJECT MANAGEMENT BEST PRACTICES

- Choice of the type and level of project management
- Quality Management System (ISO 13485)
- Recommended minimum:
  - Design Control
  - Define the Scope and Objectives
  - Define the Deliverables
  - Project Planning
  - Communication plan
  - Tracking and Reporting
  - Change Management
  - Risk Management

GENEESS GUIDELINE

VERIFICATION AND VALIDATION



- Verification: Am I building the product right?
- Validation: Am I building the right product?
- V&V activities are important because they:
  - Ensure the requirements are met.
  - Remove defects from the product, reduce cost of poor quality and rework.
  - Ensure the user's needs are met
  - Improve the quality of product and process
  - Improve productivity and performance

GENEESS GUIDELINE

DFX GUIDELINES

- Important when designing a Printed Board Assembly
- Do's and don'ts of good DfX practice
- Basic Design-for-Assembly rules
- Basic Design-for-Manufacturing rules
- Basic Design-for-Test rules
- Basic Design-for-Reliability rules

GENEESS GUIDELINE

BIOCOMPATIBILITY, BIO STABILITY AND STERILITY

- Implantable electronic devices
- Wearable electronic devices
- Natural bio-response upon implantation of foreign material
- Biocompatibility related to material-tissue interaction
- Biocompatibility realized by dedicated encapsulation
- 3 most used types of sterilization:
  - Radiation based techniques
    - Gamma radiation
    - Electron beam radiation
    - X-ray radiation
  - ETO sterilization
  - Autoclave sterilization

GENEESS GUIDELINE

ISO 13485 CHANGES MARCH 2016

- Some of the changes:
  - Risk-based approach beyond product realization.
  - Increased linkage with regulatory requirements (regulatory documentation)
  - Validation of software applications (QMS software, Process control, measurement & monitoring)
  - Appropriate infrastructure (sterile medical devices, clean environment,...)
  - Planning & documenting CAPA, implement without delay

- Guideline will be updated accordingly

GENEESS TOOLKIT
ACTIVE MEDICAL DEVICES

- Toolkit for starters & SME's
- Release end April 2016
- Focus on active medical devices (power source)
- Excluding In Vitro Diagnostic Device (IVD) and implantables.
- CE marking (EU market)

GENEESS TOOLKIT

ACTIVE MEDICAL DEVICES

- Assess strengths and weaknesses
- Assessment of active medical device
- Classification based on intended use:
  - Class I,Is,Im
  - Class IIa
  - Class IIb
  - Class III
- First assessment of required Quality management system
- Links, documents & checklist
- Evaluate impact of intended use :
  - On classification
  - On CE marking

GENEESS TOOLKIT
ACTIVE MEDICAL DEVICES

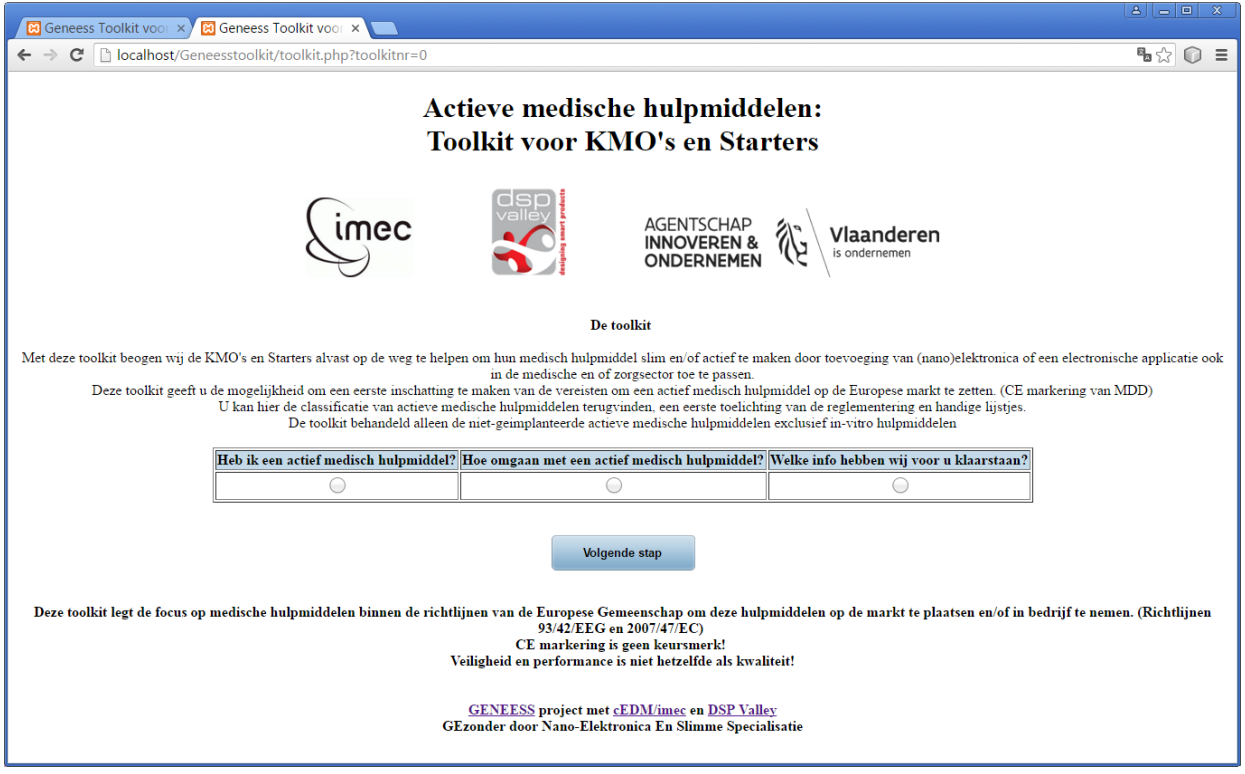
- Intended use: measure heart rate

GENEESS TOOLKIT
ACTIVE MEDICAL DEVICES

- Intended use: measure heart rate
- Diagnostic use e.g. 24 hour follow up
- Follow up of a heart condition as part of or after treatment
- Clinical trial
- Stress test:
  - Diagnostic
  - Prevention
  - Study
- Sport environment:
  - Early detection of risk factors
  - Training progress

GENEESS TOOLKIT

WEB-BASED



THANK YOU

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