



Medical Device Directive (MDD)

93/42/EEC as modified by 2007/47/EC



Objectives of “New Approach”

- Adopted by all Member States
- Efficient regulation
- Ensure safe medical devices
- Ensure manufacturer responsibility
- Ensure the product benefits the community
- Ensure that benefit outweighs risk
- Market orientation





European Directives

Medical Devices:

- Medical Devices Directive (MDD) 93/42/EEC
 - <http://bit.ly/M5MDD>
- Active Implantable Medical Devices (AIMD) 90/385/EEC
 - <http://bit.ly/AIMDDirective>
- In Vitro Diagnostics Directive (IVD) 98/79/EC
 - <http://bit.ly/currentIVDD>



Harmonization

There is presumption of conformance with the MDD if the manufacturer bases their quality system on a harmonized standard.

- EN ISO 13485:2012 is a harmonized standard

100% of MDD requirements are **NOT** covered by the ISO 13485.



Annex ZB...

Table ZB.1 — Relationship between Annex II of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1 st indent		Not covered
3.1 second sentence 2 nd indent		Not covered
3.1 second sentence 3 rd indent		Not covered
3.1 second sentence 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.



MDD-Specific Procedures



- Post-market surveillance program
- Vigilance and adverse event reporting
- Preparation of a technical file or design dossier
- Essential requirements
- How to conduct clinical evaluations
- Risk management per EN ISO 14971:2012
- Preparation of the Declaration of Conformity
- Requirements for affixing CE Mark

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MDD 93/42/EEC



- **Article 1** Definitions, scope
- **Article 2** Placing on the market and putting into service
- **Article 3** Essential requirements
- **Article 4** Free movement, devices intended for special purposes
- **Article 5** Reference to standards
- **Article 6** Committee on standards and technical regulations
- **Article 7** Committee on Medical Devices
- **Article 8** Safeguard clause
- **Article 9** Classification
- **Article 10** Information on incidents occurring following placing of devices on the market
- **Article 11** Conformity assessment procedures
- **Article 12** Particular procedure for systems and procedure packs
- **Article 13** Decisions with regard to classification, derogation clause



MDD 93/42/EEC

- **Article 14** Registration of persons responsible for placing devices on the market
- **Article 15** Clinical
- **Article 16** Notified bodies
- **Article 17** CE marking
- **Article 18** Wrongly affixed CE marking
- **Article 19** Decision in respect of refusal or restriction
- **Article 20** Confidentiality
- **Article 21** Repeal and amendment of directives
- **Article 22** Implementation, transitional provisions
- **Article 23** Directive addressed to the Member States

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MDD 93/42/EEC

- **Annex I** Essential requirements
- **Annex II** EC declaration of conformity (Full quality assurance system)
- **Annex III** EC type-examination
- **Annex IV** EC verification
- **Annex V** EC declaration of conformity (Production quality assurance)
- **Annex VI** EC declaration of conformity (Product quality assurance)
- **Annex VII** EC declaration of conformity
- **Annex VIII** Statement concerning devices for special purposes
- **Annex IX** Classification criteria
- **Annex X** Clinical evaluation
- **Annex XI** Criteria to be met for the designation of notified bodies
- **Annex XII** CE marking of conformity





MEDDEVs

Guidance Documents: <http://bit.ly/MEDDEV>

The screenshot shows the European Commission Public Health website. The header includes the European Commission logo and the text 'PUBLIC HEALTH'. Below the header is a navigation breadcrumb: 'European Commission > DG Health & Consumers > Public health > Medical devices > Documents > Guidelines'. The main content area is titled 'MEDICAL DEVICES' and contains a link to 'Go back to Medical devices > Documents > Guidelines'. The section is titled 'Guidance MEDDEVs' and contains three paragraphs of text explaining the purpose and scope of the guidelines. A disclaimer at the bottom of the text states that amendments introduced by Directive 2007/47/EC or previous amending directives have not yet been incorporated in all MEDDEVs. Below the text is a table with two columns: 'TITLE' and 'CONTENT'. The table lists two documents: 'MEDDEV 2.1/1 (19 KB) Definitions of "medical devices", "accessory" and "manufacturer" April 1994' and 'MEDDEV 2.1/2 rev.2 (14 KB) Field of application of directive "active implantable medical devices" April 1994'.

European Commission

PUBLIC HEALTH

European Commission > DG Health & Consumers > Public health > Medical devices > Documents > Guidelines

MEDICAL DEVICES

Go back to [Medical devices](#) > [Documents](#) > [Guidelines](#)

Guidance MEDDEVs

The guidelines aim at promoting a common approach by manufacturers and Notified Bodies involved in the conformity assessment procedures according to the relevant annexes of the Directives, and by the Competent Authorities charged with safeguarding Public Health.

They have been carefully drafted through a process of consultation with various interested parties during which intermediate drafts were circulated and comments were taken up in the documents. Therefore, they reflect positions taken in particular by representatives of [Competent Authorities](#) and Commission Services, Notified Bodies, industry and [other interested parties](#) in the medical devices sector.

The guidelines are not legally binding. It is recognised that under given circumstances, for example, as a result of scientific developments, an alternative approach may be possible or appropriate to comply with the legal requirements.

Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that the guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions. Guidelines are subject of a regular updating process.

Disclaimer : Please note that the amendments introduced by Directive 2007/47/EC or previous amending directives have not yet been incorporated in all MEDDEVs. The necessary revision is under way.

	TITLE
2.1 Scope, field of application, definition	MEDDEV 2.1/1  (19 KB) Definitions of "medical devices", "accessory" and "manufacturer" April 1994
	MEDDEV 2.1/2 rev.2  (14 KB) Field of application of directive "active implantable medical devices" April 1994

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Other MEDDEVs

- MEDDEV 2.12/1 – Medical Device Vigilance
- MEDDEV 2.5/5 – Translation Procedure
- MEDDEV 2.5/10 – Guideline for Authorized Representatives
- MEDDEV 2.12/2 – Post-Market Clinical Follow-up Studies



CE Marking Process

1. Determine device classification
2. Choose conformity assessment procedure
3. Select Notified Body
4. Implement QMS
5. Prepare Technical File (TF) or Design Dossier
6. Appoint an Authorized Representative
7. Audit by Notified Body of QMS and TF
8. Register product
9. Prepare Declaration of Conformity
10. Affix CE Mark



Device Classification

There are four device classifications:

- Class I
- Class IIa
- Class IIb
- Class III

Class I devices, that are non-sterile and non-measuring, do not require a Notified Body (NB). All other products require NB involvement.

Annex IX of the MDD defines the classification rules for Europe. There is also a guidance document, MEDDEV 2.4/1 (<http://bit.ly/EUClassification>) published that helps to explain classification rules with examples.



Conformity Assessment

- The following table summarizes the options for each Device Classification.

Class I Non-measuring / Non-Sterile	Class I Measuring / Sterile	Class IIa	Class IIb	Class III
Annex VII	Annex II or Annex V	Annex II or Annex V	Annex II or Annex III + V	Annex II or Annex III + V



Choose Notified Body

- A certification body is a third-party company who is accredited by an organization like ANAB (<http://bit.ly/ANABorg>), UKAS (<http://bit.ly/UKASorg>) or SCC (<http://bit.ly/SCC-org>) to perform certification audits against ISO Standards such as ISO 9001 or ISO 13485.
- Accreditation bodies verify conformity of certification audits to the ISO/IEC 17021 Standard (<http://bit.ly/IEC-ISO17021>).
- Some certification bodies are not accredited, or may be self-accredited, but you will need a certification body that is accredited in order to meet regulatory requirements.



“Special Notified Bodies”



75 NBs Today

EMDR

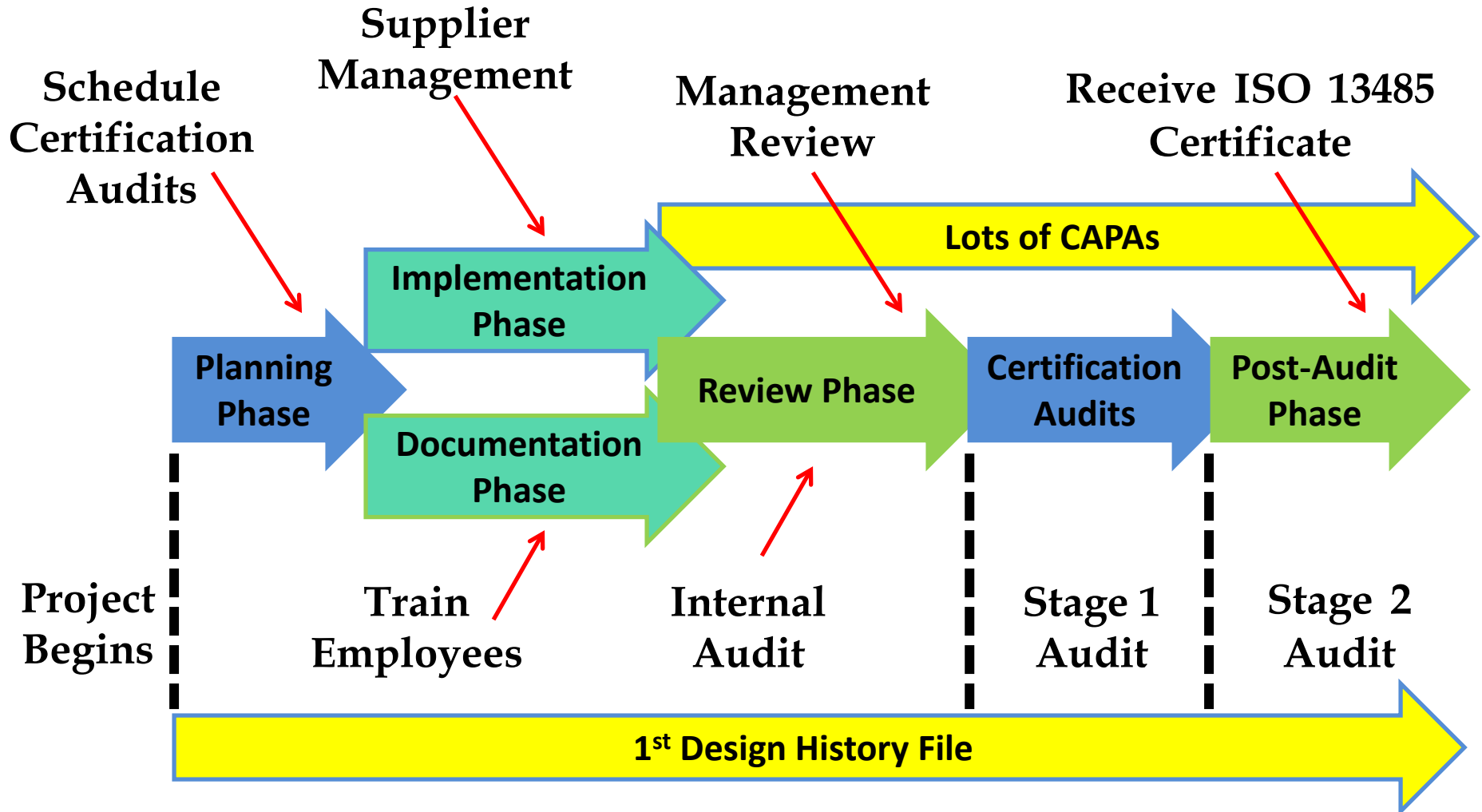


10? Tomorrow

<http://bit.ly/EMDR-Frankenstien>



Implement QMS



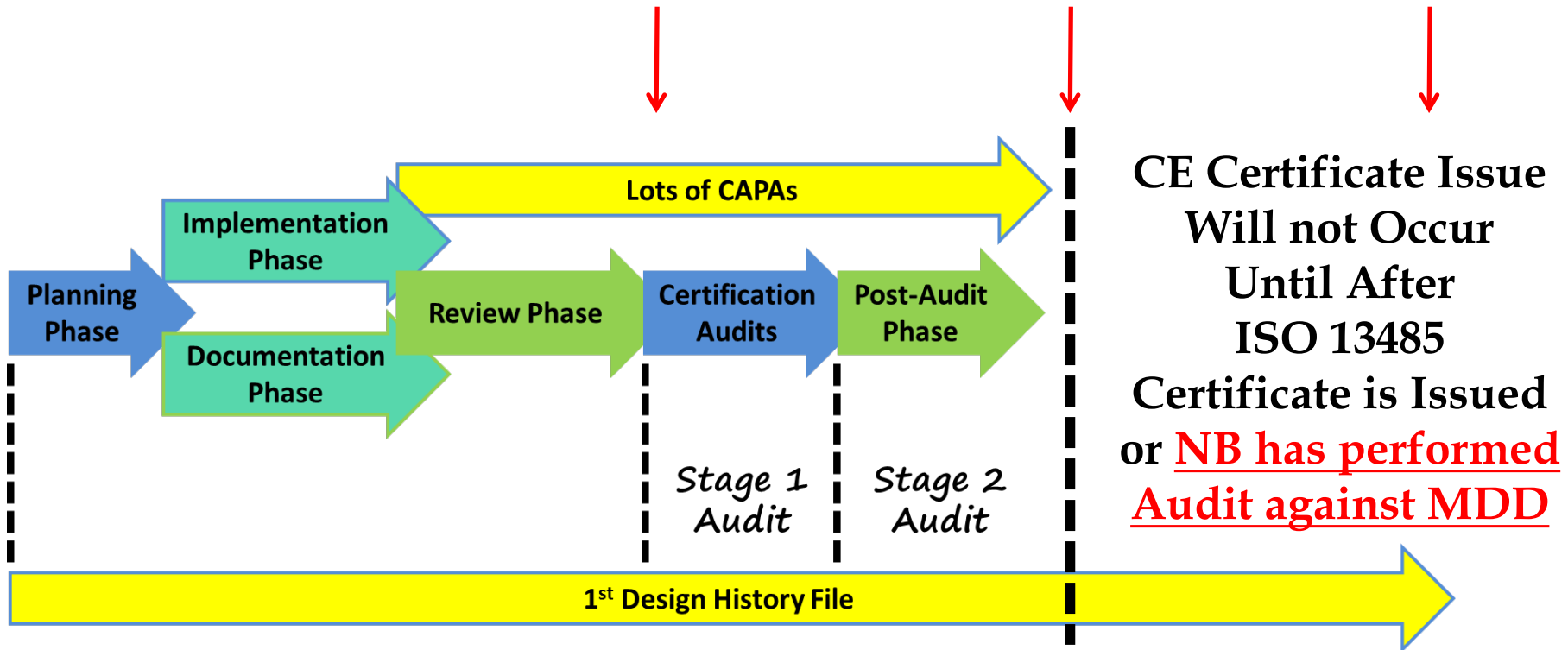


CE Mark When?

Early TF/DD Submission

ISO 13485 Certificate

Late TF/DD Submission



CE Certificate Issue Will not Occur Until After ISO 13485 Certificate is Issued or NB has performed Audit against MDD



Technical Documentation

- CE Marking of medical devices requires technical documentation (i.e., – a Technical File or Design Dossier)—based on the device classification.
 - NB-MED 2.5.1/rec 5
(<http://bit.ly/NBMED251Rec5>)
 - GHTF SG1/N011:2008
(<http://bit.ly/GHTFSTEDGuidance>)



Technical File (TF)

- There is no definition of a Technical File (TF), but in layman's terms it is the Technical Documentation required for Class I, IIa and IIb medical devices.
- The TF is the most current version.
- In fact, the phrase "Technical File" is not used in the MDD (i.e. – 93/42/EEC)



Design Dossier (DD)

- The term is only used once in Annex II.4 of the MDD. In layman's terms, the Design Dossier is the Technical Documentation plus a summary of the history of design changes for the device.
- Equivalent to the US FDA's requirements for a Device Master Record (DMR) + a DHF (Design History File)



Three Critical Differences

- Summary of history of design changes is required vs. just the current design.
- Notified Body must approve 100% of Significant Changes Prior to Implementation.
- Notified Body will Scrutinize Each Document more Carefully.
 - “...the typical review time devoted to a design dossier is “*at least double*” the time spent on the review of Class IIb technical files.”



Essential Requirements

Essential Requirements are part of the technical file or design dossier:

- Are set in Annex I <http://bit.ly/NewERCTemplate>
- Require the manufacturer to: <http://bit.ly/NewERCGap>
 - Define fitness for purpose
 - Perform risk / benefit analysis
 - Determine their product's safety
 - Choose voluntary standards to use as a tool
- A procedure is recommended to provide instructions for completing all required information.



What is an Authorized Representative?

- The Authorized Representative is the official correspondent for communication of complaints by users and patients in the EMEA, Switzerland and Turkey. A distributor may perform this function if the distributor is physically located in the EU. The roles and responsibilities of authorized representatives are defined in MEDDEV 2.5/10 from 2012 (<http://bit.ly/ECREPMEDDEV>).
- If your company does not have a physical presence in Europe, you will also need to select a European Authorized Representative (AR). My recommendation is to select an AR that is one of the 15 members of the European Association of Authorized Representatives (<http://bit.ly/EAARMembers>). The name and address of your Authorized Representative must be placed on your device labeling.



Notified Body Assessment

- This is an audit conducted by your notified body to ensure that your quality system and records conform to the requirements of the MDD.



CE Certificates

- Annex II.3 – Full Quality Assurance Certificate
- Annex II.4 – Design Examination Certificate
- Annex III – Type Examination Certificate
- Annex V – Production Quality Assurance Certificate

Note: Do not confuse with your ISO 13485:2003 certificate for the Quality Management System.



Declaration of Conformity

A Declaration of Conformity is (DoC) is the manufacturer's statement of conformity with a specific assessment process. This must be in accordance with Annex II, V, VI or VII.

It is the manufacturer's claim that:

- Product satisfies essential requirements
- Conformity assessment completed, if required
- Products are designed, manufactured, and tested in accordance with technical documentation

It is issued on the manufacturer's own authority and is a legal document. A copy may be requested by your customers.



If NB is **NOT** Required...

If your company does not require NB involvement, such as for a Class I device that is non-sterile and non-measuring, then you will be able to issue a Declaration of Conformity in accordance with Annex VII.



Product Registration

This is typically performed by the Authorized Representative, but each Competent Authority (CA) has a different process.

- The following is a list of contact points for all the CAs:
<http://bit.ly/ContactPoints>.



Affix CE Marking

- The 4-digit number next to the CE Mark is unique to your Notified Body. Here's a link for a list of the Notified Bodies with each of the 4-digit numbers: <http://bit.ly/NBDatabase>. This database can also be used to identify which Notified Bodies are able to issue CE Certificates for each type of product.
- A procedure is needed to ensure that all requirements for symbols, languages, size and placement of the CE Mark comply with the MDD requirements per Annex XII.

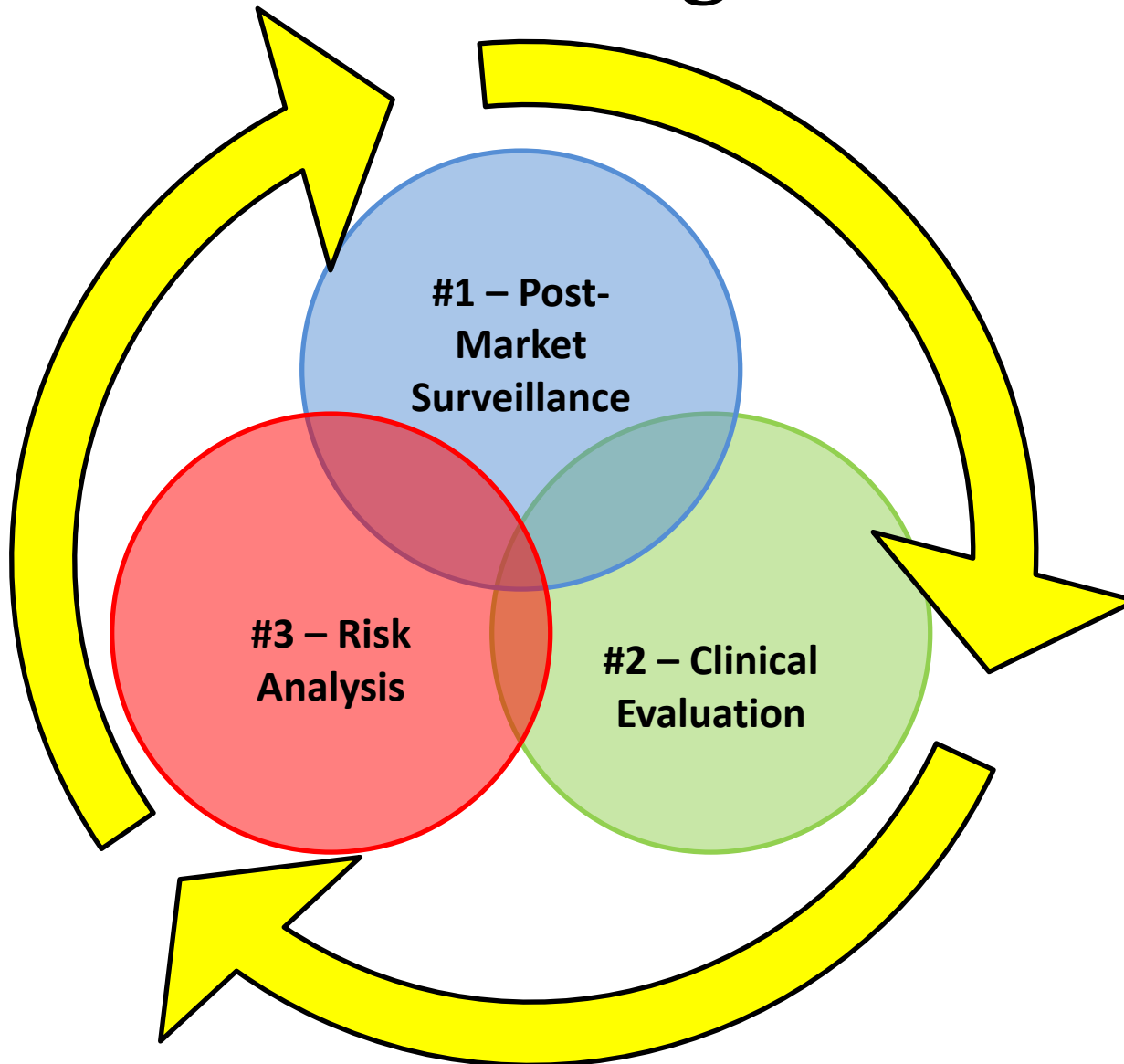


Post-market Design Changes

- Post-Release significant changes require Design Dossier Supplements
- See NB-MED/2.5.2/Rec2 rev 7
<http://bit.ly/ReportDesignChanges>



Maintaining the Lifecycle Loop



Post-Market Surveillance (PMS) Report, Including Complaints, Measure Frequency of Harm

Clinical Evaluation Report (CER) Is Updated to Verify the Clinical Risk/Benefit Based Upon PMS Report

Risk Analysis is Updated with Actual data for the Frequency of Occurrence for Harm

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Is PMCF Required?

- MEDDEV 2.12/2 rev 2 (January 2012)
 - <http://bit.ly/PMCFMEDDEV>
- 93/42/EEC; Annex X, 1.1c
- Do you have enough clinical history?
- Does your clinical data cover the entire product range?
- Have there been any changes since the clinical study?
- Is the device still considered state of the art?



This Applies to all Class III

In 2013, Medical Device Academy prepared...

- 9 Class III Design Dossiers
- 3 Class IIb Technical Files
- 2 Class IIa Technical Files
- 4 Class I Technical Files



Q & A



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Need help with CE Marking?

<http://bit.ly/Regulatory-Submissions>



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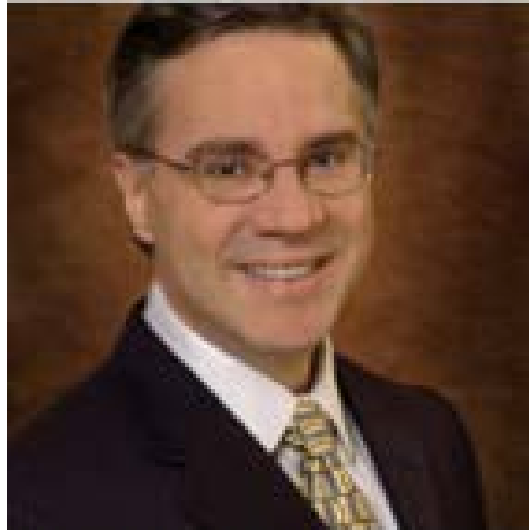
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