The EU Medical Device Regulation (EU MDR) and impact on MD industry

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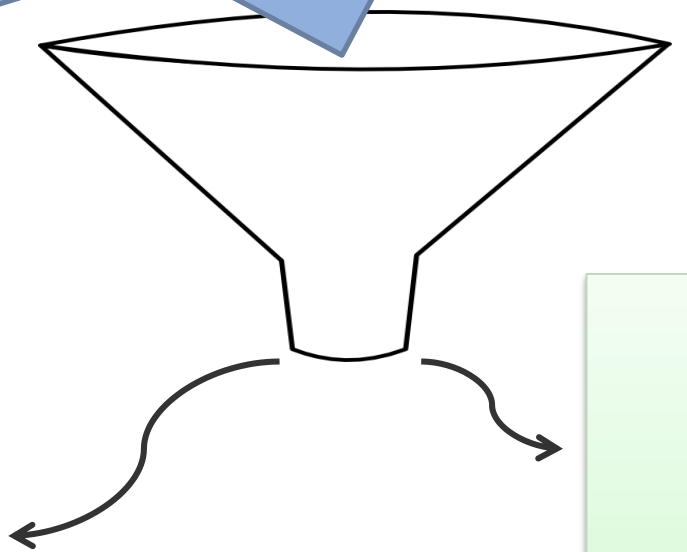
The path to a new Medical Device Regulation

2008	Survey of the EU Commission; Start of Recast
2009	Code of Conduct (BSI, LNE/G-MED, KEMA, TÜV Rheinland, TÜV SÜD)
Around 2010	Medical Implant Scandals: breast implants, metal-on-metal hip replacements, cardiac pacemaker leads
February 2012	Dalli Plan – Joint Plan for Immediate Actions
September 2012	EU Commission submits proposals for new regulations for medical devices (MDR) and in-vitro diagnostics (IVDR) to EU Parliament and EU Council
24th September 2013	Commission Recommendation (2013/473/EU) on the audits and assessments that notified bodies perform for medical devices (MD).
24th September 2013	Commission Implementing Regulation 920/2013 on the designation and the supervision of notified bodies (NoBo)

The path to a new Medical Device Regulation

- Recast
- Medical device scandals
- Dalli „Joint plan for immediate action“
- Joint assessment pilot program



Present

Commission Implementing Regulation 920/2013
Designation and Supervision of Notified Bodies

Recommendation (2013/473/EU)
Unannounced Audits

Future

MDR

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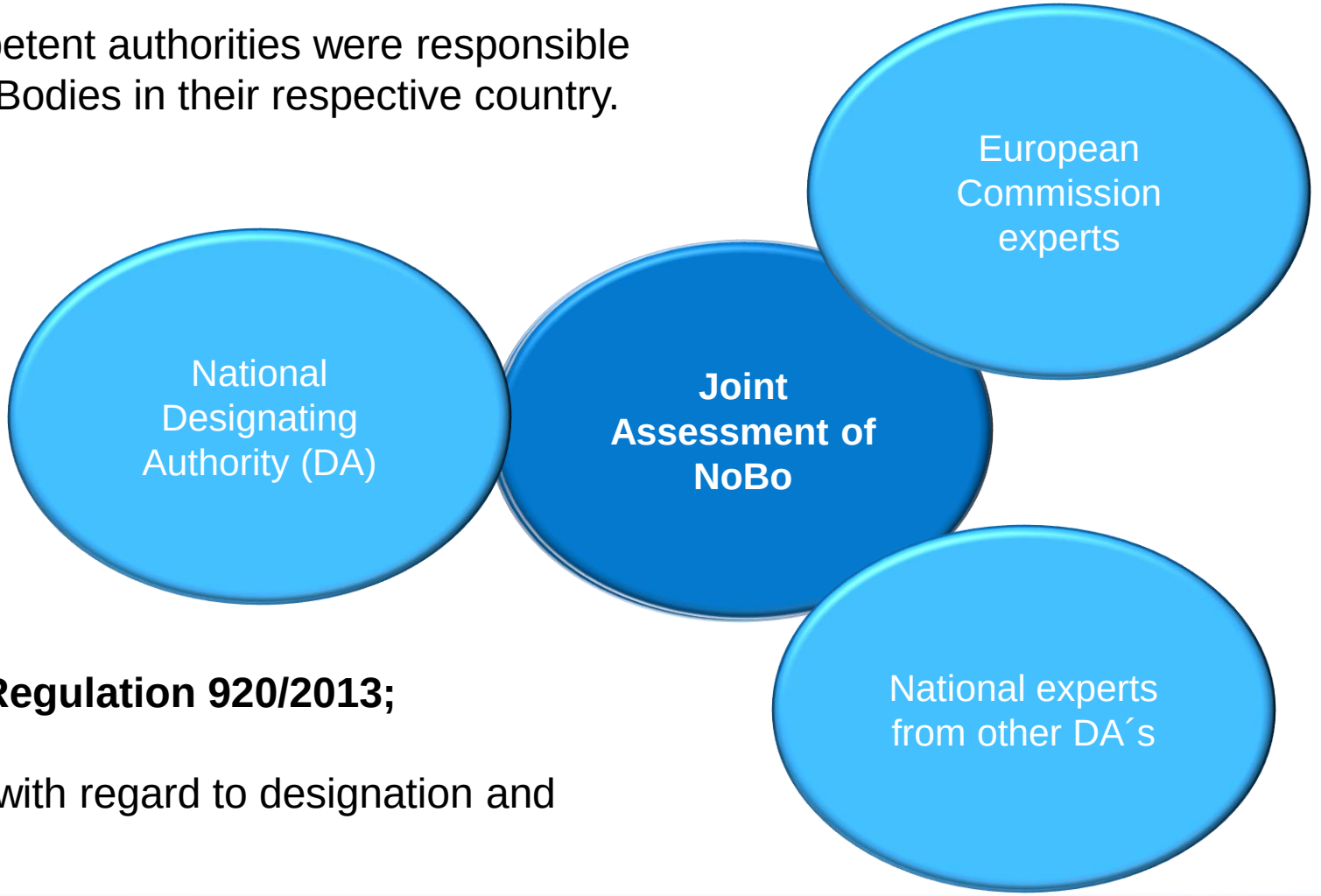
Present regulation – **920/2013 on the designation and supervision of NoBos**

Before, only the national competent authorities were responsible for the designation of Notified Bodies in their respective country.



Commission Implementing Regulation 920/2013;
„Joint Assessments”
For consistent and clear rules with regard to designation and supervision of Notified Bodies

The path to a new Medical Device Regulation

Goals of the new Medical Device Regulation

The new EU Regulation for Medical Devices

- aim is to ensure the smooth functioning of the European market
- taking as a base a high level of protection of health for patients and users
- taking into account the small- and medium-sized enterprises that are active in this sector
- sets high standards of quality and safety for medical devices to meet common safety concerns with regard to these products.

The path to a new Medical Device Regulation

Directive 93/42/EEC –
medical devices

+

Directive 90/385/EEC –
active implantable medical devices

↓

Medical **D**evices **R**egulation
(MDR)
~71 Recitals / 97 Articles / 16 Annexes

Directive 98/79/EC –
in vitro diagnostic medical devices

↓

In **V**itro **D**iagnostic **R**egulation
(IVDR)
~67 Recitals / 90 Articles / 14 Annexes

The path to a new Medical Device Regulation

EU Parliament + EU Commission + EU Council

In the trilogue the texts for MDR and IVDR were agreed and published in June 2016;
The consolidated texts need to be translated into all official languages

EU Council

1st Reading - Adoption of formal positions

EU Parliament

2nd Reading - Adoption of formal positions

Presidencies of the European Parliament and Council

With their signatures the legislative proposals will enter into force

The new MDR – **Good to know**

Current status of text (this presentation refers to version 08.08.2016):

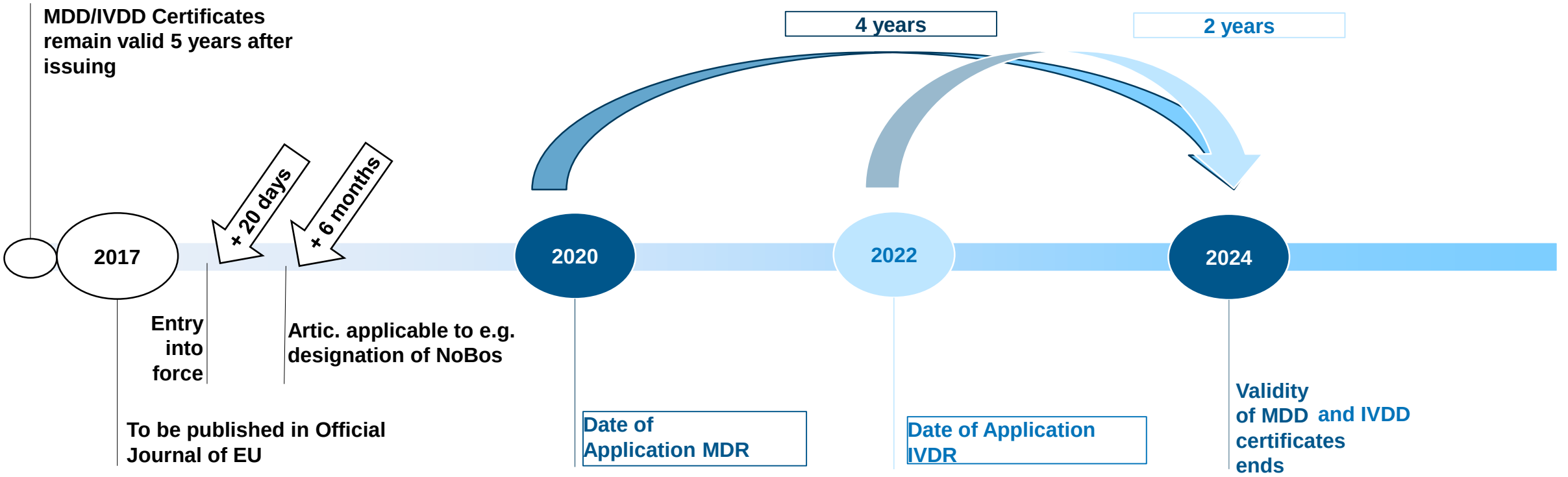
- More than 500 technical inconsistencies were found in the (German) text!
- There is a revised version of the draft regulation (change of numbering….??)
- Publishing date of the final MDR in the Official Journal: **Probably 2nd Quarter 2017**

➢ **Directives** need to be transferred into national law

➢ After the application date a **Regulation** is valid throughout Europe (no transposition into national laws!)

➢ Currently not all requirements are set in the MDR.
Modifications and adjustments by EU Commission possible without revising legislations through **Implementing (~34) and Delegating Acts (~11).**

The new MDR/IVDR - **Transition Times**



Attention – **Transition Times**

- Rules/Scopes for the designation of Notified Bodies need to be defined 6 months by implementing acts after publishing in the Official Journal at the latest.
- The designation process itself takes between 18 and 24 months!

-> Worst case: Designation of a Notified Body takes place 2.5 years after the MDR entered into force!

- Is it possible for Notified Bodies to apply right after the MDR entered into force, before the end of the 6 months?
- The designation process takes very long!
- Currently, there are 58 Notified Bodies! How many of them will be designated under MDR? Will all the other Notified Bodies have enough time and personnel in order to certify all manufacturers „in time“?

What is new??

The new MDR – **Scope enlarged**

Directive	Regulations
Only products **with intended medical purpose** were covered by MDD	**Article 1** Products for which the manufacturer claims an **aesthetic or non-medical purpose** are now covered by the Regulation (list of products see **Annex XV**) if they are **similar to medical devices in terms of functioning and risk profile**, such as: - Coloured contact lenses - Equipment for liposuction, lipolysis, lipoplasty - High intensity electromagnetic radiation (e.g. IR, UV) equipment, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment - Newly added: equipment intended for brain stimulation Still excluded: tattooing products and piercings

The new MDR – **Scope enlarged**

Directive	Regulations
Reusable surgical instruments were purely class I and thus involvement of a NoBo was not required. *For devices placed on the market in sterile condition, or have a measuring function, a limited NoBo involvement was already required.*	**Article 42 (5 c)** For **reusable surgical instruments** the NoBo involvement in the conformity assessment system is required, but limited to the aspects related to the **reuse of the device:** • **in particular cleaning, disinfection, sterilization,** • **maintenance and functional testing** • **and the related instructions for use.**

What is new??


Obligation of the manufacturer
also in regard to the
technical documentation

The new MDR – **Obligation of manufacturers**

Directives	Regulations
[not required by Directives; Similar position by German law was already required]	**Article 13:** The manufacturer has to employ a **“Person responsible for regulatory compliance“** with proven expertise in the field of medical devices. Tasks of the responsible person are related to: • Post-market surveillance • Reporting vigilance cases • Ensuring appropriate checks of manufactured product acc. QM system before release • Ensuring that technical documentation and declaration of conformity are up to date

The new MDR – **Obligation of manufacturers**

Directives	Regulations
*The manufacturer **or** his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities*	**Article 8 (4)** • Manufacturers shall keep the technical documentation, the EU declaration of conformity […] available to the competent authorities • Upon request by a competent authority, the manufacturer shall provide the **full technical documentation** or a summary thereof as indicated in the request. • A manufacturer with registered place of business outside the Union shall, in order to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 ensure that the authorised representative has the necessary documentation **permanently available.**

The new MDR – **Obligation of manufacturers**

Directive	Regulations
	Article 9 The EU Rep shall keep available a **copy of the technical documentation** and the EU declaration of conformity **Article 42 (8) – Conformity assessment procedures**: • The Member State in which the notified body is established may determine that all or certain documents, including the **technical documentation,** audit, assessment and inspection reports […] shall be available in an official Union language(s) determined by the Member State concerned. Otherwise they shall be available in an official Union language acceptable to the notified body.

Attention – **Obligation of the manufacturer**

- Transparency and responsibility in the supply chain are increasing
  e.g. EU representatives need to possess a copy of the technical documentation

- The manufacturer has to keep the **full** technical documentation

- The EU Commission clearly stated, that they do not want to keep the OEM/PLM respectively OBL mode
- TD need to be state of the art. It might be a logistic challenge, that the EU representative always possesses a copy of the current TD.
- Contracts along the supply chain need to be checked by manufacturers; new agreements are necessary?

What is new??


Collect and exchange information
in Europe and increase traceability
of medical devices

Attention - **EUDAMED + UDI**

- EUDAMED including UDI is planned to go live 2-3 months before the end of the transition period: in 2020! No modular approach is planned.
- There is no „Plan B“ for EUDAMED.
- The scope of the certificates needs to include the UDI-DI (device identifier) number.
- The UDI number need to appear on the label of the device and the device identifier on the declaration of conformity

- How will it affect the transitional provisions if EUDAMED does not go live in time? E.g.
  - Can devices without UDI # on the label be placed on the market? If yes, does the label need to be changed, when the UDI is available
  - Can certificates be issued without UDI? If yes, do they later need to be re-issued?

The new MDR – **EUDAMED + UDI**

Directives	Regulations
EU DB EUDAMED • Limited sources and functions • Access only by EU Commission + national authorities **National databases** (e.g. DIMDI DB Germany)	**EUDAMED** (European Database on Medical Devices) collect and exchange information between member states, EU Commission, Notified Bodies, economic operator, sponsors on • marketed medical devices, • conformity assessment, Notified Bodies, certificates • registered economic operators, • vigilance/adverse events, market surveillance, • clinical investigations (personal data protection!)
No related requirement	Introduction of a **Unique Device Identification (UDI)** system to improve traceability of medical devices and also help to reduce medical errors and to fight against counterfeit devices. 

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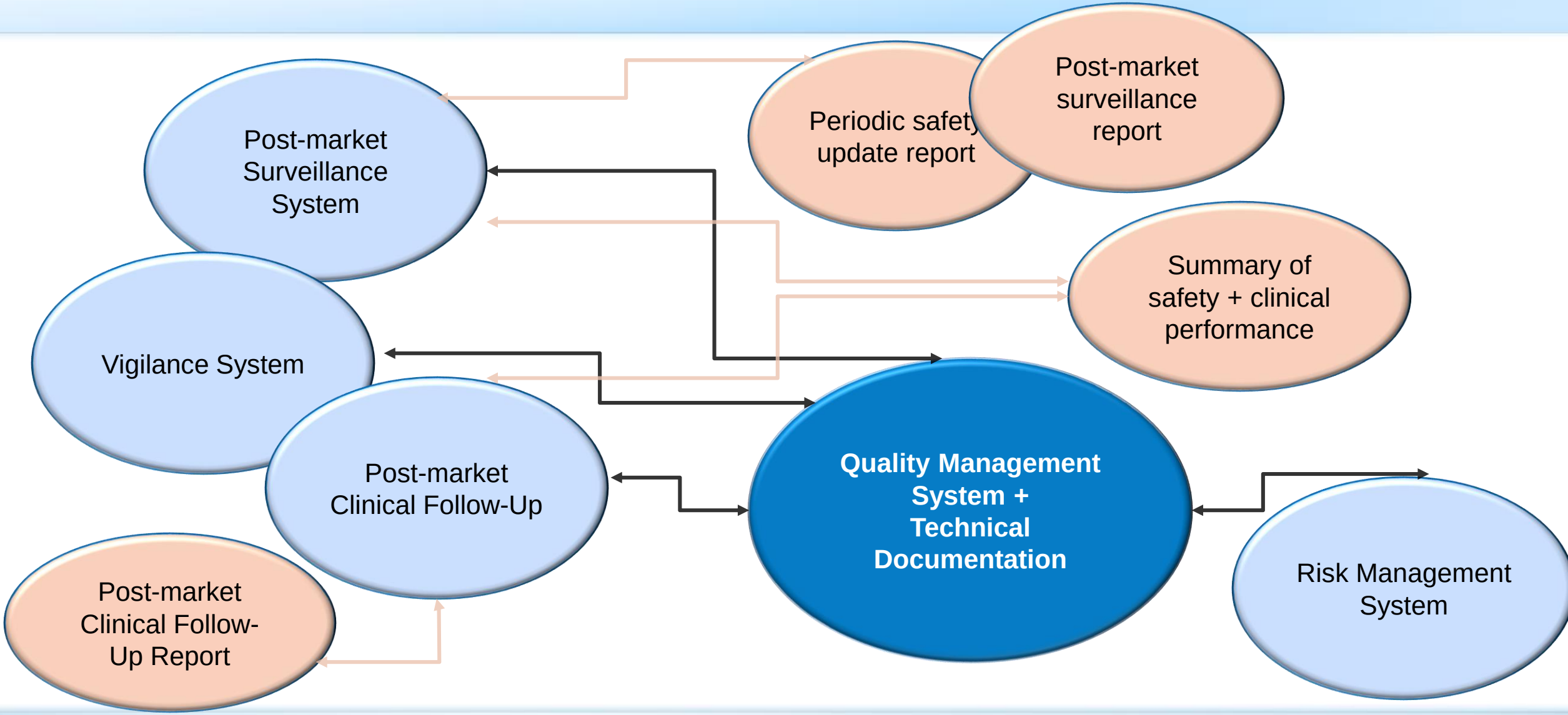
What is new??

The new MDR – “**Known requirements**”

Directives	Regulations
Directives were not very detailed: *Many additional sources were applied* - post-market surveillance system **Directive and ISO 13485** - vigilance system and clinical MEDDEV **Guiding document** - risk management system **Standard** EN ISO 14971	The following systems need to be established and to be integrated into the QM-System: - **post-market surveillance system** - **post-market clinical follow-up system** - **vigilance system** - **risk management system**

The new MDR – **Systematic approaches**



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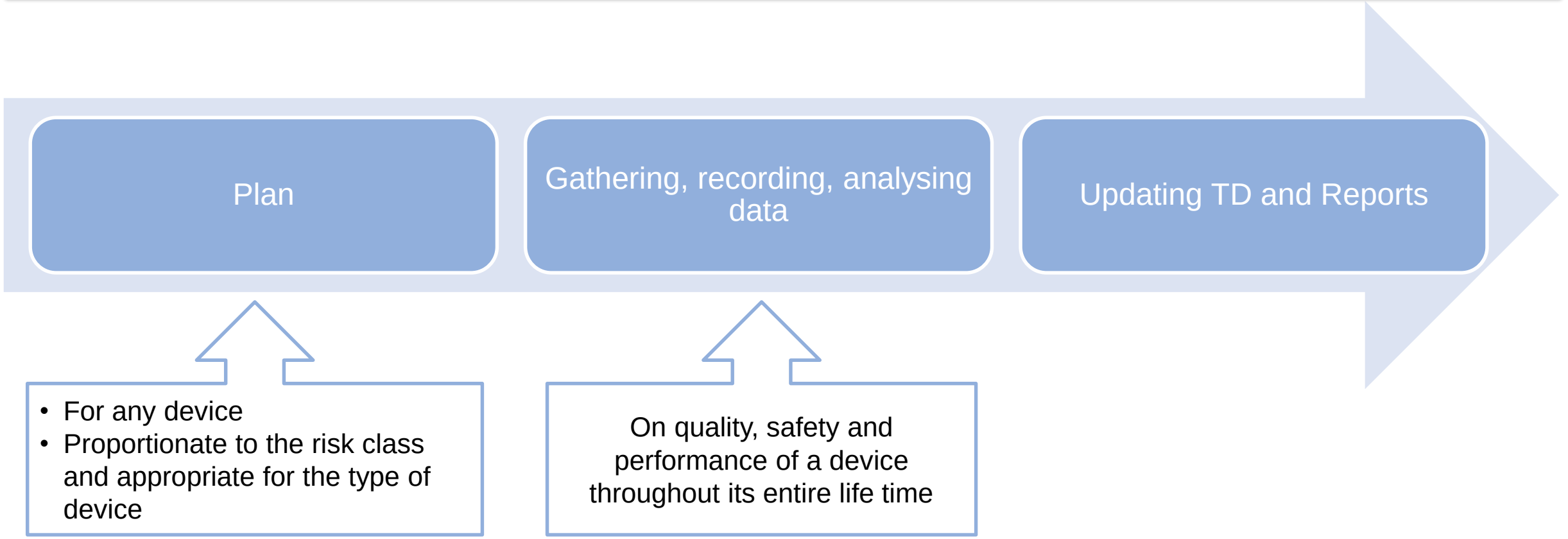
The new MDR – **Systematic Approaches (Example)**

Post-market Surveillance System
Post-market Clinical Follow-up (PMCF)



The new MDR– **Systematic Approaches (Example)**

Post-market Surveillance System

- Update of benefit risk determination and risk management, the design and manufacturing information, IFU + labelling, clinical evaluation, summary of safety and clinical performance;
- Identification of needs for CAPA or FSCA;
- Identify and improve usability, performance and safety of device;
- When relevant, to contribute to the PMS of other devices;
- Detect and report trends in case of serious incidents.

Reports	Class	Updates
Post-market surveillance report	I	As and when required
Periodic safety update report	IIa, IIb, III	Min. 1 x in 2 years annual
Summary of safety + clinical performance	III, Impl.	annual
PMCF report	III, IIb (rule 11)	Continuous updates according to PMCF Plan

What is new??

The new MDR – **Tasks of Notified Bodies**

Directives	Regulations
No related requirement	**Annex VIII, 4.6:** As a general rule, a lead auditor shall not lead [and attend] an audit for more than three consecutive years in respect to the same manufacturer.
No related requirement	**Annex VIII, 4.5:** For **Class III** devices: • the surveillance assessment shall include a test of the approved parts and/or materials, • where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of finished devices

The new MDR – **Unannounced Audits by Notified Bodies**

Directives	Regulations
Annex II, 5.4 In addition, the Notified Body **may** pay unannounced visits to the manufacturer… *<u>Interpretation</u>* *Unannounced audits were only performed, if there was a good reason, or special purpose*	**Annex VIII, 4.4:** The Notified Body shall establish a plan for unannounced audits; plan must not be disclosed to manufacturer. **Unannounced audits** • At least once every five years • Must be on-site and randomly • At manufacturers, suppliers and/or subcontractors • An adequate sample from production to be tested, for verification, that medical device is in conformity with technical documentation • May count as surveillance audit

The new MDR – **Expertise of Notified Bodies**

Directives	Regulations
MDR Annex XI: …the availability of sufficient scientific staff within the organization who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified…	**Art 29:** NoBos shall have sufficient personnel: • administrative, technical and scientific • with relevant **clinical expertise** • **permanent available** • where possible, employed by the notified body itself. **MDR class III:** The NoBo shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience of the device in question or the clinical condition in which it is utilized, for the purposes of this review.

What is new??

The new MDR – **Special procedure for high risk devices**

Applicable only for the following high risk devices:

- **implantable class III devices**
- **class IIb active devices intended to administer and/or remove a medicinal product**

Twofold Safety Mechanism

Step 1: PRE-MARKET CLINICAL CONSULTATION PROCEDURE

Step 2: POST-MARKET SCRUTINY PROCEDURE

The new MDR – **Special procedure for high risk devices**

Step 1: <u>Pre-Market</u> Clinical Consultation Procedure

Manufacturer submits Technical Documentation (TD) to **NoBo**

NoBo reviews TD and issues TD report and **C**linical **E**valuation **A**ssessment **R**eport

NoBo submits CEAR to **EU Commission**

EU Commission forwards CEAR asap to **Expert Panel**

Expert Panel (EP) has two options

EP decides not to issue a scientific opinion and informs EU Commission and NoBo regarding decision and reasons

within 21 days max.

within 60 days max.

EP decides to issue a scientific opinion and provides scientific opinion to EU Commission and NoBo

NoBo shall give **"due consideration"** to scientific opinion in its certification decision

NoBo may issue certificate

The new MDR – **Special procedure for high risk devices**

Step 2: Post-Market Scrutiny Procedure

Directive	Regulations
No scrutiny mechanism *In the conformity assessment of the manufacturer only NoBos were involved* *No consultation procedure for the specified products (only known from medicinal products and material of animal origin)*	**Scrutiny procedure applicable for high risk devices:** implantable class III devices and class IIb active devices intended to administer and/or remove a medicinal product, • NoBo informs member states about **issued** certificates via Eudamed (incl. summary of safety and clinical performance information, the assessment report by the NoBo, IFU and the scientific opinion of an Expert Panel, as applicable • In case of doubts every national authority can initiate a review by MDCG (Medical Device Coordination Group) • MDCG or Commission may request scientific advice from the expert panels in relation to the safety and performance of any device(s).

Impact on the medical device industry

- Increased requirements will have a huge impact especially on small and medium sized manufacturer!
- Niche devices for a limited number of patients may disappear!
- Lack of resources will further increase: manufacturers, NoBo´s, expert panels are all in need for clinical, regulatory and technical personnel

General recommendations for manufacturers

- Start preparations early!
- Verify, that all technical documentation
  - are state of the art; especially in regard to clinical evaluation!
  - fullfil the language requirements
- Check classification rules!
- Be aware of changes in the final text of the MDR!
- Select a stable NoBo!

Useful Links

Blue Guide 2016	http://ec.europa.eu/DocsRoom/documents/16210
Legislative Powers	http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers
European Commission – Medical Devices	http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm
TÜV Rheinland – Medical Products	http://www.tuv.com/en/corporate/business_customers/product_testing_3/medical_devices_engineering_1/medical_products.html

Thank you very much for your attention!

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Additional information

Essentials of New IVDR

Essentials of New IVDR – **Scope**

Chapter 1 – Scope of IVDR

- Software with medical purpose is now included in the definition of an IVD
- „In-house“ products with higher risk classification require a NoBo assessment
- Genetic tests and „Companion Diagnostics“ are also now included in scope
- „Near-patient testing“ (bed-side testing), intended to be used outside of a laboratory environment, is defined now
- Inclusion of IVDs for the prognosis of diseases (e.g. genetic disposition)

Essentials of New IVDR – **New classification system**

Directives	Regulations
List A: *high risk IVDs* *(e.g. blood donor screening, HIV,HCV)* ***List B:*** *moderate risk IVDs* *(e.g. prenatal markers, infectious diseases)* ***IVDs*** *for self-testing* *(lay users)* ***"other IVDs"***	**Annex VII** **Rule based classification system** Origin GHTF model 4 risk classes: **A, B, C and D**

Essentials of New IVDR – **New classification system**

Class	Risk	Examples
A	Low individual risk and low risk to public health	Analyser for clinical chemistry, sample containers
B	Moderate individual risk and/or low risk to public health	Vitamin B12, pregnancy self-tests, urine test strips
C	High individual risk and/or medium risk for public health	Blood glucose self-tests, HLA typing, PSA tests, Rubella, cancer diagnostics, CDx
D	High individual risk and high risk for public health	Blood donor screening (HIV/HCV), blood grouping (A,B,O)

Essentials of New IVDR – **New conformity assessment routes**

Class A	**Self declaration (Annex II)**	
Class B	**QMS + Technical Documentation Review** *(Annex VIII)* **(sampling approach)**	
Class C	**QMS + Technical Documentation Review** (*Annex VIII*) **(sampling approach)**	**Type Examination** (*Annex IX*) **+** **QMS production** (*Annex X*)
Class D	**QMS + Technical Documentation + Batch release** (*Annex VIII*)	**Type Examination** (*Annex IX*) **+** **QMS production** (*Annex X*) **+** **Batch release** (*Annex VIII*)

Essentials of New IVDR – **New conformity assessment routes**

2016

IVD products
NoBo non-obligatory

IVD products
NoBo obligatory

2021

IVD products
NoBo non-obligatory

IVD products
NoBo obligatory