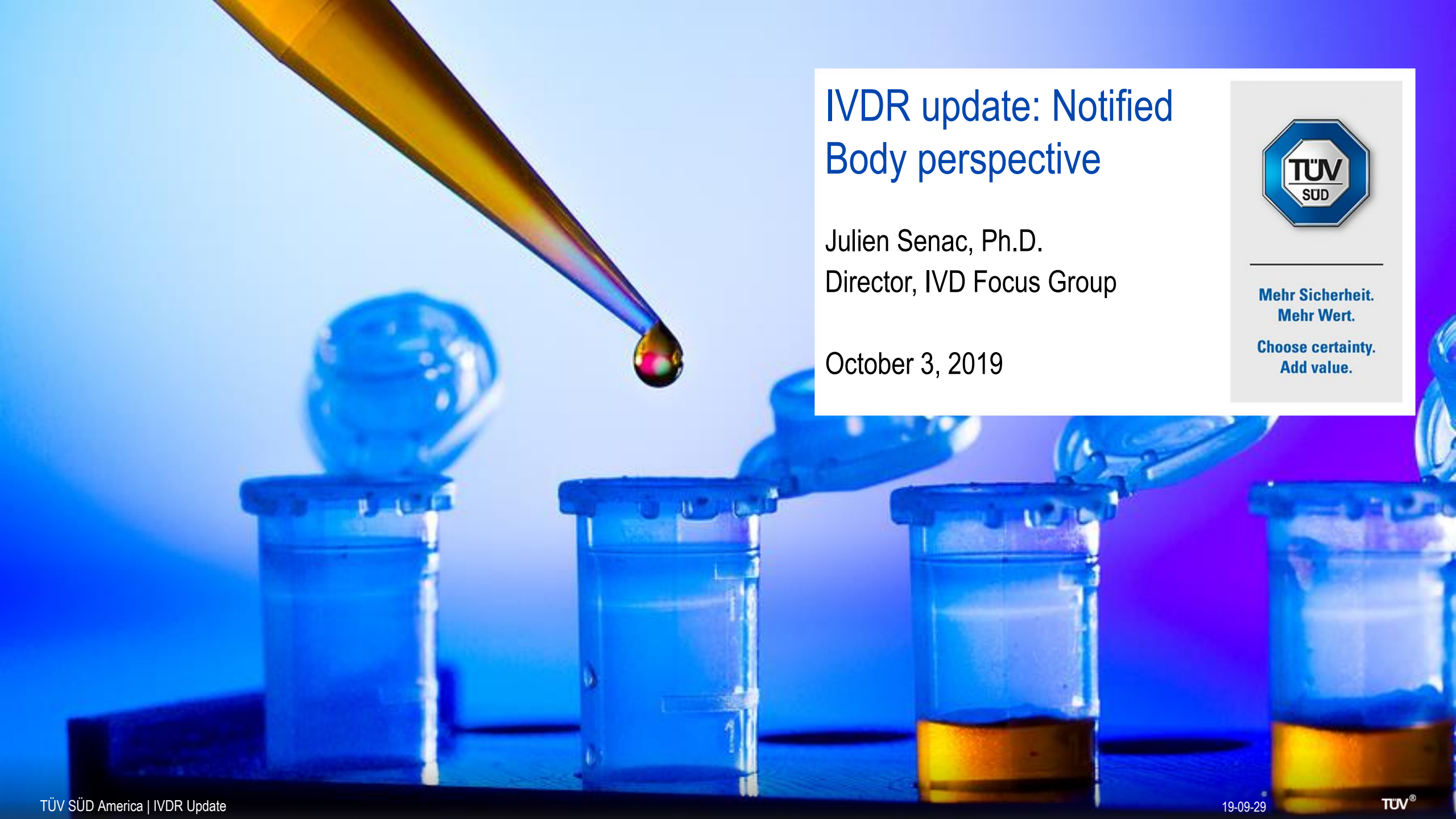


IVDR update: Notified Body perspective

Julien Senac, Ph.D.
Director, IVD Focus Group

October 3, 2019

Mehr Sicherheit.
Mehr Wert.

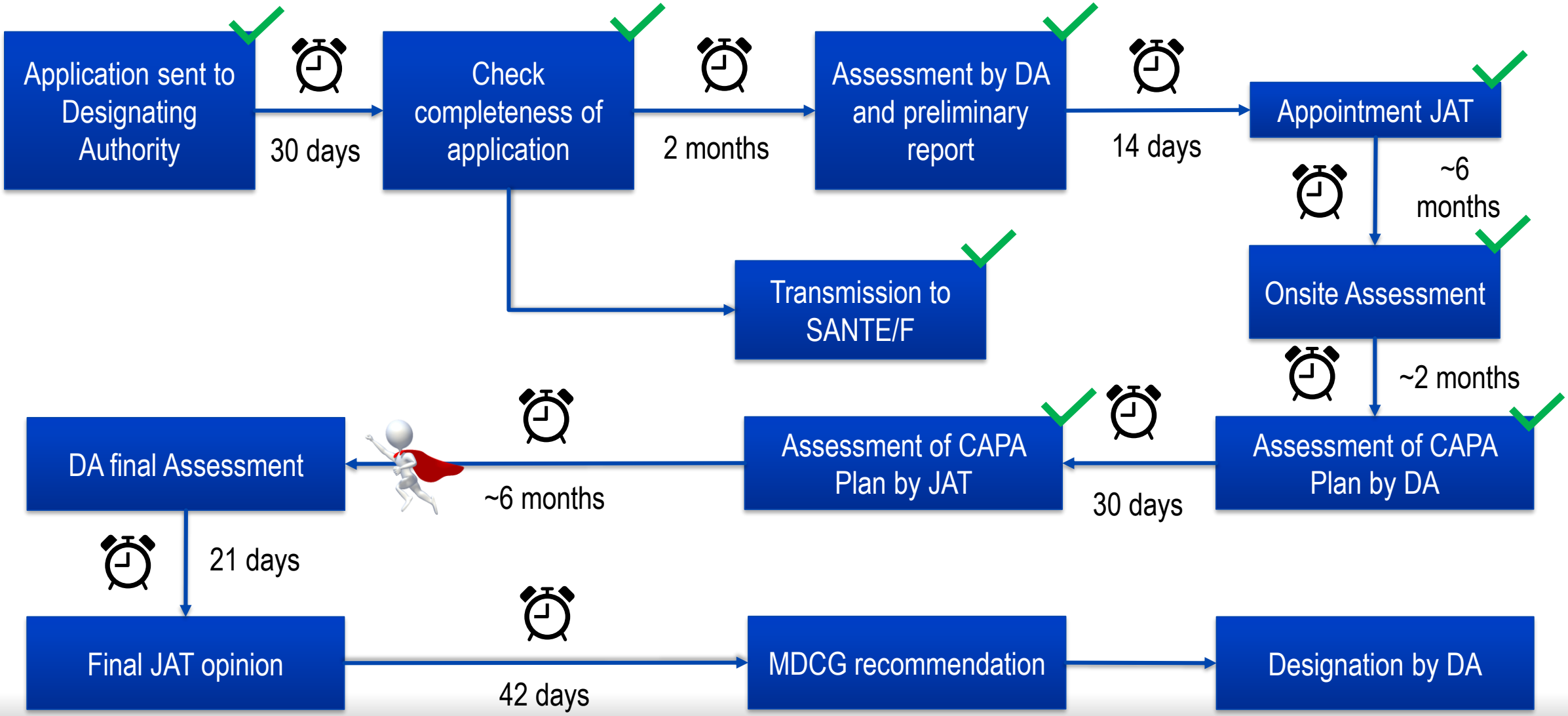
Choose certainty.
Add value.

966 days

The next 2 years, 7 months, and 23 days

- Designation of Notified Bodies
- Designation of European Reference Laboratories
- Audit of Quality Management System
- Review of Technical Documentation
- Issuance of CE Certification

Notified body designation



Notified Body designation

Notified Body designation

When did you apply for designation under Regulation (EU) 2017/746 (IVDR)?

- TÜV SÜD applied for designation under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) on the earliest date possible, **November 26, 2017**.

Under which device codes have you applied for?

- TÜV SÜD applied for all codes as per implementing act 2017/2185. Given the huge number of in-house experts in IVD scopes at TÜV SÜD we are confident that we will be granted designations for all codes.

European Reference Laboratories

European Reference Laboratories

- Article 100 IVDR: broad mandate
  - Role in conformity assessment of Class D and by request of member state in class C IVDs
  - Sample/batch testing Class D IVDs
  - Technical assistance, scientific advice, standards and CS development
  - Shall network, will coordinate methods

- Member states or Commission JRC applies for designation

- EU Reference laboratories will need to be designated
  - Article 110 (7): no EU level scrutiny or verification of Class D IVDs if no reference labs appointed
  - Reference labs can only apply as of 25 November 2020

- Implementating acts to be issued:
  - Q4 2019/Q1 2020 will set up the structure for EU Reference Laboratories
  - Q2 2020 Definition of fees for service activities performed by EU Reference laboratories

Reference Laboratory – Article 48 (5)

- The notified body performing the conformity assessment of **Class D device** shall request one of the EU reference laboratories
  - to verify by laboratory testing
    i. the performance claimed by the manufacturer
    ii. the compliance of the device with the applicable CS, or with other solutions chosen

  with focus on analytical and diagnostic sensitivity using the best available reference materials

  - To provide a scientific opinion within **60 days**

No certification if the scientific opinion provided is unfavourable

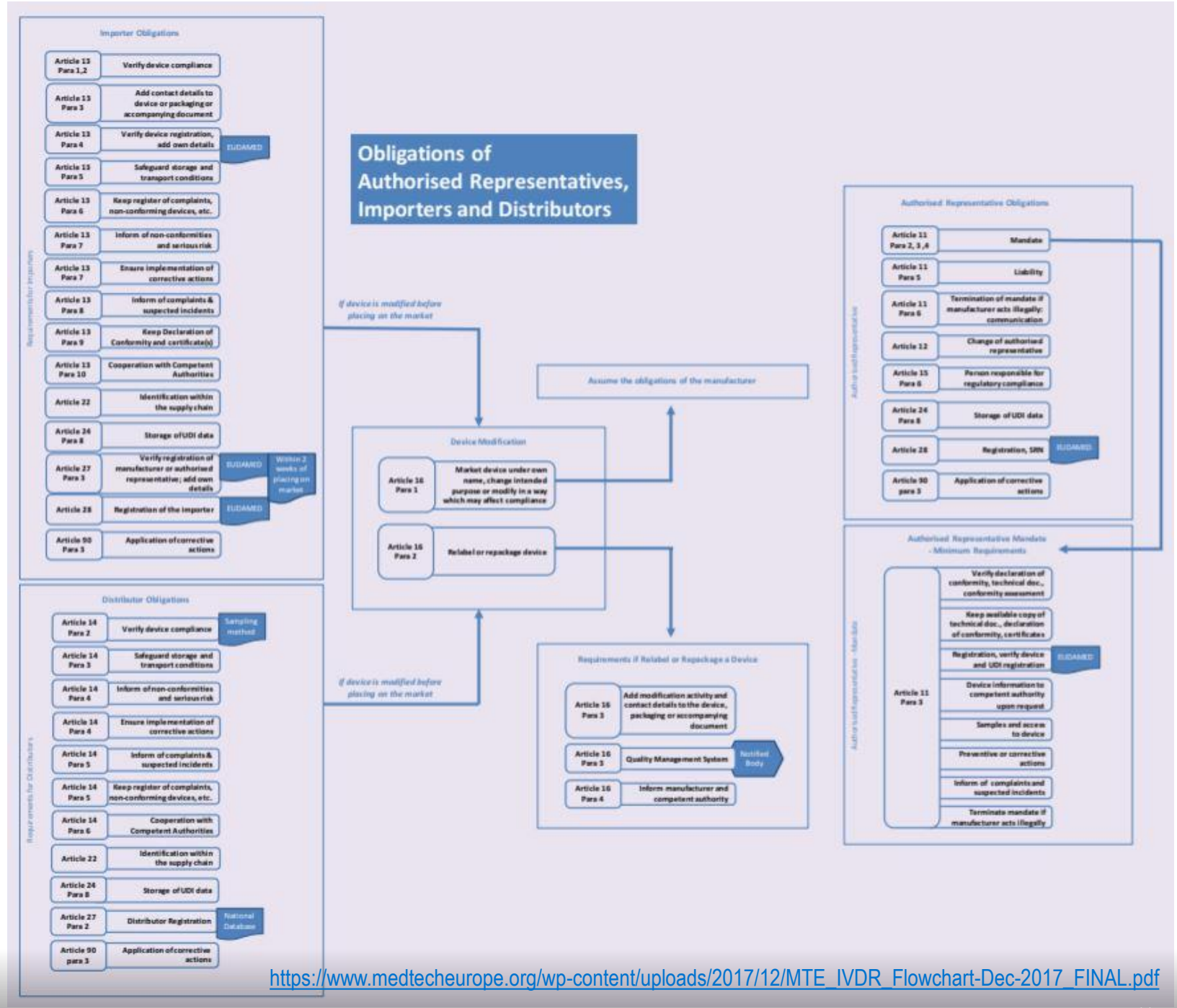
Quality management

Economic Operators

economic operator: a manufacturer, an authorised representative, an importer or a distributor.

Importer: Any natural or legal person established within the Union that places a device from a third country on the Union market.

Distributor: Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.



https://www.medtecheurope.org/wp-content/uploads/2017/12/MTE_IVDR_Flowchart-Dec-2017_FINAL.pdf

Economic Operators

- **Placing on the market**
  - first transfer of a device from the manufacturing stage into the Union distribution chain after final quality control release as finished goods (includes packaging or labelling); and
  - the device must be freely available for supply or final use within the Union supply chain (customs cleared and intent to distribute in Union)

- **Making available**
  - device must be supplied for distribution, consumption or use in the Union in the course of a commercial activity, either for payment or free of charge
  - Implies offer or agreement, physical handover not required

EO Activities and Obligations

Manufacturer

- Places non-imported devices on the market

Importer

- Places imported devices on the market
- Established in the Union

Distributor

- Makes devices available
- Can be manufacturer (or not) under art. 16 conditions (branded distribution
- May put devices into service

Authorised Representative

- Name on device
- CE + DoC
- GSPR
- UDI
- PRRC

- Name on device
- Check Eudamed
- Register of complaints
- Check DoC + cert
- Assist with corr. action.
- Safeguard storage conditions
- Assist authorities
- Not make available if conformity compromised

- Forward complaints
- Safeguard storage conditions
- Assist with corr. action.
- Assist authorities
- Not make available if conformity compromised

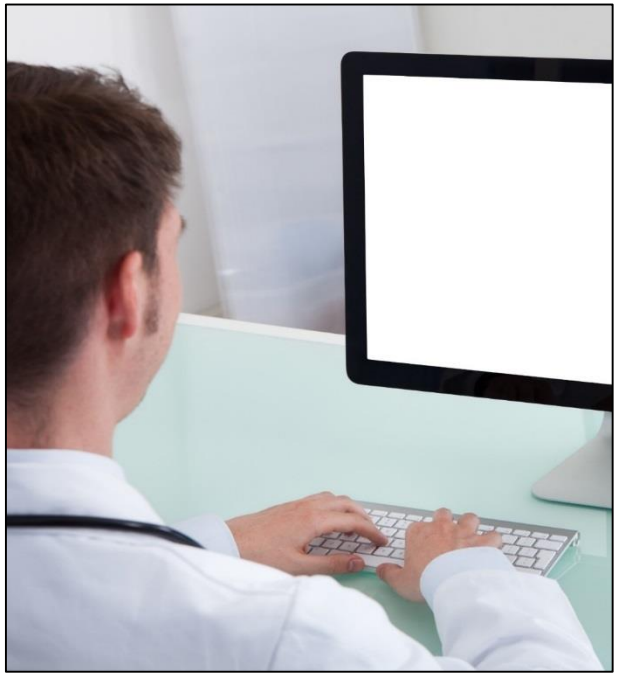
Verify compliance:
- CE +DoC
- AR assigned
- Labeling
- UDI

Verify compliance:
- CE +DoC
- IFU present
- Importer details added
- UDI

Person responsible for regulatory compliance

Manufacturer

EU Representative



- Check of device conformity before release
- Technical Documentation + DoC
- Post Market Surveillance
- Vigilance Reporting
- Statement for devices for interventional performance studies

Person responsible for regulatory compliance

Proof of Qualification

Formal qualification:

- University degree
- a course of study recognized as equivalent in law, medicine, pharmacy, engineering, or another relevant scientific discipline

+

At least one (1) year of professional experience in **regulatory affairs**

OR

in **quality management systems** relating to **IVD medical devices**

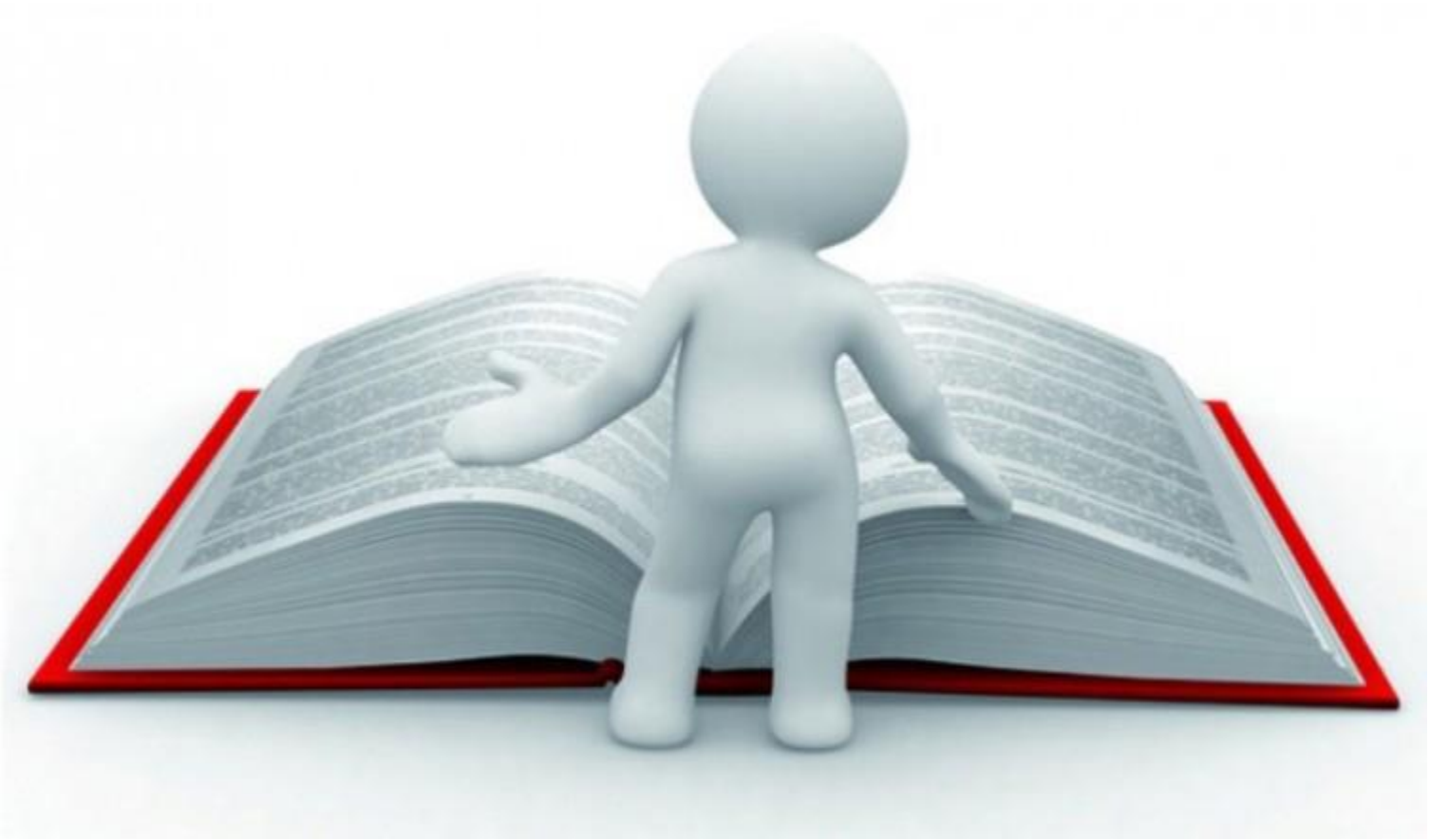
OR

Four (4) years of professional experience in **regulatory affairs**

OR

In **quality management systems** relating to **IVD medical devices**

Technical Documentation



Clinical Evidence

- Demonstration of compliance with the general safety and performance requirements
- Support the intended purpose of the device
- Sourced from performance studies
  - Scientific Validity
  - Analytical Performance
  - Clinical Performance
- Updated throughout device life-cycle
  - Post Market Performance Follow-up
  - Periodic Safety Update Report (PSUR) or Post Market Surveillance Report (PMSR)

Clinical Evidence – Clinical performance

- Ability to yield results that are correlated with a clinical condition or a physiological or pathological process or state in accordance with the **target population** and **intended user**

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical Evidence – Legacy Products

- Clinical performance studies to be performed to answer any gap.

Claimed intended patients

V.S.

Current patient data

Claimed near-patient testing

V.S.

Available data

Performance evaluation report

shall in particular include:

- **the justification for the approach** taken to gather the clinical evidence;
- the **literature search methodology** and the **literature search protocol** and **literature search report** of a literature review;
- the **technology** on which the device is based, the **intended purpose** of the device and **any claims made about the device's performance or safety**;
- the **nature and extent** of the scientific validity and the analytical and clinical performance data that has been evaluated;
- the clinical evidence as the acceptable performances against the **state of the art in medicine**
- any new conclusions derived from **PMPF reports**.

Technical Documentation review - Sampling

- **Class B: Sampling per device category**
  - Category based on IVR code according to Regulation (EU) 2017/2185 on the codes for the designation of notified bodies.

IVR 10X	IVR 20X	IVR 30X	IVR 40X	IVR 50X	IVR 60X	IVR 70X
IVR 101	IVR 201	IVR 301	IVR 401	IVR 501	IVR 601	IVR 701
IVR 102	IVR 202	IVR 302	IVR 402	IVR 502	IVR 602	IVR 702
IVR 103			IVR 403	IVR 503	IVR 603	
IVR 104				IVR 504	IVR 604	
IVR 105				IVR 505	IVR 605	
IVR 106				IVR 506	IVR 606	
					IVR 607	
					IVR 608	
					IVR 609	

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2185&from=EN

Technical Documentation review - Sampling

- **Class C: Sampling per generic group**
  - Generic group based on the 4th level of the CND nomenclature in respect of the IVDR

W0101	W0102		W0103	W0104	W0105	W0106	W0201	W0202
W010101XX	W010201XX	W010211XX	W010301XX	W010401XX	W010501XX	W010601XX	W020101XX	W020201XX
W010102XX	W010202XX	W010212XX	W010302XX	W010402XX	W010502XX	W010602XX	W020102XX	W020202XX
W010103XX	W010203XX	W010213XX	W010303XX	W010403XX	W010503XX	W010603XX	W020103XX	W020203XX
W010104XX	W010204XX	W010214XX	W010304XX	W010404XX	W010504XX	W010699	W020104XX	W020204XX
W010105XX	W010205XX	W010215XX	W010306XX	W010405XX	W010505XX		W020105XX	W020205XX
W010106XX	W010206XX	W010216XX	W010307XX	W010406XX	W010506XX		W020106XX	W020206XX
W010107XX	W010207XX	W010290XX	W010308XX	W010407	W010507XX			W020290XX
W010108XX	W010208XX		W010399	W010408XX	W010508XX			
W010190XX	W010209XX			W010499	W010509XX			
	W010210XX				W010590XX			

http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_11_file.pdf

Novel Class D devices – Expert committee consultation

- Limited to “novel” devices (type of device **certified for the first time**), where **no Common Specifications** are available
- Performance Evaluation Report of the manufacturer (no report of the Notified Body) to be submitted to a specific **Expert Committee** within 5 days after receipt.
- Expert Committee “to provide views” within 60 days
- In addition and in parallel to testing and scientific opinion by **Reference Laboratory**

Companion diagnostic – Consultation

Consultation

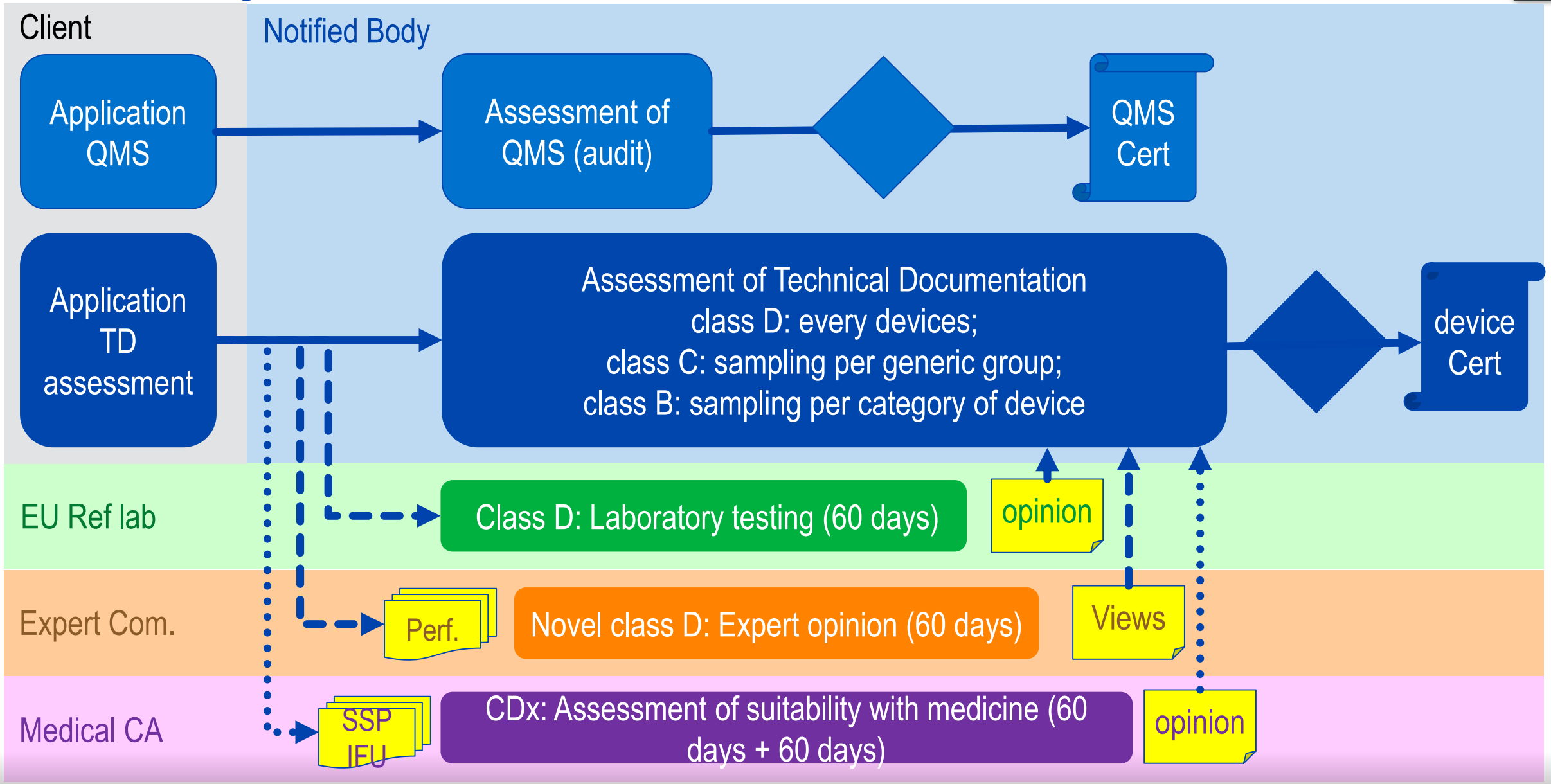
- Of medicinal products competent authority of Member States or EMA*
- According to IVDR Annex IX 5.2 or Annex X 3(k)
  - Regarding suitability of the device in relation to the medicinal product concerned
  - Based on draft SSP and draft IFU, no report of the Notified Body to be submitted

- Scientific opinion of Competent Authority within **60 days**, period may be extended once for further **60 days** on justified grounds

*: specified biotechnologically manufactured medicines, medicines for novel therapies, with novel substances, or for rare diseases

Notified body shall give due consideration to scientific opinion when making decision

CE marking assessment



The European IVDR race

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www.tuv-sud.com/e-ssentials

Thank you!

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www.tuv-sud.com/mhs

Mehr Sicherheit.
Mehr Wert.

Choose certainty.
Add value.