An SME perspective on combined medicines and devices development.

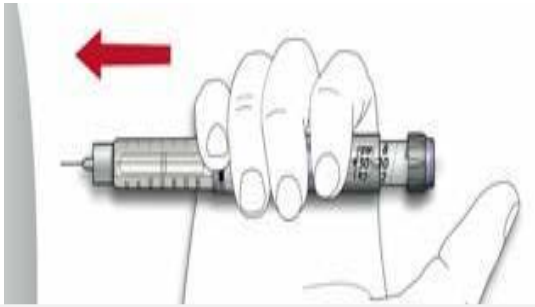
SME info day

Friday, 26 October 2018

Agenda

- The case
- MDR and relevant excerpts – What is new?
- Involvement of Notified Body
- Revised business model for a SME?
- New operational process
- Next steps and reflections

The case

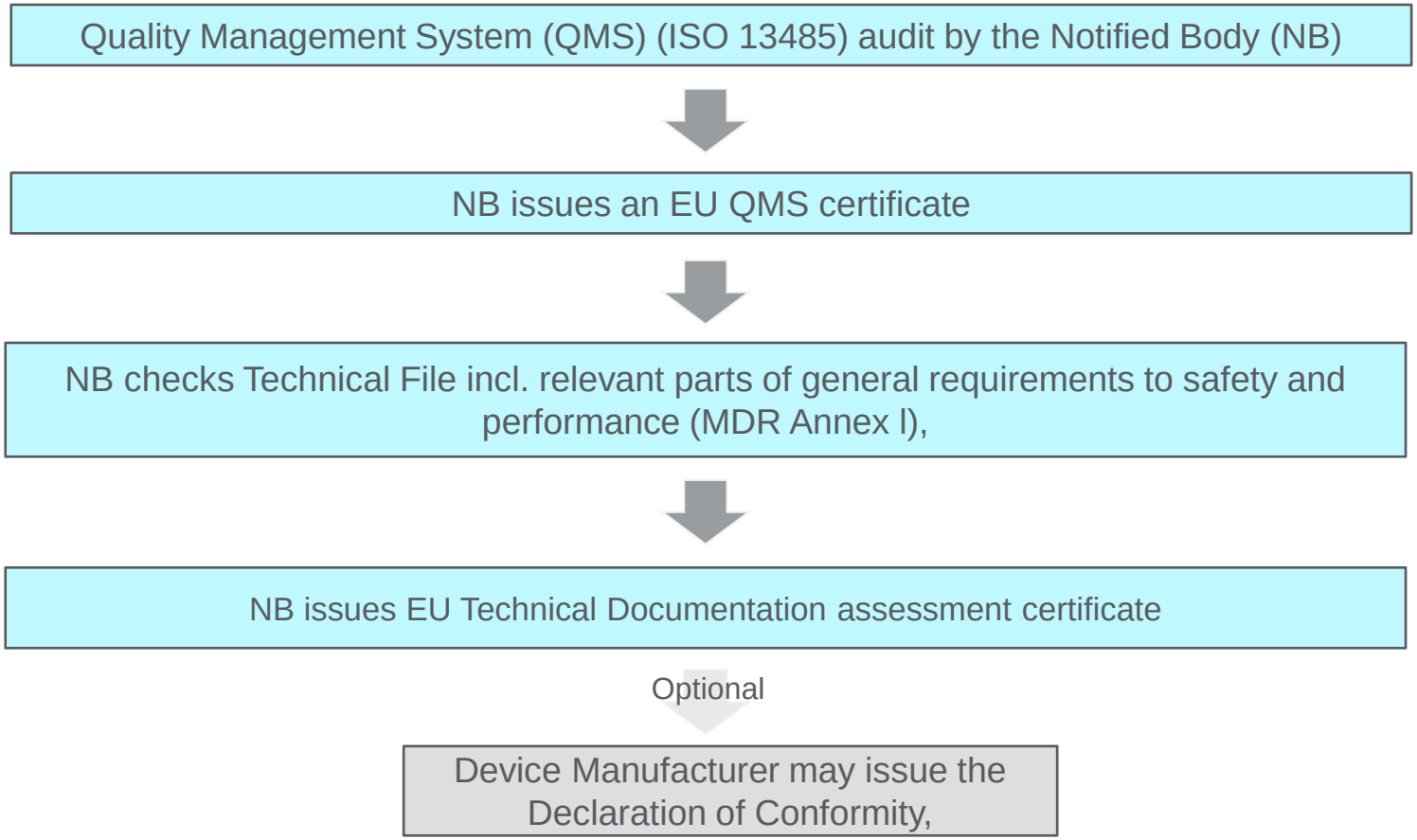


- You are a small drug developer
- You are developing peptide/protein formulations
- You are combining the drug with a disposable delivery system e.g. pre-filled syringe or pen-injector
- Your Marketing Authorisation Application is planned for May 2020 or beyond

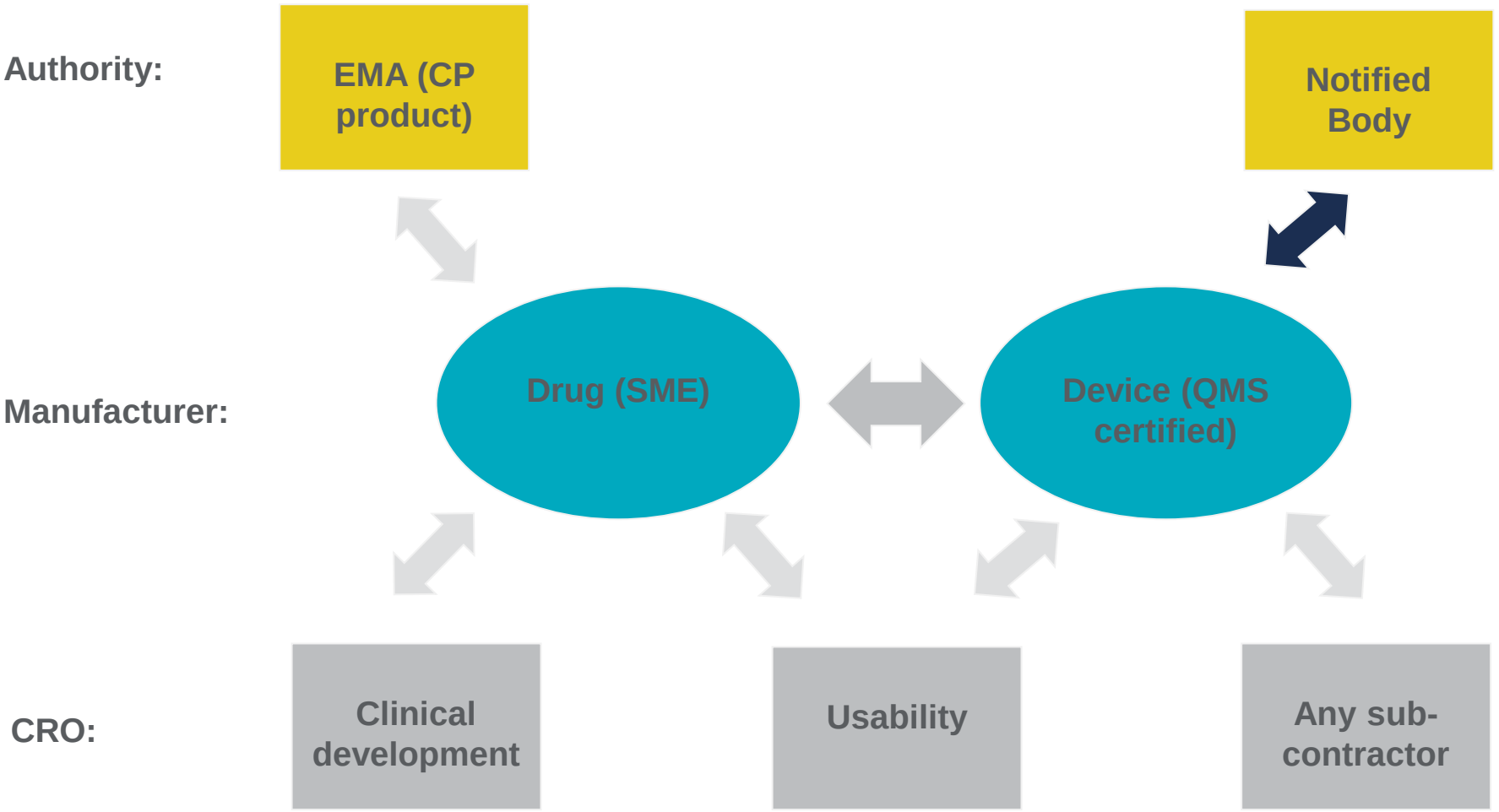
MDR and relevant excerpts – What is new?

No changes	Article 117 is new
If: • Single integral drug-device product • Only for use in the given combination • Not reusable Then: Medicinal Product Directive applies but the relevant **general safety and performance requirements set out in Annex I** to the MDR shall apply for the device component	The marketing authorization dossier shall include either: • Device manufacturer´s EU declaration of conformity or • Certificate issued by a Notified Body
Ref.: MDR Parts of Article 1 – subject matter and scope	Ref.: MDR Article 117 – Amendment to Directive 2001/83/EC

Implication of MDR Article 117 – Involvement of Notified Body



The MDR Article 117 impact on the business model for a SME



From SME to Device Manufacturer to Notified Body "approval"

Examples of SME input:
- **Intended use**
- **Risk analysis**
- **Usability**

Device manufacturer's technical file applicable for Drug-Device Combination Product:

- Device description and specification
- Design and manufacturing information
- General safety and performance requirements (Annex 1)
- Benefit-risk analysis and risk management
- Product verification and validation

EU declaration of conformity or Notified Body certificate

Next steps and SME reflections

Next steps:

- New and updated guidelines are approaching e.g.:
  - EMA guideline: "*Quality requirements of medicinal products containing a device component for delivery or use of the medicinal product*"
  - European Commission guidance MEDDEV 2.1/3: "*Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative*"

Reflections:

- Transparency in Competent Authority and Notified Body remit
- No duplication of assessment
- Timing of delivery of the Notified Body certificate
- Notified Body resource constraints