Safety challenges in arthroplasty - Manufacturer's views

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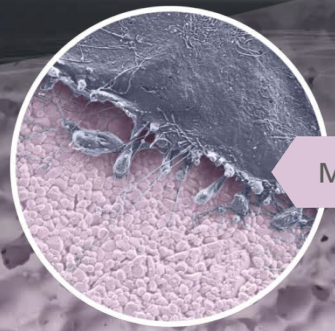

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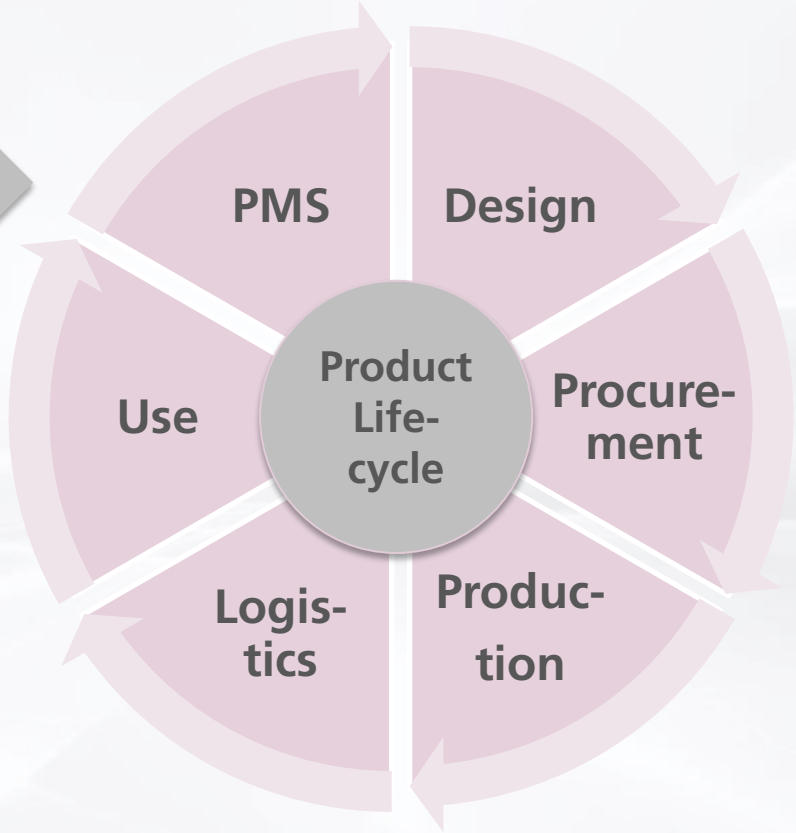
Introduction

Conformity Assessment / Product Registration



Introduction

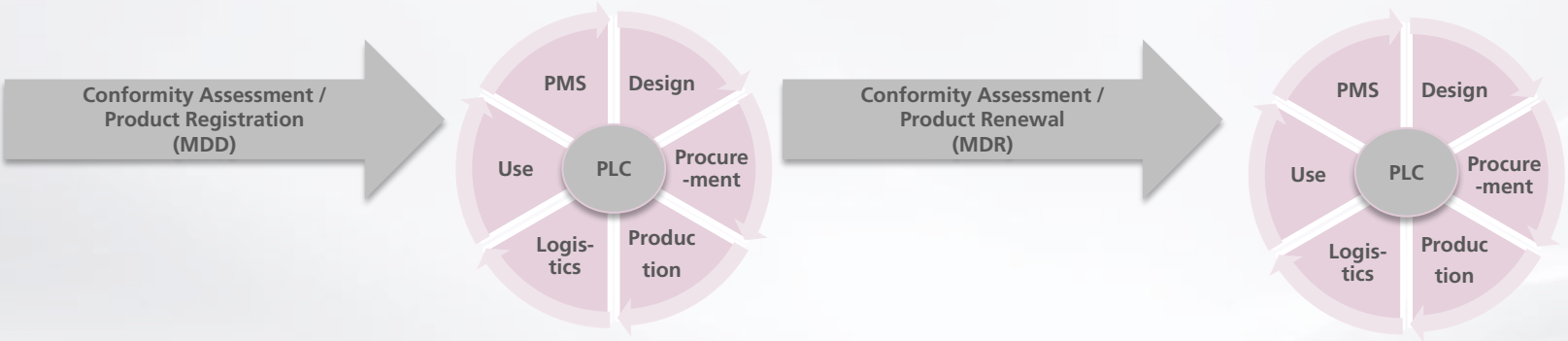
With the new **Medical Device Regulation (MDR)** the regulatory **requirements will be intensely increased** for Medical Devices in the EU.

→ The general intention is to improve product quality and safety

→ i.a., this is to be achieved by providing more data and increased transparency

These new requirements will not only affect new devices but will also **challenge the already approved devices on the market**.

Introduction



From manufacturer / supplier perspective:

The **regulatory requirements** will become one of the biggest challenges that might influence the **availability of safe and clinically proven devices in the near future.**

Regulatory Challenges

Product specification / performance	Processes	Product quality / safety
• Clinical data: retrospective studies / data for approved devices • Equivalence: only if access to the TD is granted • Common Specifications • GSPR • …	• UDI • Eudamed • PMS-TD • …	• Amount of requested data for TD will increase • Supply chains will become more complex • IP-protection • amount of suppliers will might be reduced • …
➢ widely discussed / **obvious** within MDR	➢ widely discussed / **obvious** within MDR	➢ Results from MDR requirements / **not** that **obvious**

Question

Why **MDR might challenge the product quality /safety** for already approved products in some points?

Amount of data

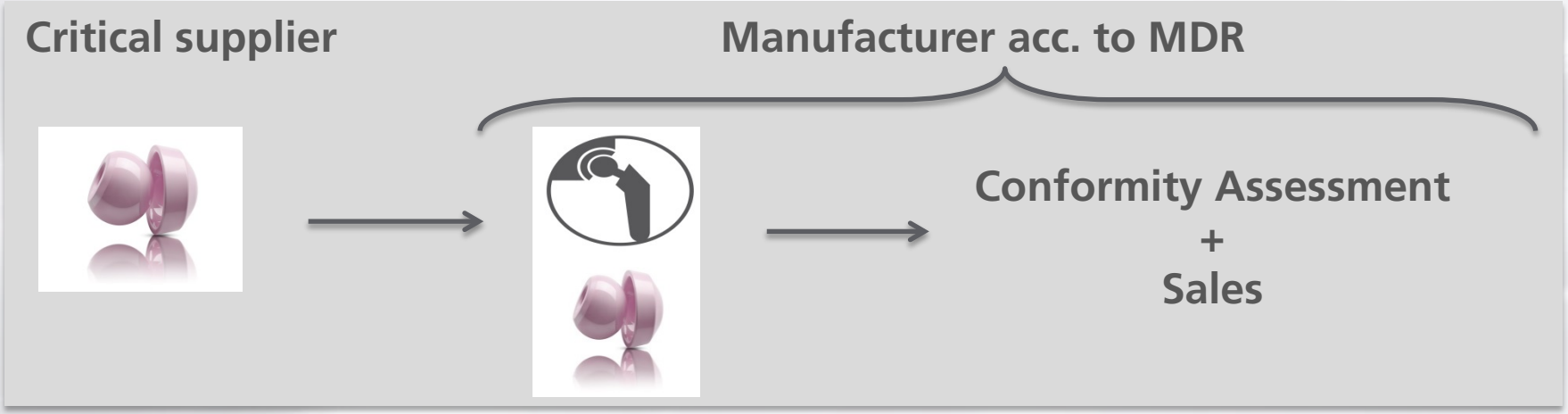
Annex II of MDR is outlining in detail what information needs to be included in the TD

- This includes data from the manufacturer itself, as well as data from all suppliers / subcontractors etc.
- the increased amount of data could lead to important information being lost / overlooked
- review times will increase /availability will be delayed
- content is often complex and not comprehensible without further explanation (especially when data comes from subcontractors)

→ **in this case more is not automatically better**

Supply chains

Products or components that require a high degree of know-how and specialization are often provided by critical suppliers



→ **nevertheless the conformity assessment and provision of data is solely performed by the legal manufacturer**

Supply chains

MDR requirements are mainly addressed to (legal) manufacturers of medical devices, but:

- suppliers take over important steps or even the complete process of „physical“ manufacturing
- in some cases the „critical suppliers“ are mainly involved / responsible for the product development and maintain most of the expertise
- Documentation of the suppliers needs to be involved in the TD

→ **involvement during conformity assessment might be required**

IP-Protection

Annex II of MDR outlines the content of the TD, including data from suppliers / subcontractors

- As the products delivered through critical suppliers are often not processed, a lot of **information** included in the TD needs to be **provided through the critical supplier** itself, to cover MDR requirements
- However, the required information often include **internal know-how**, of the supplier, e.g. validation documents with process parameter, machine settings or detailed working instruction

→ **IP-protection might endanger highly specialized and qualified suppliers**

Possible solution → amount of data

- involve the critical suppliers into the conformity assessment process
- don't collect as much „paper" as possible but focus on the important steps (together with the supplier)
- Outline and use the supporting verification measures such as on-site inspection, QMS, quality contracts etc.

→ **Risk-based approach**

Possible solution → Supply chain

Supplier

support of conformity assessment
→ **risk-based approach**

Focus on inspections / summaries
→ **risk-based approach**

Manufacturer

Conclusion

→ Regulatory requirements will influence the availability of safe and well-known products in the future

→ There are many challenges that are not that obvious on a first site within MDR

→ A strong collaboration between all involved parties will be required

→ Existing tools / processes must (again) be given more validity

→ Alternative ideas must be found and discussed

I am happy to answer your questions.