Congenius

5-minute guide to:

The interface between Risk Management & PMS

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Both risk management and post market surveillance (PMS) are key processes to monitor and maintain a medical device.

• **Risk management** is a systematic process to identify, evaluate, and mitigate risks during the whole life cycle of a medical device

• **Post market surveillance (PMS)** collects data about the medical device in the market, such as clinical data, incidents, market surveillance data, and feedback, which on the one hand input to risk management, and on the other may serve to evaluate the effectiveness of risk mitigations



However, the interplay between risk management and PMS is more complex than this direct interface.

In this 5-minute guide our Head of Quality Dr. Dirk Hüber takes a brief look at how risk management and PMS interface and how to make this interface efficient and effective.



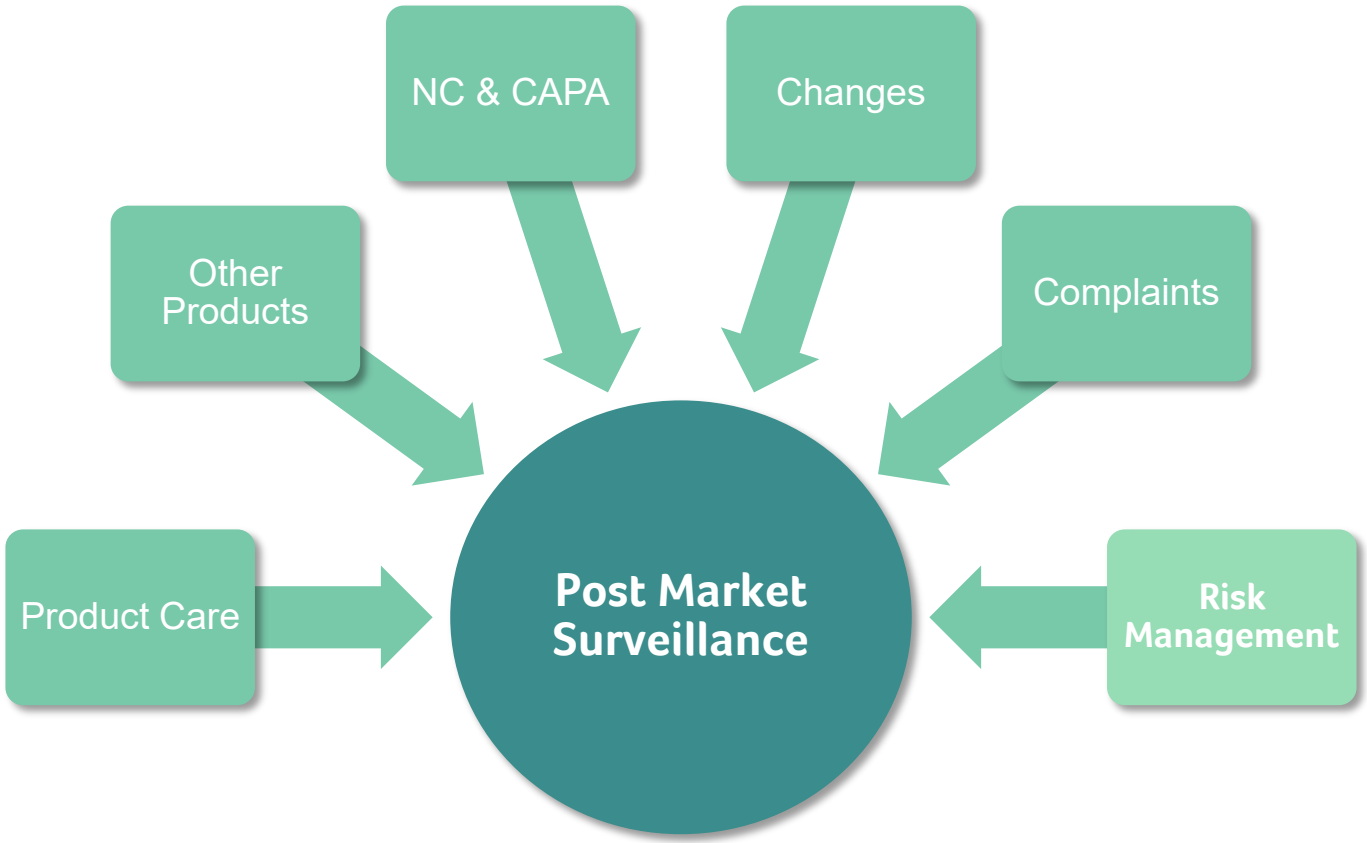
The interfaces between Risk Management & other processes

The most important interfaces between risk management and other processes are:



The interfaces between PMS & other processes

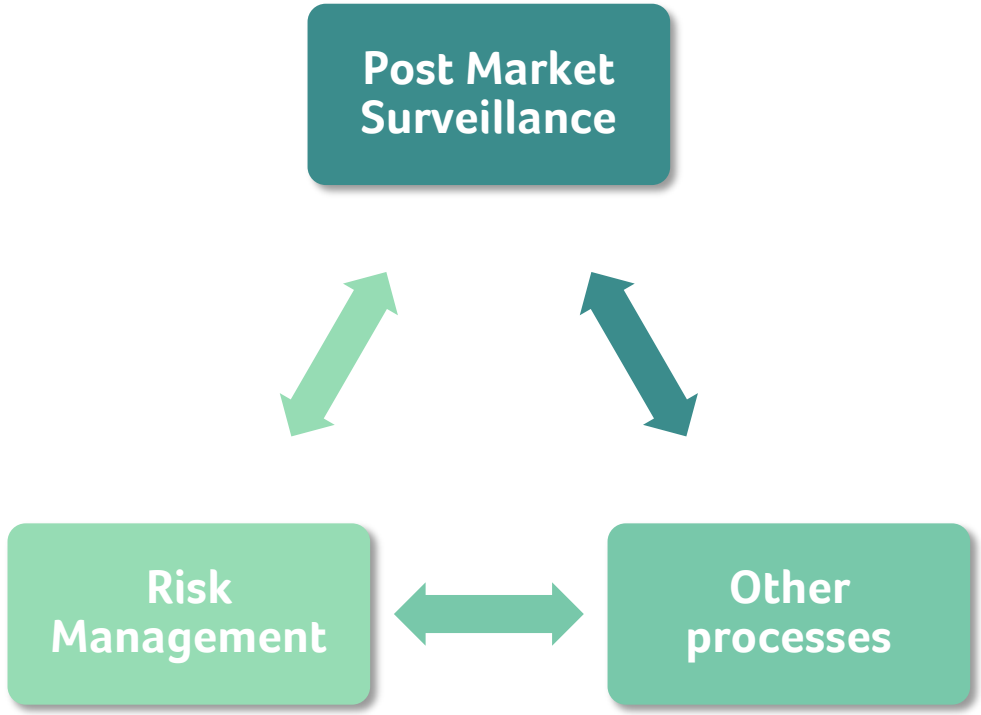
The most important interfaces between post market surveillance and other processes are:



The interfaces between Risk Management & PMS

As you can see from the previous two figures, **risk management and PMS interface largely with the same processes.**

Thus, risk management and PMS **also interface indirectly via other processes**:





The interfaces between Risk Management & PMS

This means in essence:

- Risk management and post market surveillance **serve the same goal**: to keep medical devices safe and effective during their life cycle
- The two processes provide **different tools** for achieving this goal
- These **tools are directly and indirectly connected** to each other
- Thus, risk management and post market surveillance are **complementary processes that supplement each other**

How to ensure efficient & effective interplay

To make the interplay between risk management and post market surveillance efficient and effective, the following aspects are key:

Proactive Action

Manufacturers should not only react to issues but must also proactively search for new information to identify and minimise risks early on.

Continuous Improvement

The risk management file is not static, updated just once per year - it must be updated continuously with new information and resulting risk evaluation and mitigation.

Transparency

The risk management file and the PMS documentation, together with the documentation from the other interfacing processes, prove that the manufacturer identifies risks in due time and reacts appropriately - therefore fulfilling the respective regulatory requirements.

For more on the connection between Risk Management & PMS see here.

And should you have a Risk Management or PMS challenge related to your medical device, get in touch with our experts today.

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