

Business Benefits

- Pharmacovigilance processes extended to devices
- Product complaints used to drive FDA MDR and eMDR
- Device activities integrated into broader business
- Quality systems established
- A single source of high quality product information throughout the product lifecycle
- R&D organisations aligned to comply with regulations and efficiently use resources
- Common governance drives regulatory insights and strategies

Drug meets Device

Successfully integrating Combination Products and Medical Devices into a pharmaceutical environment

New combination product and medical device legislation increasingly focuses on safety, oversight and regulatory compliance. As more and more pharmaceutical companies include combination products or medical devices in their portfolio, the existing pharmaceutical governance models, processes and supporting databases are tested to their limits. This is becoming increasingly evident in regulatory inspection findings. The FDA has issued warning letters and threatened marketing authorisation withdrawal where it found significant deficits in the development documentation and safety reporting of combination products. The European Competent Authorities have instructed their Notified Bodies to focus more on manufacturers' safety and quality systems in their inspections, in the hope of avoiding another breast implant-like scandal. Typical observations in warning letters and inspection reports include:

- Lack of clear governance and insufficient collaboration across different stakeholders
- Cross-functional processes inadequately implemented
- Lack of end-to-end oversight
- Insufficient safety data analysis, alignment of quality and safety data, and reporting
- Insufficient alignment of regulatory pathways and requirements, e.g. meeting both current Good Manufacturing Practices (cGMP) and Quality System Regulations (QSR)
- Inadequate understanding of the relationship between Adverse Events and device design

How can functions such as Global R&D, Regulatory Affairs or Drug Safety ensure compliance and operational effectiveness for medicinal products as well as combination products or devices in their portfolio, whilst maintaining existing structures and processes as much as possible?

At Navitas Life Sciences, we believe that at least three initiatives are key.

1. Proactive cross-functional governance and organisation

Pharmaceutical companies typically have a Drug Safety function for adverse event collection, assessment and reporting. This function is usually separate from the Quality function that receives product-related complaints. For combination products and devices, this Quality function is likely to receive most safety input, as users usually report adverse events, malfunctions or incidents as product complaints. European device vigilance requirements and FDA Medical Device Reporting (MDR) rules require many malfunctions, design errors, user errors, labelling deficiencies or misuses to be reported to authorities. Similarly, risk management for devices is a proactive technique to identify all possible failure modes or harms that can occur during production and use, or are the result of an inadequate product design. The additional complexity that a device constituent part brings to a combination product requires companies to collaborate closely across traditionally disconnected functions.

Why Navitas Life Sciences?

- Combination product, medical device and pharma domain knowledge and track record of delivery
- Track record of successful implementation of complex regulatory reporting requirements for combination products or products with mixed (drug/device) registration across different regions
- Understanding of linkages between industries and advanced concepts such as IDMP, UDI and MDM
- Unique insight on issues and approaches from our industry networks (pvnet, pvconnect, pvtech, labelnet, rimnet, and cmonet)
- Engagement model covering strategy, process, governance and technology
- Technology partner for Axway Track & Trace solutions, Oracle Argus and Sparta Systems TrackWise

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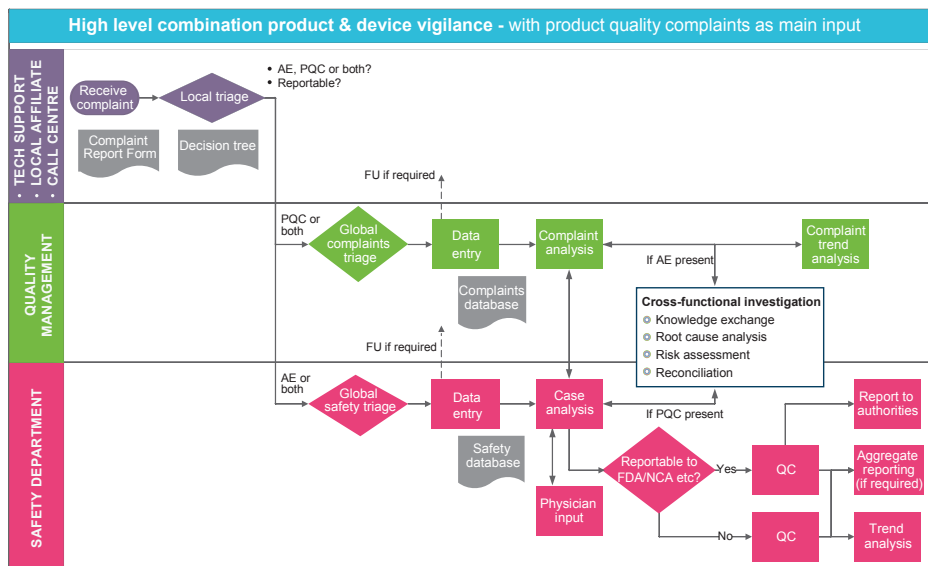
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A TAKE Solutions Enterprise

2. Aligned drug and device processes



Many pre- and post-marketing device processes are broadly similar to drug processes; however, tasks such as submission management, collection of regulatory intelligence or liaison with authorities become quickly inefficient and counter-productive if the pharma approach to these activities is used without understanding device specific requirements. For example, a regulatory strategy to marketing a combination product as a device in Europe requires following a risk-based approach to obtain a CE mark, setting up a Quality Management System and working with Notified Bodies. Many parts of existing pharmaceutical processes can be re-used, and, for example, cGMP processes may be largely sufficient for the Quality Management System; nevertheless, a gap analysis is required to identify process shortcomings and create a plan on how to bridge these.

3. Forward-looking UDI and IDMP integration

By July 2016, drugs in Europe have to adhere to the Identification of Medicinal Products (IDMP) legal requirements. Some devices in the US already have to comply with Unique Device Identification (UDI) requirements, depending on their risk class and product characteristics. Many elements, such as unique identification and traceability, are similar in both initiatives. For maximum efficiency, a product portfolio that contains drugs, combination products and devices should therefore invest in an organisational and technological setup that covers both IDMP and UDI requirements. Ensuring data consistency across the organisation will require a fundamental rethinking of data and system governance. This approach to Master Data Management (MDM) creates a system with a single point of view and clear ownership of product data. It ensures that companies comply with new regulations but that they also achieve the greatest return from their investments. An enlightened understanding of UDI and IDMP allows for full mining of the newly generated data.

In order to achieve any of these items, top-level management needs to support any change initiatives. New governance structures or IDMP & UDI integration are large topics that deliver significant benefits but require a willingness to break with the old and try the new. Where internal initiatives cannot break through existing barriers, external consultants provide an outsider's perspective and bring experience from similar projects at other companies. Navitas Life Sciences is perfectly placed to assist with the design or revision of governance models, processes or technologies to successfully incorporate Combination Products or Medical Devices.

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