A TAKE Solutions Enterprise

NAVITAS LIFE SCIENCES

Pathways for successful UDI implementation

Our offerings include:

- Identification of exact UDI requirements in context of the current product range and pipeline
- Conceptual and detailed design of UDI solutions, spanning the product range, processes and the organization across most functions
- Achieving stakeholder consensus on UDI solution and implementation plan
- Set up of supporting IT infrastructure
- Implementation of tailored governance model
- Design and implementation of effective and efficient supporting processes and compliant procedures as well as the integration thereof into the overall business strategy
- Extensive pharma knowledge, allowing alignment to IDMP initiatives where appropriate
- Implementation partner for Axway Track & Trace technology solutions, perfectly suited for the UDI environment

Leveraging product life cycle insights to minimize risks, enhance organizational performance and maximize patient safety

The Unique Device Identification (UDI) Final Rule, adopted by the FDA in September 2013, builds the groundwork for medical device manufacturers to track and trace their products throughout the product life cycle. The Final Rule requires manufacturers to include Device Identifiers (DI) and Production Identifiers (PI) on the device labels, in FDA submissions and on device vigilance reports. This allows authorities to more easily identify devices, device data and device users; it supports users in finding more information about their product quickly; and it allows manufacturers to track and trace their products across supplier and distribution channels, and to the end user. Manufacturers of class III medical devices in the United States have to implement the regulation since September 2014, followed by class II devices in 2015 and class I devices in 2018.

Mastering the Implementation

UDI implementation affects departments ranging from Marketing, Sales and Regulatory Affairs all the way down to Production and Supply Chain Management: Whereas IT departments have to ensure that systems are in place that support the identification and evaluation of the generated data, Regulatory Affairs is responsible for submitting the data to the FDA. The Operations function has to ensure that the label with barcode is printed correctly and the Supply Chain function needs to involve suppliers and partners. In siloed organizations, with focus only on its own tasks, the management of such a horizontal process is often difficult. Hence, setting up integrated processes, systems and respective procedures, aligning and training resources across functions to successfully manage the information throughout the product lifecycle of the devices, is crucial to ensure compliance. This task represents a significant effort and challenge due to necessary cross-functional commitment.

Maintaining a functioning UDI process

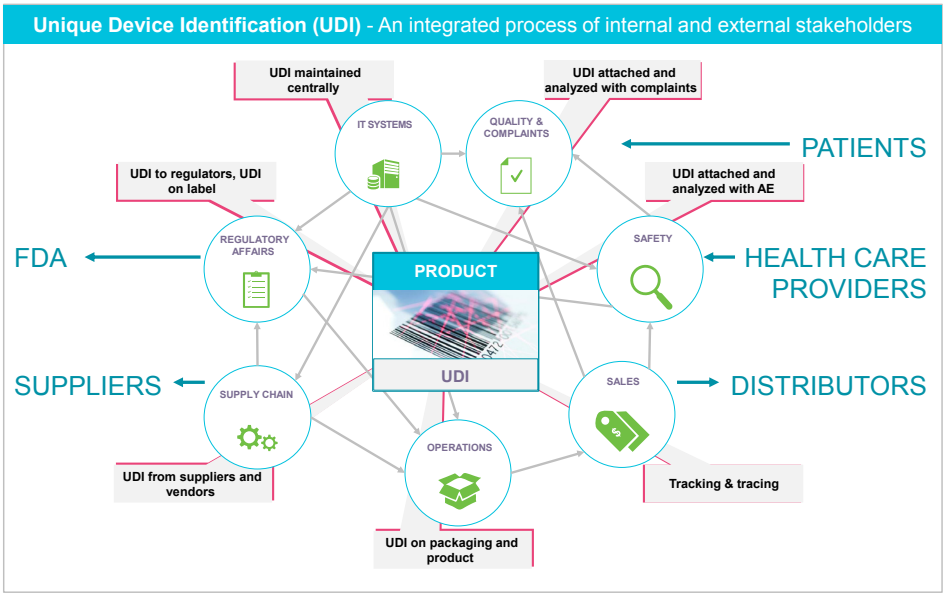
Once the implementation is complete, organizations will have to establish processes to validate the medical device product information in all their systems and determine how to best exchange this information with health authorities and strategic partners. At the same time, cross-functional oversight and governance need to ensure continuous processing of data, as well as ensuring that complete data sets are available. Design principles, such as a single owner of a specific data set, make this process significantly easier.

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, RIM and MDM
- Unique insight on issues and approaches from our industry networks (pvnet, pvconnect, labelnet, RIM Roundtable)
- Engagement model covering strategy, process, governance and technology
- Technology partner for Axway Track & Trace solutions, Oracle Argus and Sparta Systems Trackwise

Leveraging new datasets for performance management

The new datasets shed light into organizational processes that have previously been non-transparent to most companies. Significant gains can be achieved by considering the UDI requirements holistically and within the wider landscape. The identification of new metrics used to support strategic key performance indicators can drive performance management throughout the entire product life cycle and can identify quality risks at an early stage. Taking the application of a UDI implementation into a wider business perspective will therefore be key to successfully navigating the market environment.



Expertise in UDI and implementing business processes with focus on Safety and Supply Chain make Navitas Life Sciences a trusted partner to implement tailored UDI solutions.

We serve clients from, and related to, the medical device and combination product industries across our three regions; Europe, United States, and India. We deploy local project teams as well as benefiting from our international collaboration, which has allowed our projects to be executed on a domestic, but also global level.

Deep industry insight, paired with professional project experience, equips our team to perform assessments in the areas of process, people, and technology. Our guidance has enabled companies to maximise their performance according to pre-defined criteria in both a feasible and realistic way. As an industry partner, we understand improvement measures, ranging from an analysis phase to a concept and design phase in which we jointly develop a future state and provide the necessary support to deliver.

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About Navitas Life Sciences

Navitas Life Sciences delivers platform-driven full-service Clinical, Regulatory and Safety solutions and services. As the dedicated life sciences brand of TAKE Solutions, Navitas Life Sciences operates across North America, Europe, Asia pacific and Latin America. Navitas Life Sciences combines the knowledge and experience of three legacy brands - Ecron Acunova, Navitas, and Intelent. Thus, Navitas brings together the capabilities of a full-service CRO, a technology-led life sciences services provider, and expertise in analytics and data sciences to address critical challenges and drive outcomes for life sciences. Backed by insights derived from our proprietary industry networks, and over 300 strategic safety consulting engagements, Navitas supports both in-trial and post-authorization pharmacovigilance to ensure better patient safety.

For more information

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