Quality & Compliance

Unique Device Identification

Proactive management of the UDI regulatory requirements

Navitas- the leading industry partner for UDI implementation

Expertise in implementing business processes with a focus on safety and supply chain make Navitas Life Sciences an ideal partner to implement UDI solutions.

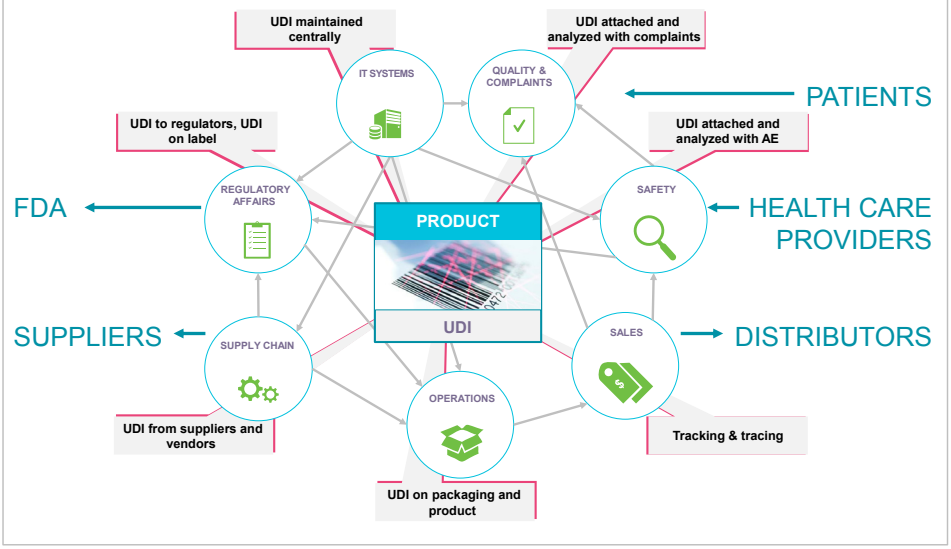
We have a proven approach to implementation of UDI requirements in which we tailor the following project components to client needs:

- Conducting a gap analysis between current capabilities and UDI requirements
- Designing realistic and efficient supporting processes and compliant procedures, including the updating of existing SOPs and work instructions
- Implementing a tailored governance model, likely to involve multiple stakeholders across many functions
- Integration of UDI requirements into the overall business strategy
- Set up of supporting IT infrastructure

To improve patient safety, oversight and post market surveillance, the Food and Drug Administration (FDA) published a Final Rule on Unique Device Identification (UDI) in September 2013. By September 2014, manufacturers of class III medical devices had to adhere and implement the Final Rule, finding that significant time and effort was required to collect, collate and submit all the data that the FDA requires to be uploaded and made publicly available on the Global UDI database (GUDID). Manufacturers of life-supporting or life-sustaining class II products are about to face similar challenges when they strive to meet the UDI rule by September 2015. Other class II products follow in September 2016, with class I products in 2018.

Setting up UDI processes, governance structures and supporting technologies across multiple functions is crucial to successfully manage the information flow throughout the product lifecycle and ensure compliance to the Final Rule. This requires significant effort and poses many challenges for manufacturers: organizations will have to collect information from different stakeholders across functions, define a master data set, validate the data, determine process owners and exchange information with health authorities, strategic partners and production facilities. However, whilst being an initial burden, proactive and skillful manufacturers can also use the new datasets to open up business opportunities: better tracking and tracing of products allows better control of the supply chain and insights into customer needs. Manufacturers should aim to utilize the new regulations for maximum benefit, rather than just complying with the minimum requirements for compliance.

Unique Device Identification (UDI) - An integrated process of internal and external stakeholders



About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

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