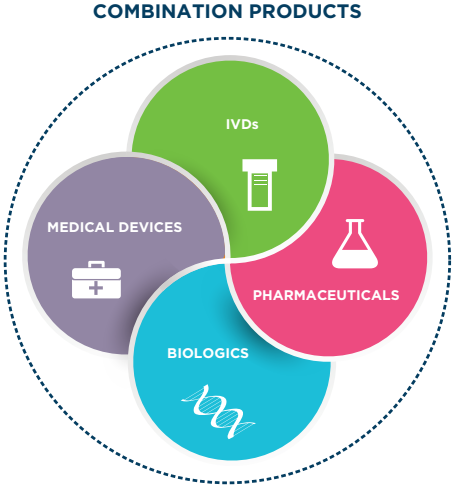
Quality & Compliance

Combination Products

The complexity of Combination Products and their regulations

How can companies effectively leverage existing processes and structures in order to stay compliant and operationally effective for Combination Products in their portfolio?

Companies should not need to re-invent the wheel in order to integrate Combination Products in their portfolio. However, a full review of governance, existing processes and technologies is required to stay compliant; whilst many drug, device and biologics processes are similar, there are differences in approach that need to be addressed.



Combination Products are a major growth area for pharmaceutical and medical device companies: Combination Products allow the creation of platform delivery systems, the combination of technologies, and novel ways of treatment. Most pharma companies already have Combination Products in their portfolio and medical device companies are increasingly involved in their design and development.

By definition, Combination Products consist of drug, device or biologics constituent parts. In general, each constituent part is required to meet its own set of regulations, even if the overall product is governed by a different regulation. As a result, pharmaceutical companies have to deal with areas that they are less familiar with and that do not fit into their typical organizational structures. For example, for a pre-filled syringe a pharmaceutical company may have to consider compatibility issues, or has to carry out human factor studies or device risk assessments that consider use error. Similarly, device companies will have to familiarize themselves with medicinal product or biologics regulations that they are less familiar with.

Navitas Life Sciences assesses the suitability of existing drug or device processes

Navitas Life Sciences offers a full review of suitability and capabilities of existing processes, technologies and governance models for Combination Products and Medical Devices. We typically start with a gap analysis that helps clients to proactively identify gaps and shortcomings in current regulatory, quality or safety processes and supports inspection readiness and compliance. Navitas Life Sciences aims to not only ensure full compliance with regulations but also to identify and implement efficiency gains and performance improvement opportunities while revising the process and governance models.

Navitas Life Sciences typically carries out a high-level review in a first phase of a medical device or Combination Product process project. A second phase provides detailed technical, process and organizational solutions and draws in experts from within the client and Navitas Life Sciences with relevant device or pharmaceutical expertise for, for example, the US or European market. Navitas Life Sciences also guides the client into the third phase which usually represents the implementation and ensures that tasks are executed and improvements are realized as planned. We pride ourselves in achieving buy-in throughout all project phases and aim to create implementation plans and solutions that provides quick wins and are realistic as well as efficient.

NAVITAS LIFE SCIENCES

A TAKE Solutions Enterprise

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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