Quality & Compliance

Complaint Handling

Complaint Handling: the center of product surveillance

In the area of Complaint Handling and device vigilance, Navitas Life Sciences offers

- Process review and design as a basis for a streamlined approach towards efficient and effective complaint and safety processing, including resource capacity assessment and process improvements
- Assessment of appropriate governance models to integrate processes and provide escalation paths
- Integration of full system management, including the integration of IT architectures and databases as well as assessing the technology landscape and helping with technology selection
- Documentation management and support, creating or revising policies, Standard Operating Procedures (SOP) or work instructions

Quality and safety are becoming ever more important drivers and differentiators in a competitive market place. When receiving complaints from patients, Health Care Providers (HCP) or other sources, organizations need to investigate and take action: quality or safety complaints are key indicators for safety and performance issues. Regulations require companies to follow-up on individual complaints, impose risk mitigation measures and report adverse events and malfunctions to regulatory authorities. Any failure to adhere to regulations is likely to result in authority warning letters, legal action and/or negative publicity.

Regulators are increasingly focusing on Complaint Handling, product safety and device vigilance. This is not only true in Western markets, but also in emerging markets that are quickly catching up. For example, the Indian government has recently announced the introduction of medical device regulations and a focus on safety data. Harmonization of international regulations, laws and standards forces medical device organizations to review their existing product development and post-marketing procedures.

The Navitas Life Sciences approach for successful Complaint Handling

Navitas Life Sciences has worked with many clients to review and assess Complaint Handling and safety processes and governance structures. Navitas Life Sciences has developed a framework for an integrated, proactive approach towards Medical Device Product Surveillance:

- Understanding the complexity of Complaint Handling starts with cross-functional quality and safety oversight, taking into account internal and external stakeholders. Navitas' expertise supports companies in identifying appropriate governance models and escalation paths that fit a company's needs and ensure a sustainable operating model.
- Full buy-in into the integration of Complaint Handling and safety reporting. In order to ensure long-term success, new processes, governance models and technologies have to be understood and successfully applied by each employee in the organization. Often, the shift from operational task execution to knowledge-based activities requires a different set of capabilities, qualifications and experience.
- Automation at intake, an effective triage system as well as a seamless process environment enables organizations to fully explore the complaint data at aggregate level, with trending and signal management activities leading to early identification of quality and safety issues, and allowing standardization and facilitating regulatory reporting of safety issues to regulatory authorities.
- Full use and alignment of quality and safety databases, using systems such as TrackWise, ARGUS, ARISg or others to facilitate data handling, reconciliation, trend analysis and reporting. Integration with Unique Device Identification (UDI) initiatives leads to further efficiency gains for the company.

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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