

Are you challenged with global delivery of local Risk Management?

Benefits

- Successful global implementation of risk minimization that is compliant with local health authority regulations
- Effective and compliant procedures to evaluate the effectiveness of risk management activities

Development of a Risk Management system that delivers a global strategy and core position on product risks is key to successful implementation of local risk minimization

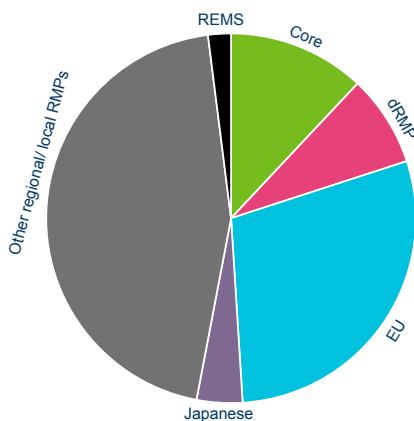
Key issues addressed

- Lack of oversight of local risk management document preparation
- Ineffective engagement of local resources in RM plan execution
- Inefficient RM document authoring and submission at the affiliate level
- Inability to successfully track local Risk Management implementation
- Challenges complying with local health authority RM requirements
- Compliance exposure in measuring the effectiveness of RM activities

Navitas Life Sciences provides an integrated approach leading to impactful results

- Assessment of Risk Management Governance/local affiliate engagement/implementation of Risk Management activities/technology solutions
- Develop improved processes and procedures that deliver a core risk management position but allow local adaptability – best practice
- Implement integrated processes and governance spanning both global and local levels

Industry 2017 | Risk Mgmt Document Format



Deliverables

- Risk Management document development process that delivers a consistent, global strategy and core position on product risks
- Refinement of SOPs, work instructions, templates and job aids to support Risk Management
- Identification and implementation of appropriate technology to implement and track risk management, specifically Risk Management Documents (RMD) and Risk Management Activities
- Support for the maintenance of risk management based on diverse local regulatory requirements that are continually evolving

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 Intelnet—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.

For more information

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