Quality & Compliance

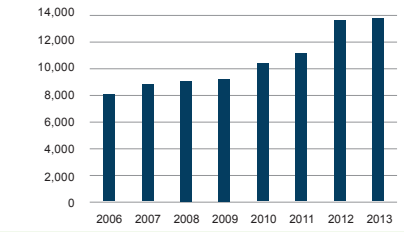
Combination Products and Devices

Will you be ready to comply with the Combination Product Regulations?

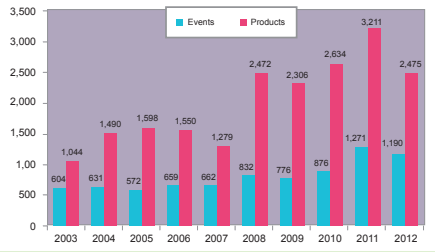
Benefits

- Alignment on device and combination product definitions across regions
- Compliance with regulatory requirements for various countries and regions
- Efficient process breaking the siloed mentality and providing cross-functional oversight from quality, regulatory and safety
- Technical solution to implement the new regulatory requirements

Device Incidents Reports received by MHRA



FDA Recall events and Product Numbers by Fiscal Year



Sources

- Medical Device Recall Report, FY2003 to FY2012, FDA CDRH, Office of Compliance, Division of Analysis and Program Operations: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM388442.pdf
- MHRA: Medical devices – adverse incidents reported to MHRA 2011 to 2013: http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/dts-aic/documents/publication/con377632.pdf

Key issues that organizations are facing

- Different regulatory definitions for devices and combination products
- New and changing regulations: Increasing enforcement with new regulations in EU, China, India etc
- Complex new technologies blurring the line like novel drug-delivery systems, combination packs, personalised medicine and apps
- Divergent device regulatory requirements in complaint handling and incident reporting across different regions
- Regulatory scrutiny
- Cross-functional processes inadequately implemented
- Lack of end-to-end oversight and control

Navitas Life Sciences provides an integrated approach leading to impactful results

- Align drug and device processes while accounting for product differences
- Work cross-functionally across the organization (Quality, Regulatory and Safety)
- Build up internal device expertise
- Leverage upcoming EU Medical Device Regulations as a catalyst for change

Deliverables

- Define and implement governance structure that aligns processes and the organization and ensures compliance
- Updated processes and procedures to allow for transfer of quality and safety information with clear triggers while maintaining oversight
- Regulatory reporting matrix defined and agreed across sponsors and vendors
- Technology review and roadmap for implementing additional device reporting

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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