ASPIVIX SA

Products without sector-specific legislation

General product safety and our quality plan

introduction training



Mauro Rinaldi

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Products without sector-specific Legislation : why a quality plan?

- **Regulatory obligations**
  Some products fall outside dedicated sector-specific frameworks, while remaining subject to Market applicable general product safety requirements. Professional use and B2B sales alone do not exclude these obligations.

- **Our responsibility**
  Exercise due diligence to identify and meet all applicable regulatory requirements in each Market and demonstrate that the product is safe for its intended and reasonably foreseeable use, before marketing it.

- **Purpose of the quality plan**
  Translate these requirements into proportionate activities, responsibilities and documented evidence. It define which procedures of the existing QMS apply and how they are adapted to ensure compliance and support product safety throughout its lifecycle.

Regulatory framework

EU and US frameworks provide the starting point for this assessment.

- **European Union**
  - GPSR, Regulation (EU) 2023/988: general product safety. Assess reasonably foreseeable use by consumers.

- **Unated States**
  CPSA and applicable CPSC rules: independently assess the definition of “consumer product” and any exclusions.

- GPSR: General Product and Safety Requirements
- CPSA: Consumer Product Safety Act
- CPSC: Consumer Product Safety Commission

Quality plan structure - Overview

Quality Plan QP-01 adapts the existing ISO 13485 QMS to the requirements and risks of Products without sector-specific legislation (non-medical products in Aspivix's case)

- **Basis of the plan**
  Identification of EU/US requirements and review of company procedures, with evidence and controls proportionate to the product.

- **Applicability matrix**
  For each requirement: referenced procedure and sections, applicable activities, adaptations and limits of applicability.

Quality plan structure – Key points for compliance: Development

- **Design History File**
  Develop a proportionate Design History File documenting how responsibilities are assigned, decisions are taken and how marketing, user, regulatory and product safety requirements are identified, translated into design inputs and verified, providing evidence of compliance with applicable requirements.

  Existing ISO 13485 QMS development controls are applied proportionately to the product's intended use, complexity and risks.

  Testing is proportionate to the product's characteristics and risks.

Quality plan structure – Key points for compliance: Development

- **Material selection**
  Select and verify materials for performance and safety throughout the product's intended lifetime, considering intended and foreseeable use.

- **Use and integrity**
  As appropriate, include foreseeable use, breakage, edges, detachable parts, cleaning and lifetime.

- **Packaging and environment**
  Consider product protection during transport and storage, including environmental conditions. Assess packaging and waste requirements.

Quality plan structure – Key points for compliance: Production

- **Production and release**
  Approved instructions and specifications, material controls and records. Final checks and documented batch release.

- **Identification**
  Product type/reference and a traceable identifier. The existing QMS uses a batch number linked to specifications, including materials, production process and controls, labelling

- **Label and information**
  Manufacturer and contact details, including complaints contact, warnings and necessary instructions as applicable. Importer and responsible EU operator, as appropriate (under assessment).

Quality plan structure – Key points for compliance: Marketing

- **Market access**
  Traceable orders and shipments.

- **Ongoing monitoring and actions**
  Record and investigate complaints and safety signals, respond, and update risks and actions. Block, withdraw/recall and communicate where necessary. No general periodic submission of complaints, but assess every safety signal.

- **EU, where GPSR applies**
  Dangerous product: immediate action and notification.
  Accidents causing death or serious health effects: notify without undue delay via Safety Business Gateway.

- **US, under CPSC jurisdiction**
  CPSA §15(b): report within 24 hours of information supporting a reportable condition. An accident need not have occurred.

CerviTrainix – potential GAPs – discussion and next steps

- **Development**
  Review of the DHF to confirm compliance.
  Review of regulatory assessment to include applicable EU and US regulations (in plan)
  Review of labelling and packaging requirements to ensure compliance
  Document EU GPSR compliance (checklist)
  Document testing and link with the risk assessment as needed

- **Production**
  Implement a production history record sufficient to demonstrate compliance to specifications, materials, controls and include Lot release record. Note: existing products under NC

- **Operations**
  Confirm that the chain Manufacturer-importer-distributor-user is ensured via Odoo records.

- **Commercial**
  Ensure feedback collection and prompt escalation of safety issues (contracts).

Thank You!!