

Product and service quality and safety

Ensuring excellence: A snapshot of product and service quality and safety at Vimian Group

Product and service quality and safety is fundamental to Vimian Group AB (publ) and its subsidiaries (“Vimian”) ensuring the trust of customers and regulators, and safeguarding the well-being of individuals and animals served by our products and services.

In 2024, an assessment was done to provide an overview of product and service quality and safety at the seven producing entities in Specialty Pharma; Nextmune Italy, Bova UK, Bova Australia, Nextmune BeNeLux, Nextmune US, Nextmune LABS and Nextmune Spain, and the central function in the MedTech segment that overlooks the product and service quality and safety.

In summary:

- **Vimian has managerial responsibility for product/service safety:** Product and service quality and safety is managed by the segments and individual entities and overseen at director level e.g., country manager or quality and operations director.
- **Vimian has regularly tested emergency response procedures to ensure product/service safety:** Emergency response procedures occur one to two times annually depending on the entity.
- **Vimian has regular employee training on product/service safety:** Employee training is thorough and ongoing, with accessibility to policies through various internal channels, ensuring that all staff are well-informed about quality and safety protocols from the onset of their employment.
- **Vimian conducts product/service safety risk assessments:** Risk assessments are conducted annually to address product quality and safety concerns, with established preventive measures.
- **Vimian has targets product/service objectives and targets:** Objective and targets are part of being ISO-certified e.g., reduce number of complaints, reducing waste and customer satisfaction.
- **Vimian has policy commitment to ensure product/service safety and conducts regular external product/service safety audits:** Specialty Pharma upholds a robust safety framework, evidenced by ISO9001, ISO14001, GMP (Good Manufacturing Practice), and GDP (Good Distribution Practice) certifications held by 6 of the 7 entities, each of which also undergoes regular external audits. Quality policies are in place with focus on product and service excellence, customer satisfaction, and continuous improvement. MedTech has a product quality and safety policy in place focused on complaint handling, non-conformance handling, first article inspections, production level inspection plans and mentorship customer education.
- **Vimian has incident investigation and corrective action:** Measures are in place for incident investigation and response, and the entities are equipped with systems to collect, investigate and respond to incidents. This includes root cause analyses, impact evaluations, and risk assessments that inform corrective actions.
- **Vimian monitors product/service safety performance and gathers feedback for continuous improvement:** In Specialty Pharma, Veterinary Pharmacovigilance is mandatory for all produced Veterinary Medicinal Products, involving detailed adverse event reporting and data summation in the Eudravigilance database (a system for monitoring the safety of medicines. Its components facilitate electronic reporting of suspected adverse reactions related to medicines and the effective analysis of data. This enables the early detection of potential safety issues). In addition the Specialty Pharma segment, gathers feedback for continuous

improvement through a combination of structured reporting, analysis of processes and results, and regular team interactions. They utilize digital tools along with performance reviews and collaboration with the sales team, to gather relevant data. The MedTech follows similar protocols as Specialty Pharma with digital reporting and comprehensive incident resolution processes, reinforcing a strong quality and safety culture.

Patrik Eriksson

Patrik Eriksson (Oct 28, 2024 11:57 PDT)

Patrik Eriksson, CEO Vimian Group






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Final Audit Report

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