

Product Compliance Services

FAMAR
we innovate

FAMAR is committed to safeguard Product Compliance and Operational Excellence via an integrated Quality Management System with embedded principles of risk assessment, continuous improvement and agile adherence to the ever-changing legislative landscape.



INPUT

MANAGEMENT RESPONSIBILITY

OUTPUT

Our Regulatory Intelligence surveillance program provides a proactive adaptability to forthcoming legislative changes with customized offerings to ensure requirements are met in due time with a wide range of product Life-Cycle compliance management services.

FAMAR has a strong and efficient network of skilled and trained professionals with high-caliber subject matter expertise and proven industrial experience, promoting our Quality Culture and customer focused service offerings to all our relationships with suppliers, customers and strategic partners.

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REGULATORY INTELLIGENCE

FAMAR's Quality Unit professionals, enabled by leading industry digital platforms on Regulatory Intelligence, continually survey national and international emerging legislations for prompt identification of new requirements and design of quality systems elements to implement.

ANALYTICAL METHOD OPTIMIZATION & VALIDATION

Our Analytical Science & Technology (AS&T) experts design and perform Analytical Method Validation and Transfer for Physicochemical & Microbiological methods, achieving a smooth transition of materials and products' analytical testing in FAMAR Business Units during the Transfer of Technology phase.

PROCESS VALIDATION AND CONTINUED (ONGOING) PROCESS VERIFICATION - CPV

FAMAR's Subject Matter Experts provide services of redesigned Process Validation schemes under the principles of Quality Risk Management during the Technology of Transfer phase as well as, a fully developed program of Continued (Ongoing) Process Verification, as part of products' lifecycle compliance services to evaluate Process capability and robustness under an advanced statistical data analysis evaluation.

SUPPLIERS COMPLIANCE

FAMAR has developed an advanced suppliers and service providers compliance program, including risk assessment and auditing processes, in support of initial or alternative sourcing evaluations. The inspectors have extended auditing experience and utilize FAMAR's integrated methodologies for risk-based audit planning, preparation, execution, report out, CAPA management and follow up.

STABILITY STUDIES

All FAMAR sites are equipped with stability chambers in a variety of environmental conditions to develop stability profile services of own manufactured products and as ad-hoc stability services provided to customers.

PRODUCT QUALITY REVIEW - PQR

FAMAR's harmonized Group Quality System and applied eQMS provides an integrated methodology on performing Annual Product Quality Reviews offered as a service to the Marketing Authorization Holders under a concise and thorough evaluation of their annual product performance.

PRODUCT QUALITY RISK MANAGEMENT

With deep knowledge of Quality Risk Management principles, FAMAR provides integrated or ad-hoc services of risks evaluation and reporting on a variety of segments such as:

✓
EXCIPIENTS

✓
API FMD

✓
ELEMENTAL IMPURITIES

✓
NITROSAMINE IMPURITIES

✓
MANUFACTURING PROCESS