# Regulatory Services

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Famar's Regulatory Affairs team has extensive experience in providing support in Scientific and Technical Regulatory Affairs writing, Regulatory CMC compliance gap analysis as well as, Regulatory Affairs submission and variation strategy proposals.


In direct collaboration with our customers, at Famar we define the best regulatory strategy for their product portfolio for a smooth entry into the foreseen markets, to overcome any regulatory challenges with accuracy and efficiency, while we ensure its continuous support during products regulatory life-cycle management.

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## SCIENTIFIC WRITING: CTD MODULE 3

Famar's Regulatory Affairs experts compile medicinal product quality information in the CTD format for submissions on behalf of their customers and marketing authorization holders.

Regulatory affairs specialists provide advice, as well as technical and scientific due diligence of registered dossiers for formatting, completeness and compliance. They also prepare and review dossiers and keep them up to date at all times according to the current legislation.

## TECHNICAL WRITING:

### NON-PHARMA PRODUCTS (COSMETICS, BIOCIDES, MEDICAL DEVICES, FOOD SUPPLEMENTS)

Organizing customer's data and other technical information for their Cosmetics (PIF), Biocidal products, Medical Devices (Technical dossier) and Food Supplements, enables maintenance of products compliance as per market relevant requirements.

## CATEGORIES OF GAP ANALYSIS

**1) REGULATORY GAP ANALYSIS**
A Regulatory Gap Analysis is the comparison of two dossiers either of medicinal products (e.g. Module 3 vs Module 3) or of two technical files for non-medicinal products.

**2) COMPLIANCE GAP ANALYSIS**
A Compliance Gap Analysis is the comparison of the current manufacturing and testing practices versus the currently registered and approved dossier of the product.

**3) TRANSFER GAP ANALYSIS (NPIS)**
There is no better way to initiate a New Product Introduction than to perform a Technology of Transfer Gap Analysis. Famar's Regulatory Affairs team provides to its customers the guidance to take all the necessary steps in order to capture in one file everything that is needed for their product.

## REGULATORY AFFAIRS SUBMISSION STRATEGY

A regulatory/submission strategy will always safeguard Famar's customers with the authorities' requests and needs. The RA team will identify the type and the number of the variations needed, flag potential pitfalls & conditions, and identify the appropriate documentation (CMC and extra documents) required to be submitted.

## FOLLOW-UP UNTIL APPROVAL BY HA AND HELP TO RESPOND IN REQUESTS AND DEFICIENCY LETTERS

For any quality related extra requests or responses to Deficiency Letters with regards to quality matters, Regulatory Affairs team's expertise and broad network of experts within Famar, will assist its customers to overcome any additional authority requests.