Regulatory Services

IQVIA aims as a partner able to provide consultancy based on the specific needs of companies, offering, thanks to a team of experts in the regulatory field, both activity-specific and strategic support, in order to ensure complete compliance with legal and regulatory requirements and a solid and focused support to address the challenges of the pharmaceutical sector.

In this context, IQVIA plays a crucial role in managing the entire Company product portfolio, represents the direct point of contact with regulatory authorities on behalf of the Company and directly manages communications with the Global Regulatory Department and affiliates, ensuring continuity of activities thanks to a dedicated team.

There are several activities for which IQVIA acts as a reference provider for companies.

Specifically, the main focus of the activities is aimed at providing strategic and operational support during all phases of a drug's life:

Development of the registration dossier	Submission of the registration dossier	Life cycle management
IQVIA is able to support companies during the pre-registration phases of a medicinal product through the drafting of the various modules that make up the dossier, taking into account all the regulatory requirements, providing support in case of need for scientific advice/pre-submission meeting and carrying out feasibility studies, due diligence, gap analysis through a team of experts.	IQVIA aims to provide support during the phase of submission of the dossier to the regulatory authority through the various CP, MRP/DCP and national procedures and the related follow-up until the granting of the marketing authorization, through continuous contact with local authorities and the preparation of all necessary documentation.	Once marketing authorization has been granted, IQVIA offers complete regulatory support to pharmaceutical companies, in order to ensure the maintenance of medicinal products on the market in compliance with national and European regulatory requirements.

Examples of services provided in MRP/DCP, CP, NP product management include:

Type I (A, B), II (single, group or worksharing procedure) variations, renewals, line-extension	consolidated expertise in the use of relevant regulatory databases and direct relationship with the authority during the procedure evaluation and follow-up, and management of any Deficiency letter
Product Information (PI) updates and artwork management	translations into the local language, ensuring compliance with the templates required by regulation and managing relationships both with the authority during the review phase and with the various Company functions in the post-approval phase
Marketing Authorisation transfer, sunset clause, withdrawals, deficiencies	coordination of the various Company functions, preparation of the necessary documentation, submission and management of relations with the authorities
Regulatory Intelligence	timely monitoring of the regulations and guidelines released by the regulatory authorities as well as the monitoring of competitor companies
Management of local RA activities Ex. Italy — Drug traceability, peelable stickers (bollini ottici) and serialization; Farmastampati, bilingualism, databases	management of purchase requests via specific platform, shipping of peelable stickers and support in managing the peelable sticker/data matrix transitional period; sending the patient information leaflet and/or labels to the Farmadati database and managing the updating of the patient information leaflet in German language through a specific platform following the update of the PIs

In conclusion, in order to optimize management procedures for all areas of regulatory activity within the Pharmaceutical Company, IQVIA offers support in the drafting and/or review of **Standard Operating Procedures (SOP)** thus maintaining an updated quality system and allowing the highest level of compliance with the standards to be achieved for passing audits.

CONTACT US

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