

Due Diligence & GAP Analysis

IQVIA supports customers in their growth and development on a daily basis, constantly striving to respond to their specific needs.

Pharmaceutical companies often need support to manage in-depth evaluations of medicinal dossiers during **Mergers & Acquisition** processes or for new **Business Development** strategies for their products. In case of acquisition of pharmaceutical dossiers or if one intends to apply for MA in Italy or in other countries (EU and non-EU), the analysis of the documentation contained in the dossiers becomes of fundamental importance.

In order to improve its competitive advantage and evaluate any risks, IQVIA assists Pharmaceutical Companies by carrying out **Due Diligence and Gap Analysis** of these dossiers, producing an exhaustive and complete analysis of their document status and providing strategic assistance for business decisions.

It is therefore essential that the documentation complies with the latest regulatory requirements, sector regulations and current guidelines, all the quality

aspects involved up to the placing on the market of a drug and to evaluate any deficiencies in information that could compromise the outcome of new registrations and therefore new business.

It is necessary to identify in good time any potential gap in the pre-clinical, clinical and quality documentation of the products analyzed and their possible impact on the registration process or on life-cycle maintenance in the event of acquisitions.

IQVIA can provide a complete Due Diligence and Gap Analysis support, for different types of products (e.g., new chemical entities, biological medicinal products, orphan drugs, generic drugs, OTC, herbal medicines, homeopathic medicines). Together with various partners and thanks to a consolidated global network, IQVIA can support companies with worldwide assessments.

The proposed services can be grouped into the following phases which define step by step the support given by IQVIA to Companies:



Due Diligence & Gap analysis

In-depth evaluation of dossiers to ensure they comply with the main regulations and guidelines. Check that the documentation can support registration in European and non-European countries.



Critical issues

Investigate the critical issues of the documentation available and evaluate their possible impact in the event of new registrations or acquisitions. Define the necessary regulatory actions to be taken (**Remediation Plan**).



Regulatory strategies

Define a regulatory strategy to facilitate business-related decisions. Highlight the **best option** and support companies in the actions to be taken to achieve their objectives.

CONTACT US

Federica Santagostino

Regulatory & PhV Engagement Manager IQVIA

federica.santagostino@iqvia.com

IQVIA Solutions Italy S.r.l. | Via Fabio Filzi, 29 | 20124 - Milano - Italy

[iqvia.com](https://www.iqvia.com)