IQVIA RSS Services: Your Regulatory Partner When You Need It Most

As a new era evolves at the FDA, formal meetings and interactions with regulators are increasingly necessary throughout the development paths of both drugs and medical devices. Whether your product is in pre-clinical development or being tested in clinical trials, or you are seeking to expand the reach of your already-approved product through labeling expansion, transparent yet nuanced engagement with regulators is key for regulatory success. Robust and efficient preparation for engagements with regulators is paramount to reduce delays in agency decision making.

At IQVIA, our Regulatory Science and Strategy (RSS) team is dedicated to guiding your products through the complex regulatory landscape. With a focus on drugs, biologics, and medical devices, we have leveraged real-world evidence to support **over 35 indications**. As a team comprised predominantly of former FDA experts, RSS approaches regulator interactions through the lens of the regulator to bring unparalleled experience in leading regulatory engagements across divisions and countries. RSS has a **100% success rate** in obtaining formal meetings with regulators for Sponsors.

Effective and productive meetings with regulators can save sponsors at least 3-4 months of time and resources that would otherwise be spent preparing for each subsequent formal interaction. With the evolving regulatory landscape, particularly in the U.S., partnering with IQVIA's ex-FDA regulatory subject matter experts can enable more efficient and optimized engagement, saving you time and resources.

What sets IQVIA apart?

Extensive regulatory experience: Our team has global expertise with CBER, CDER, and CDRH within the U.S. FDA, and international regulators like EMA, MHRA (UK), PMDA (Japan), and Health Canada.

Broad areas of expertise: From oncology, to psychiatry, to medical devices, and all areas in between, our team of scientists and former regulators can support your regulatory interaction regardless of the therapeutic area.

Customized strategizing: Our diverse backgrounds include work in both the emerging biopharmaceutical and big pharma environments enabling us to build an optimized interaction strategy specifically suited to your product.

Comprehensive support: From strategy development to regulatory interactions, we cover all aspects of the regulatory procedure, including meeting requests, briefing documents, preparing sponsors to anticipate regulator queries, attending formal meetings with sponsors, and post-meeting strategy.

Specialist teams: Our network of industry associates allow us access to data partners and specialists in epidemiology, biostatistics, and market access.

Thought leadership: With our vast resume of successful guidance, IQVIA is leading the way in building and supporting real-world regulatory strategy with industry partners.

IQVIA RSS services include:

- Developing and confirming strategies for regulatory interactions
- Navigating scenarios with little to no regulatory precedent to de-risk strategy and define paths forward
- Crafting topics and justifications for discussions with regulators
- Preparing meeting requests and briefing documents in collaboration with sponsors
- Preparing sponsors to anticipate regulator queries and developing regulatory justifications
- Conducting workshops and meetings to provide additional regulatory rationale
- Assimilating pre-meeting feedback from multiple agencies
- In-person or virtual attendance in formal meetings side-by-side with Sponsors
- Orphan Drug Application drafting and FDA comment response

Partner with IQVIA to navigate the regulatory landscape with confidence and precision.

IQVIA (NYSE:IQV) is a leading global provider of clinical research services, commercial insights and healthcare intelligence to the life sciences and healthcare industries. IQVIA's portfolio of solutions are powered by IQVIA Connected Intelligence™ to deliver actionable insights and accelerate innovations. With approximately 88,000 employees in over 100 countries, IQVIA is dedicated to accelerating the development and commercialization of innovative medical treatments to help improve patient outcomes and population health worldwide.
Learn more at www.iqvia.com

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