BIOPHARMA

Global Regulatory Consulting Solutions

Streamline your regulatory interactions, writing and submissions to expedite development

Navigating the regulatory landscape and staying up to date with the latest regulatory changes is a complex process that requires extensive insight into current guidelines. Leveraging regulatory consultancy solutions can help you achieve an efficient development pathway that meets stringent regulatory requirements while optimizing timelines and resources.

Your pathway to regulatory success

Gain insight and develop a strategic plan that delivers on your business objectives.

Navigate compliance

Specialized, in-depth knowledge of laws, guidelines and processes and vast experience in regulatory writing and submission

Avoid setbacks

Risk management strategies to identify and mitigate regulatory risks early in the drug development process

Optimize market entry

Local insights and a strategic approach to submissions and interactions with authorities across many regions specialization in US FDA, UK MHRA, EU EMA

Meet your unique needs

Stand-alone and integrated solutions spanning strategically managed programs, regulatory scientific advice, meeting support and regulatory submissions across all development phases

Save time and resources

Dedicated global team with 20+ years' experience complimented by a network of subject matter experts to advise on topics such as DART, juvenile studies, genetic toxicology and ocular and advanced therapies

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Full suite of nonclinical consultancy and regulatory solutions to support biologics, combination products, biosimilars, new chemical entities, medical devices, rare and orphan drugs and vaccines

Regulatory scientific review and gap analysis

- Detailed review of nonclinical data packages
- Gap assessment and recommendations
- General nonclinical consultancy
- Regulatory foresight and risk mitigation

Regulatory meeting support services

- US FDA Pre-Investigational New Drug (Pre-IND)
- US FDA INTERACT
- UK MHRA Scientific Advice
- EU EMA Scientific Advice
- Other regional regulatory authorities upon request

FDA Special Protocol Assessment (SPA) support for carcinogenicity study protocols

- Preparation and finalization of SPA submission document
- Regulatory project management and tracking of submission components
- Interactions with FDA during review process
- Carcinogenicity waiver requests and overall carcinogenicity strategies

Regulatory writing services

- Writing support for Marketing Authorization Applications (MAA), e.g., Sections 2.4 and 2.6
- Investigator Brochure writing and editing support
- Preparation of early Target Product Profiles (TPP) and associated strategic advice
- Pediatric development strategies and pediatric investigation plans (PIP)

Preferred partners are available for services needing additional CMC and/or clinical support

Why choose Labcorp as your global laboratory science partner from discovery to market?

Advance confidently, collaborating with our experts in science, regulatory and medicine to effectively and compliantly navigate your development journey. Leverage world-class decision data, insights, and technology to develop your next breakthrough while gaining scale, speed and efficiency through our global network capabilities powered by passion and delivered with urgency. From discovery to market, we provide a full portfolio of lab testing and study solutions including toxicology, metabolism, pharmacology, bioanalytical, CMC analytical, central labs, consulting and sponsored-testing solutions.

To learn more about our regulatory solutions, contact us today at **labcorp.com/biopharma**.

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