Our Regulatory Services

The Regulatory Affairs (North America) team at Emmes has experience in interpreting the applicability of food and drug law, FDA regulations and guidance documents for client programs that facilitate the conduct of investigational studies.

We have extensive knowledge in the development and commercialization of drugs, biologics and medical devices. Our team is focused on providing strategic regulatory advice, scientific and subject matter input and operational support throughout the product development lifecycle to our clients. We are committed to providing regulatory workflows that decrease your time-to-market as well as marketing approaches that optimize your product's development schedule.

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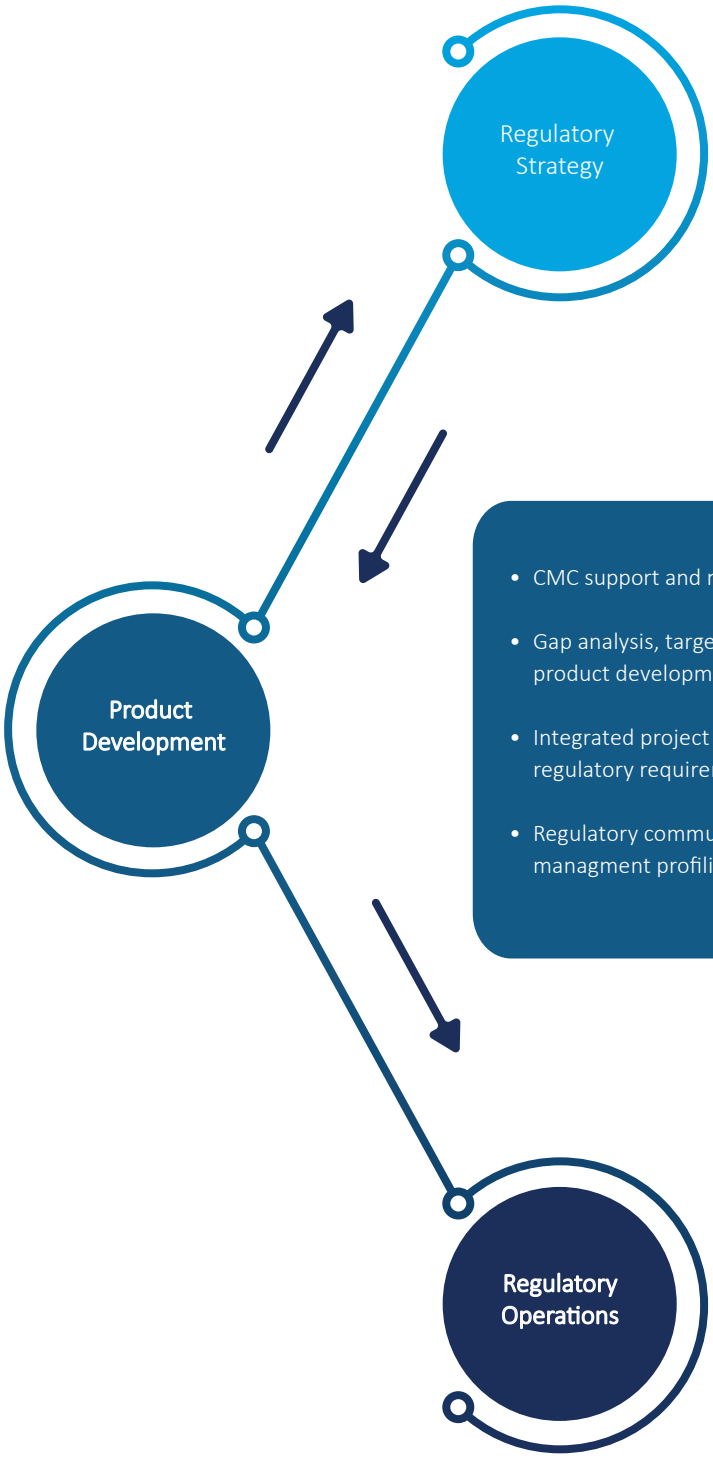
Our wide range of services can satisfy full-service or functional outsourcing requirements



- Strategic planning
- FDA pre-meeting package preparation, discussions and panel participation
- Regulatory document preparation (IND, NDA, BLA and ODD)
- Clinical Research Document preparation (protocols, consents, IBs and CSRs)
- Module 2 Summary Sections

- CMC support and management
- Gap analysis, target product profile and product development planning
- Integrated project teams to inform clients on regulatory requirements
- Regulatory communication and risk managment profiling

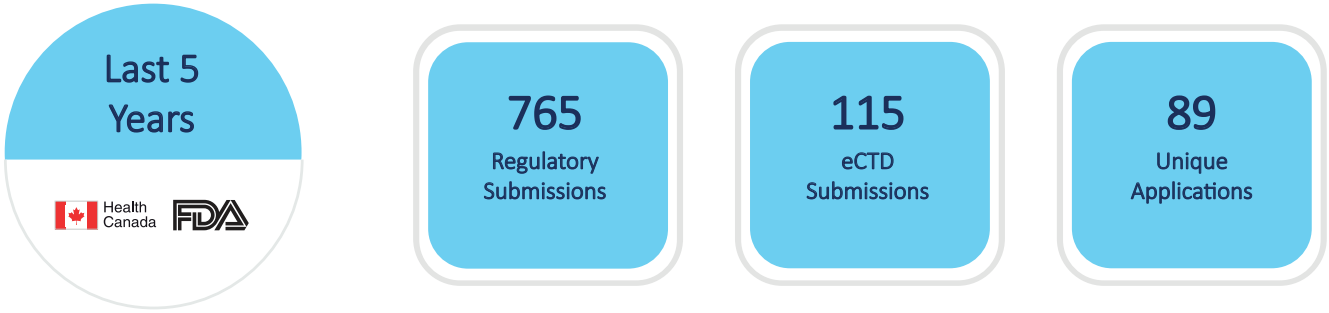
- Preparation and transmission of regulatory submissions to US FDA using the FDA's Electronic Submissions Gateway and CDER NextGen Portal
- eCTD document preparation and submission publishing using reputable eCTD publishing software and tools

Our team and experience at a glance

Members of our team have many years of experience in industry working on a substantial number of novel biotechnology projects (including industry or government) in the following therapeutic areas:

- Rare/Metabolic Diseases
- Ophthalmology
- Infectious Diseases
- Neurology/Substance Use Disorder
- Maternal/Child Health
- Immunology/Oncology

We have supported regulatory activities from INTERACT and Pre-IND submission and throughout early and late phases of clinical development. In total, the Regulatory Affairs team has worked on over 1,400 regulatory submissions to the FDA and Health Canada, including 125 IND submissions to FDA in eCTD format. These submissions were in support of 125 unique applications. In the last five years, the team has worked on over 765 regulatory submissions to the FDA and Health Canada, including over 115 IND submissions to the FDA in eCTD format. These submissions were made in support of 89 unique applications.



Over the years, we have supported more than 50 clients, cultivating many long-term relationships as an integral member of product development teams. In addition to our 30+ years of combined experience, several team members hold a Regulatory Affairs Certification (RAC), an important credential for regulatory professionals.

Key highlights and accomplishments

- Provided support to The National Heart, Lung, and Blood Institute (NHLBI) sponsored Production Assistance for Cellular Therapies (PACT) program for 35 cell and genetically modified cell therapy programs to 27 Investigators including gap analyses (17), INTERACT (7), and Pre-IND (8) meeting support and IND projects (3).
- Provided regulatory communication and supported non-clinical and clinical product development to an academic team developing an ex-vivo CRISPR modified cell therapy for the treatment of a rare genetic, hematologic disorder. Following our multi-year support for the US FDA INTERACT, extensive review of technical documentation for IND, Pre-IND meetings and the compilation and submission of the IND in eCTD format, the study was allowed to proceed.
- Provided regulatory and subject matter support for a progenitor cell therapy for the treatment of an ophthalmic disorder. The program began with support to a non-profit organization that successfully transitioned into a joint venture that submitted and initiated an IND that is presently ongoing.
- Durable (2011- present) support has been provided to PATH, including full-service regulatory support for approximately 27 infectious disease clinical studies.
- Provided ad hoc regulatory affairs and full clinical operational support for a recently licensed cell transplant product by the FDA.

For additional information on our Regulatory Services, please visit
https://www.emmes.com/regulatory-affairs