

Regulatory Strategy

Comprehensive Assessments and Innovative Solutions

Synchrogenix provides global regulatory strategy consulting harnessing all of Certara's capabilities, and leveraging our technologies and domain expertise.

- Regulatory gap analysis of development programs and global dossiers to increase probability of success for approval and patient access
- Agency engagement preparation, communications, and leadership
- Review of Agency correspondence, analysis of relevant regulatory guidelines and precedent
- Competitor labeling assessment to identify opportunities for competitive differentiation; labeling preparation and negotiations
- Proactive stakeholder consultation to achieve alignment
- Modification of development plans to incorporate Agency advice, including innovative approaches to address divergent regional perspectives or requirements
- Consideration of expedited regulatory pathways
- Integration of Health Economics Outcomes Research (HEOR), risk mitigation, modelling and simulation approaches, and post-authorization activities into drug development and regulatory strategies
- Due diligence assessments for in-licensing and partnering, including proposals to increase value proposition
- Applications; dossier preparation; and submission leadership
- Incorporation of regional regulatory requirements (United States, European Union, Asia-Pacific, Latin America)

Key Features

- Proof-of-concept
- Accelerated approval pathways
- In-and-out licensing
- Global dossier development

For more information, visit our website at www.synchrogenix.com or email contactus@synchrogenix.com.

Synchrogenix - Regulatory and Communications Strategy, Science, and Solutions

Synchrogenix provides regulatory and communications strategy, science, and solutions to life science companies worldwide. Our regulatory expertise and innovative technology bridges the full regulatory continuum to propel treatments to the market by meeting the needs of all stakeholders and improving public health outcomes.