

Global Stakeholder Communications

Synchrogenix is your most essential, scalable, and valuable resource - as a consistent partner and at your most critical time periods. We consider the complete story, including short-and long-term goals across your entire portfolio, with a pulse on how today's decisions impact the future. Meaningful content is developed with the recipient in mind: patients and care-givers, healthcare providers, regulators, and payers.

Offerings:

- Regulatory Writing and Medical Communications
 - Non-Clinical, Clinical, Chemistry Manufacturing and Controls (CMC), Safety and Pharmacovigilance
- Global dossier development
- Device and diagnostics
- Health Economics Outcomes Research (HEOR)
- Transparency & Disclosure
- Publications planning

Key benefits:

- Efficient and effective cross-functional planning and implementation
- Content reuse
- Submission management and compilation
- Artificial Intelligence technology
- Risk mitigation
- Proactive program and project management

Synchrogenix provides solutions to address the industry's greatest challenges:

- Effective messaging to all stakeholders
- Combination products
- In-and-out licensing
- Global transparency and disclosure requirements
- Drug safety and aggregate reporting demands
- Life cycle management and regional expansion
- Rare and orphan drug designations, development, and approval
- Pediatric investigation planning, agreement, and development
- Accelerated timelines

Key Features

- More than 300 regulatory science professionals, including over 100 PhDs and MDs
- Over 67 marketing applications since 2012, with 100% approval*
- Industry leading AI-enabled authoring and redaction technology
- Cross-functional support: nonclinical, clinical, CMC, and drug safety/ pharmacovigilance

* for completed submissions for which the agency has reached a decision

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.