Gulfstream Intelligence Launches Connected Regulatory Intelligence and Execution Platform for Pharmaceutical and Biotech Teams

Built by regulatory professionals with more than 25 years of industry experience, Gulfstream Intelligence connects regulatory intelligence, global labeling, gap assessment, health authority preparation, submission planning and regulatory document analysis in one platform.

WELLINGTON, Fla., August 13, 2026 — Gulfstream Intelligence today announced the launch of its regulatory intelligence and execution platform built specifically for pharmaceutical, biotechnology and life science organizations.

Developed by Gulfstream Life Science and created by regulatory professionals with more than 25 years of experience in the pharmaceutical and biotechnology industry, Gulfstream Intelligence grew out of firsthand experience managing global development programs, health authority interactions, submissions, labeling, regulatory strategy and the day to day challenges regulatory teams face.

Regulatory teams have access to more information and more technology than ever before, but much of their work remains disconnected. Regulatory intelligence may live in one system, submission plans in another, labeling in separate documents and spreadsheets, while health authority preparation, gap assessments and program decisions are managed through email, presentations and individual files.

Important context can be lost along the way.

Gulfstream Intelligence was built to bring that work together and help regulatory professionals move from finding information to understanding what it means for a program and determining what needs to happen next.

One Platform for Regulatory Intelligence and Execution

Gulfstream Intelligence brings together several core regulatory functions within one connected environment.

Global Regulatory Intelligence & Policy
Monitor guidance, legislation, policy changes and health authority developments across major global markets and understand how those changes may affect development programs.

Global Labeling
Support the development and lifecycle management of global product labeling, including Core Data Sheets and regional labels such as the U.S. Prescribing Information, EU Summary of Product Characteristics and Canadian Product Monograph. Teams can compare regional

labeling, identify differences, evaluate new safety and efficacy information and maintain greater consistency between global and local labeling positions.

Global Regulatory Gap Assessments
Evaluate programs and regulatory documentation against regional health authority expectations to identify gaps, risks and actions that may be needed before an interaction or submission.

Health Authority Preparation & Simulation
Prepare for meetings and interactions with FDA, EMA, MHRA, PMDA, Health Canada and other global authorities by identifying likely questions, areas of concern and issues that may require additional justification.

Submission Planning & Critical Path Management
Develop structured submission plans, timelines, dependencies and deliverables for INDs, BLAs, NDAs, MAAs and other regulatory milestones while maintaining visibility into activities that may affect the submission timeline.

Regulatory Document Intelligence
Review regulatory documents to identify inconsistencies, missing information, potential risks and areas that may require additional attention.

Decision Ready Deliverables
Turn regulatory analysis into structured reports, summaries and editable presentations that can be shared with regulatory teams, development teams and leadership.

Connecting Regulatory Information to Action

The goal is to maintain the connection between the regulatory source, the professional interpretation of that information, its impact on the development program, the actions that result from it and the final regulatory deliverable.

“The problem is not simply finding regulatory information. It is what happens after the information is found,” said Scott Morvay, Founder of Gulfstream Intelligence. “After more than 25 years working in regulatory affairs, we have seen how quickly important context can become disconnected as information moves between systems, documents and teams. We built Gulfstream around the way regulatory professionals actually work, from understanding an issue to deciding what it means for the program and ultimately doing something about it.”

For larger pharmaceutical organizations, Gulfstream Intelligence provides a way to maintain greater continuity across programs, functions, regions and health authorities. Regulatory intelligence, labeling, health authority preparation, submission planning and document review can remain connected rather than becoming separate workstreams managed across multiple systems.

For emerging and mid sized biotechnology companies, Gulfstream provides many of those same capabilities in one environment. This can be particularly valuable for regulatory teams managing broad responsibilities with limited internal resources.

Built by Regulatory Professionals for Regulatory Professionals

Gulfstream Intelligence was not created by taking a general technology platform and adapting it to regulatory affairs. It was built from the experience of regulatory professionals who understand how development programs evolve, how health authority expectations affect strategy and how regulatory decisions are carried through to submissions and labeling.

That experience shaped both the platform and the way its capabilities work together.

Gulfstream uses artificial intelligence to assist with research, comparison, analysis, planning and drafting while keeping qualified regulatory professionals responsible for reviewing information, interpreting regulatory requirements and making regulatory decisions.

“AI can help us work faster, but regulatory affairs is not simply an information problem,” Morvay said. “Experience matters. Judgment matters. Understanding the development program matters. Gulfstream was built to give regulatory professionals better tools to apply that experience.”

The platform does not replace professional judgment, provide legal advice or independently submit materials to health authorities.

Supporting the Regulatory Lifecycle

Gulfstream Intelligence is designed to support regulatory teams throughout development, from monitoring changes in the global regulatory environment and assessing program readiness to preparing for health authority interactions, developing global labeling and planning major submissions.

As programs progress, information generated through those activities can remain connected rather than becoming isolated across separate systems and documents.

The result is a regulatory working environment designed to give teams greater visibility into what has changed, what it means for their program, what needs attention and what needs to happen next.

About Gulfstream Intelligence

Gulfstream Intelligence is a regulatory intelligence and execution platform developed by Gulfstream Life Science for pharmaceutical, biotechnology and life science organizations.

Created by regulatory professionals with more than 25 years of industry experience, Gulfstream Intelligence brings together global regulatory intelligence and policy, global labeling, regulatory gap assessment, health authority preparation and simulation, submission planning, regulatory document analysis and decision ready deliverables within one connected environment.

The platform is designed to help regulatory teams navigate increasingly complex global development programs while keeping experienced regulatory professionals at the center of strategy and decision making.

Learn more: gulfstreamintelligence.com

Media Contact

Gulfstream Intelligence
Scott Morvay
Scott@gulfstreamintelligence.com
gulfstreamintelligence.com