



# Regulatory Submission Documentation Intelligence

## Client

Global Pharmaceutical Corporation in Research Triangle Park, North Carolina

## Industry

Global Pharmaceutical Development Regulatory Affairs

## Solution

AI-Enhanced Regulatory Documentation Submission Management Platform

## Challenge

Research Triangle Park pharmaceutical corporation preparing global regulatory submissions faced 14-month average submission preparation timelines, \$8.4M annual costs from manual document compilation and regulatory writing, inconsistent formatting and content quality across different regulatory regions, difficulty maintaining version control and regulatory compliance across multiple therapeutic areas, and challenges coordinating complex submission timelines with clinical trial completions.

## AI Consulting Approach

- **Regulatory Process Analysis:** AI consultants analyzed existing submission workflows, regulatory requirements, and documentation patterns to identify automation opportunities using natural language processing and regulatory intelligence technologies.
- **Intelligent Documentation Platform:** Advanced algorithms processing clinical trial data, regulatory guidelines, and submission templates to automate document generation and ensure regulatory compliance across global markets.

## AI Solution

- **Automated Document Generation:** AI application creating regulatory documents, clinical study reports, and submission dossiers using trial data and regulatory templates with consistent formatting and compliance
- **Regulatory Intelligence System:** Machine learning platform monitoring global regulatory changes and updating submission requirements across different therapeutic areas and geographic regions



- Version Control Compliance: Intelligent system maintaining document versioning, tracking regulatory changes, and ensuring submission completeness across multiple regulatory authorities
- Submission Timeline Optimization: Advanced scheduling algorithms coordinating clinical trial milestones with regulatory submission deadlines to optimize approval timelines

## Implementation (32 weeks total)

- Regulatory Analysis (7 weeks)
- Platform Development (12 weeks)
- Document Integration (10 weeks)
- Compliance Testing (3 weeks)

## Key Results

### Submission Efficiency:

- 8-month average submission preparation (vs. 14 months), \$5.1M reduction in regulatory documentation costs, improved submission quality and consistency

### Regulatory Compliance:

- 95% reduction in formatting inconsistencies, enhanced compliance with global regulatory requirements, faster regulatory authority feedback cycles

### Business Impact:

- \$6.8M annual value creation, accelerated drug approval timelines, 235% consulting ROI, strengthened global regulatory capabilities

### Technologies:

- Regulatory documentation automation
- natural language generation



- compliance monitoring systems
- global regulatory intelligence platforms
- submission management tools