End-to-end lifecycle submission management of 10 product portfolios for a top 50 global pharma

Case Study

PROJECT DETAILS

Top 50 Global Pharma

North America, Europe and APAC

SCOPE

- End-to-end lifecycle regulatory submission management for 10 product portfolios
- Activities included product renewal tracking, renewal management, annual report management for US submission
- Submissions included labelling updates, artwork changes, CMC variations

THERAPEUTIC AREA

Cardiovascular, Pain and Diabetes segment

PROJECT TYPE

Multi-year – Delivery based model

PRODUCT CATEGORY

Small Molecules - Established Marketed Products (5+ years)

TECHNOLOGY

Liquent Insight Publisher, Goose, Documentum

DELIVERY EXCELLENCE

PROJECT TEAM

10 Regulatory Affairs Specialist
2 Artwork Specialist
1 Labelling Subject Matter Expert
4 Publishing Experts

BUSINESS DELIVERED

- Project Transitioned within a span of 14 weeks (Client to Provider transition)
- Deployed submission planning framework for timely tracking of upcoming submissions using client technology of MS project
- Improved internal Turn-around-time targets by dedicated submission planning team and ensured 99.5% achievement of internal timelines and 100% of regulatory timelines
- Helped customer in updating labelling process SOPs as part of process consulting assignment and ensured process is ready for audit
- Identified 3 process automation projects as part of “regulatory process innovation”
- Future innovations planned - Embedding Regulatory Intelligence, Robotic automations in Submission planning and renewal tracking, Standard templatization for variation submission

ANNUAL SUBMISSIONS

- 70+ minor and major variation
- 15+ Renewal
- 30+ annual reports
- 100+ artwork mockups
- 800+ submissions published
- 3 product market expansion – in-progress