

Redefined the end-to-end global regulatory submissions process for a leading biopharmaceutical company



Leading biopharmaceutical company

Situation

Advised a global biopharmaceutical leader to redesign its end-to-end regulatory submissions process to improve consistency, scalability, and inspection readiness across regions. The existing model had evolved over time, resulting in fragmented processes, unclear roles, and varying levels of documentation maturity across SOPs, work instructions, and job aids. The objective was to establish a clear, future-ready global submissions framework.



Our approach

- Conducted a comprehensive current-state assessment to evaluate existing submissions processes, documentation, roles, and handoffs
- Reviewed and analyzed existing SOPs, work instructions, and job aids to identify gaps
- Facilitated cross-functional process-mapping workshops to design the future-state global submissions process
- Defined a structured process architecture, including clear L1, L2, and L3 process steps with associated objectives, guidance, roles, limitations, and inputs/outputs
- Drafted new and updated SOPs, work instructions, and job aids aligned to the optimized future-state process
- Led training and change-management activities to support adoption and consistent execution across teams
- Established key performance metrics to enable ongoing measurement, governance, and continuous improvement



Impact and outcomes

- **End-to-End Global Submissions Model:** Delivered a clearly defined, standardized submissions process spanning planning through lifecycle management
- **Inspection-Ready Documentation:** Updated and newly developed SOPs, work instructions, and job aids aligned with regulatory expectations while avoiding over-prescription
- **Role Clarity & Accountability:** Clearly defined responsibilities and handoffs across global and regional teams
- **Improved Scalability:** Created a process framework capable of supporting future portfolio growth and evolving regulatory demands
- **Sustainable Change:** Enabled long-term adoption through targeted training, change management, and measurable performance indicators