GLOBAL PROVIDER OF PHARMACOVIGILANCE & REGULATORY SERVICES

Labeling and Packaging Process Improvement

Background
A large global pharmaceutical company failed an internal audit of their labeling process and subsequently received a warning letter from an FDA inspection. The letter outlined several compliance problems with their packaging. Some of the issues the company faced were:

- No overall accountability for labeling and no governance structure
- Confusing labeling change control processes resulting in rework of labeling content and packaging
- No labeling prioritization
- Last minute changes to packaging to support latest marketing initiatives resulting in costly rework.
- Claims inserted into the packaging process based on a misunderstanding about scientific claims vs. market research claims and the support required for both.
- Health Authority-driven regulatory changes to labeling were not completed by the commitment date.
- In inconsistencies between monograph requirements and packaging
- Discrepancies between formulation listed in batch records and the ingredients listed on the labeling

Solution
Foresight Group resources leveraged prior labeling project experience with change control processes and structured product labeling for large pharmaceutical companies to identify and implement improvements to the current process. Foresight carried out the following improvements:

- Established executive governance bodies for issue escalation, decision-making, and risk management
- Clarified accountability of labeling-related processes across Regulatory Affairs, Medical Affairs, Research & Development, and Manufacturing divisions.
- Designed and implemented a new labeling structure across Regulatory Affairs and Manufacturing Packaging Services
- Defined job descriptions and assisted HR with the rollout
- Designed and implemented processes associated with the categorization, prioritization, and implementation of new and revised labeling
- Harmonized Rx and OTC labeling processes and governance structure
- Implemented improved regulatory controls and embedded quality oversight into the labeling text and artwork process
- Managed a full product label review (hundreds of SKUs) to ensure consistency among batch record, bill of material, formulation, labeling compendia, OTC monograph, CFR, NDA, submission records, labeling content documents, claims, and packaging.
- Created a Corrective Action Plan
- Consolidated ownership of formulation and ingredient information into a single organization
- Prepared and managed training
Results

The process changes and implementation of the new organizational structure and executive governance produced tangible business benefits. Some of the benefits of this project are outlined below.

Significant Process Improvements:

- Early and broad visibility to upcoming changes across functions
- Prioritization of change requests to support batching decisions
- More focus on planning leading to less effort and rework in execution
- Complete documentation for the change
- Reduced ability to ‘tweak’ changes mid-stream; no ‘pile-on’ of additional changes in the routing/approval process

Organizational and governance improvements:

- Established a key partnership between Manufacturing (Implementation) and Regulatory & Medical Affairs (Content)
- Cross-functional, operational-level governance / oversight
- Ensured coordination of efforts and priorities across functional boundaries
- Allowed for early visibility to issues with a clear escalation path
- Allowed all required stakeholders to provide input through labeling implementation teams
- Implemented a temporary change control tool to allow the organization to receive the benefits of the new processes while waiting for a global labeling change control system to be implemented