

PHARMACEUTICAL PACKAGING & LABELING SERVICES

Design | Standardize | Implement

Trends

Packaging errors or mislabeling on pharmaceutical products result in recalls and increased efforts in recertification. As per industry experts, a single recall can cost up to \$5-7 million in revenue. In the six months of 2019, there were a total of 455 product recall notices, out of which 51% were attributed to mislabeling and 13% because of faulty packaging.

Additionally, new product launches, patent timelines, and mergers and acquisitions call for new artwork creation, updates, and maintenance of label changes.

The industry is witnessing constant evolution of regulatory requirements to address complexities and streamline processes while achieving entire traceability to ensure serialization of product labels from production to patients.

A wrong label with outdated information and faulty packaging techniques poses a significant risk to the user and tarnishes the brand image. It can potentially result in hefty fines and loss of licenses.

Opportunities

A significant challenge for pharmaceutical companies is ensuring that critical product information (safety, usage, etc.) is promptly communicated to the end-user. This could be achieved by a connected, streamlined, and well-defined end-to-end processes that are efficiently operated with the latest technologies.

Another challenge for the manufacturers is to address the significant and continuous developments in the packaging and delivery systems. There is a need for high-quality packaging solutions, human factors, security labels, label codes, RFIDs, child-resistant packaging, and protection against adverse external influences such as counterfeiting/adulteration across the supply chain.

Overall, the entire lifecycle needs to remain consistent and in compliance with the latest regulatory requirements while ensuring minimal operational issues by leveraging technology innovations and standardizing processes across manufacturing facilities. Therefore, it is imperative for the companies to keep abreast of the latest advancements and have a holistic approach towards packaging and labeling.



Consumer Benefits

- Communicating safety, usage, performance, and therapy-specific information on the label to the end-users in an effective and timely manner
- Ensure patient safety, longer product shelf life, and brand authenticity
- Sustainable packaging for recyclability, biodegradability, and reduced carbon footprint

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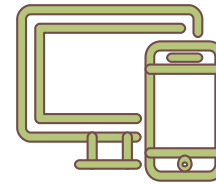
Consulting

- Comprehensive assessment of existing label lifecycle management process
- Identification of opportunities for consolidation, streamlining, standardization, and harmonization
- Objective technology consulting for label management tool, PLM tool, automation, and integration strategy
- Identification of printed packaging material vendor



Core Services

- RA/ Clinical labeling: Creating, reviewing, updating CCDS deviations, CCDS updates
- Drafting, updating and maintaining labeling documents (USPI, USMG, SmPC, PIL)
- Structured authoring and content management services, SPL/SPM Conversion
- Artwork creation and revisions
- End-to-end label lifecycle management
- Packaging engineering
- Cloud migration services, IT solutions governance across multiple functions (PV, RA, Medical Affairs, Supply Chain, Partners)



AI Tools

- **iReg:** Regulatory intelligence platform
- **eproof:** Automated proofreading tool
- **aiDOC:** NLP-based robotic process automation for auto-updating labeling documents
- Customized workflow solutions

Service Assets



Interdisciplinary team of packaging & labeling engineers and regulatory experts



Standard SOPs & customizable templates



Packaging testing facility



Ecosystem: Partnerships & alliances

Differentiators

- Home-grown automation and intelligence platform for quick turnaround time and improved operational efficiency
- End-to-end service portfolio from identifying and adopting the right enterprise LMS, validating the implementation to label creation and verification
- Extensive expertise on tools such as Solidworks, ArtiosCAD, NiceLabel, Prisym, Label Vision, Adobe suite of tools, etc.
- Strategies for optimizing additional packaging tests through robust rationales

Cases

Achieved up to 50% packaging cost reduction, by employing blister packaging design, without compromising on quality

- Improved time to market and reduced development cost
- Maintained drug efficacy by achieving desired shelf life in all climatic conditions

Creation of clinical labeling documents (USPI, SmPC, etc.) as per regional guidelines

- Rigorous QA/ QC process improved the quality of updated labels and reduced error rate to less than 1%
- Facilitated triaging to meet tight deadlines