TATA ELXSI

PACKAGING & LABELING SERVICES

Design | Standardize | Implement

Trending

As per FDA, about 21% of all recalled medical devices in 2018 were due to mislabeling while packaging errors accounted for ~47% of class I medical device recalls in 2014-18 period. Recognizing these issues, regulatory requirements for packaging & labeling in major geographies have been amended leading to significant impact on the global businesses.

Additionally, consolidation of medical device industry with greater number of M&As lead to significant effort in rebranding activities. Businesses with multiple manufacturing sites are centralizing their enterprise systems and standardizing their labeling lifecycle.

Moreover, medical device manufacturers are exploring sustainable packaging solutions to tackle biomedical waste rampant across the industry.

Opportunities & Challenges

To cope with the increased regulatory requirements, companies are required to establish cross-functional collaborations, such as R&D, regulatory, quality etc., to gather essential inputs, thereby ensuring effective change process.

Increased number of M&As call for standardizing and automating the labeling processes across all manufacturing sites or plants to improve operational efficiency and reduce discrepancy created due to multiple systems.

With the rising eco-consciousness, companies are investing in the development of sustainable packaging solutions to minimize medical waste. Additionally, it is time-consuming to design and test packages that demonstrate the ability to facilitate sterilization and maintain sterile barrier properties throughout its shelf life.

Benefits for the consumers

- Effectively communicating safety, usage, performance, and manufacturing-specific information on the label
- Sustainable packaging for recyclability, biodegradability, and reduced carbon footprint
- Robust and validated packaging ensuring safe and sterilized device out-of-the-box

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Tata Elxsi's Packaging and Labeling Service Assets

Standard SOPs & customizable templates as per 21 CFR Part 801, ISO 15223-1:2016, ISO 11607, IEC 60601-1 etc.

Multi-disciplinary team of packaging & labeling engineers and regulatory experts

Packaging testing facility to perform underwater leak, compression, gelbo flex, vibration, tensile test etc.

Packaging and Labeling Service Framework

Assessment and Requirement Gathering

- Consumer insight study
- Trends analysis
- Technology, materials & process study
- Requirements gathering by business marketing team

Packaging Development

- Design proposal & selection of packaging material
- Development of selected concept and prototyping
- Packaging concept approval
- Stability & aging testing

Labeling Development

- Label stock/artwork
- Label content creation (texts, schematic, symbols, graphics, company logo etc.)
- Approval by packaging/ marketing/ regulatory/ R&D/ SMEs

Commercialization

- Package production
- Commercial print with variable data at distribution center

Verification & Validation

- Automated QC of documents
- Character-by-character proofing
- Artwork & label design verification
- Package design verification including stability/ aging testing
- Test method design & validation
- Process validation (IQ, OQ, PQ)

Differentiators

- 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, Catia, ArtiosCAD, Prisym, Bartender, Label Vision etc.
- Strategies for optimizing additional packaging tests through robust rationales

Cases

Centralized label lifecycle management software leading to 30 – 35% increase in efficiency

- Significant operational cost saving through process standardization across all manufacturing sites
- Reduced conversion duration and client dependency through process automation

Remediating sterile and non-sterile packaging for medical devices

- Prepared a lean approach gap analysis tool compliant with ISO 11607- Part 1 & 2: 2019, leading to 24% reduction in lead time
- Timely compliance with EU MDR requirements for notified body review

info@tataelxsi.com