

xmLabeling

Centralization — Process Control — Transparency



xmLabeling streamlines labeling content tracking and management across the complex global labeling process: from creating core data sheets to health authority approval of local labels, including variations.

By applying a unique combination of automation and best practices with an open API, xmLabeling reduces the complexity and increases the insight into global label management and tracking processes. xmLabeling removes the need for error-prone tracking spreadsheets and facilitates a broader view of how global labeling content is managed.

xmLabeling Features:

Regulatory Compliance

- Tracks IDMP information in a centralized location in order to meet the EMA's July 2016 deadline
- Provides style sheets to automate the generation of agency compliant output, such as QRD and SPL formats
- Exposes a robust labeling library to support regulatory information management initiatives

Centralized Translations and Tracking

- Offers one centralized source for local labeling content, translations and variations
- Ensures end-to-end compliance, reporting and alignment with goals through closed loop management
- **Replaces spreadsheets with automated workflows, tracking and reporting**

Robust Infrastructure

- Complies with 21 CFR Part 11 requirements with electronic signatures and audit trails
- Incorporates over 10 years of production experience into the product design and development
- Leverages the proven compliance and content control of EMC's Documentum platform

