A Roadmap for Global Labeling

By Mark Shal, October 3, 2016

Labeling errors as a category are a major cause for Field Corrective Actions (FCA), and Non Conformance Reports (NCR's). What are the ratios in your case?
What is the percentage of content/process errors in your labeling NCR's and FCA's?
Lack of standardized labeling content and process reduces efficiency and extends cycle time. What is your process cycle time from the receipt of a label request to its delivery?
What are your costs of translations?

The following is a roadmap goal to establish a robust, accurate, and flexible content, artwork, and process management with a suitable system infrastructure. The system will facilitate standardization of content creation, artwork reuse, and labeling operations (purchasing, storing, issuing, scanning, printing, applying, verifying), improve business efficiency and cycle time, and eliminate/reduce labeling errors.

Proceed in light of the history, and use a total life cycle approach (map the process end to end).

- Document an SOP Manual for Labeling. Ensure its compliance with applicable laws
- Document Users Requirements (Internal and External customers) for GLS
- Documented Regulatory Requirements for all geographical regions and languages
- Document historical failures (field, and NCR by content and by process)
- Identify types of labels, printers for each occurrence (scope of products, and locations)
- Document the labeling process for each case (same process in more than one?)
- Ensure identification, segregation, and labeling of incoming and in-process labeling
- Identify software platform
- Build a flexible, reliable, consistent, safe, and accurate system
- Validate the system – who? How? When? This includes external suppliers if any part of the process is outsourced. Establish a revalidation period
- Establish contingency/mitigation plans for high risk failures
- What is the lead time to Design, Approve, Document, and approve a label request?
- What is the ECR approval time?
- What is the training time?
- Where are the labels stored? Are they secured and controlled?
- Are the labels forward and backward traceable?
- Is the Electronic labeling system part 11 compliant?
- Is there a formal archiving and back up process? Has it been validated?
- How often is the system reviewed and update of regulatory requirements?
- Are the changes controlled, tracked?
- What is the rate of NCR's/FCA's? What is the cycle time? What is the cost of translation?