Medical Device Labeling Overview

Labeling Task Group IOPP Medical Device Packaging Committee

October 22, 2003



Forces that drive the move toward bar codes

- Device Manufacturers use bar codes to reduce cost, reduce errors, and streamline the supply chain. They also help track products accurately and economically from manufacturing through finished goods distribution and invoicing.
- Hospitals/end users utilize bar codes to reduce inventory management costs and deliver drugs, biologics, and devices to the patient more accurately and with a much greater degree of traceability.
- The FDA is working with the industry to create bar coding standards with the goal of reducing the nations health care bill and substantially reducing medication errors and the resulting mortality rate which exceeds that of our annual national highway fatality toll.

FDA Initiatives

- A proposal was issued in the March 14, 2003 Federal Register [68 FR: 12499-12534], that would mandate bar codes on all prescription drugs and biologics (including vaccines), as well as any over-the-counter drugs that are commonly used in hospitals
- FDA considered whether to include medical devices in the rule after letters were received from Premier Inc, a group purchasing organization, and HIBC. Device manufacturers generally opposed the inclusion of devices because they present different issues compared with drugs, biologics, and blood products. The device industry advocated more study of such issues, a separate rule, or voluntary guidelines.

Bar code standards

- The standards are mainly *data structure* standards that require specific data, the order in which the data is presented, barcode symbologies used, and what data is to be encoded in human readable form.
- The HIBC Supplier Labeling Standard was developed specifically for healthcare manufacturers and distributors and has been in existence since 1984. It is mainly used in Europe and the US. Symbology used is Code 39
- UCC EAN has been in use over 25 years in retail and manufacturing and is widely accepted throughout the world in over 100 countries. Symbology used is UCC/EAN 128.
- There appears to be no effort at this time to consolidate the two standards. An informal poll seems to indicate that UCC/EAN will become the more widely accepted world standard.

Bar code alternatives

New 2D bar code systems

- Large data capacity, well founded optical technology, error detection/correction, and are printed like linear codes. The disadvantage is they need to be read by image processors (2-D array of CCD sensors) and are read only.
- Data matrix was invented in 1990 and approved by the Japanese Medical Manufacturers Association in '96, the first industry sanctioned 2D code.
- UCC developed the RSS (Reduced Space Symbology) code as its 2D solution to the space restraint issue.

Bar code alternatives

 RFID (Radio Frequency Identification) or "smart labels" have an RFID integrated circuit embedded in them which can be stored, read, or updated via radio signals.

> Advantages are no battery needed, unlimited life, good environmental endurance, working distance of 3+ feet, and the ability to read/append or read/rewrite on the fly

• Disadvantages are the cost per tag and the equipment required to read and program them.

Regulatory Labeling Trends

• Local language labeling requirements are growing.

- Less label space = More symbol usage
- Overall streamlining of documentation
- More Bar Code usage (HIBC, UCC, 3-D)
- Industry movement towards electronic labeling.
 - Labeling/Documentation contained on CD ROMs / DVDs
 - Labeling/Documentation distributed via company web sites

Regulatory Agency Links

- U.S. Food and Drug Administration (FDA)
 - <u>http://www.fda.gov/</u>
- European Union TUV
 - <u>http://www.tuvps.com/</u>
- Australia Therapeutic Goods Administration (TGA)
 - <u>http://www.health.gov.au/tga/</u>
- Canada Health Canada: Therapeutic Products Program (TPP)
 - <u>http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/</u>

Other Regulatory Links

- U.S. Center for Device and Radiological Health (CDRH)
 - http://www.fda.gov/cder/regulatory/default.htm
- UK Medical Device Agency (MDA)
 - <u>http://www.medical-devices.gov.uk/</u>
- European Commission Harmonized Standards
 - <u>http://europa.eu.int/comm/enterprise/newapproa</u> ch/standardization/harmstds/reflist.html

Focus on Label Validation

- Typical components of a labeling "system".
 - Consumables: Label and Ribbon and ???
 - Hardware: Printer, Computer, Scanner etc.
 - Software: User Interface, Database and Templates
- Which require formal validation (qualification)?
 To some degree, all of them.



Consumables

 Printed labels, as applied, typically are validated as part of packaging qualification testing

- Distribution testing (ASTM 4169)
- Accelerated aging testing
- Method of evaluation
 - Visual inspection
 - Mechanical testing (ie: peel and rub test)

Hardware and Software

 The system (hardware and software) follows a qualification path resulting in a validated system.

- Installation Qualification (IQ)
 - System conforms to agreed upon specifications. This includes hardware (owners' manual) and software specifications.

Hardware and Software, cont.

Operational Qualification (OQ) In a test scenario, the system performs under boundary testing, corner cases and other challenge conditions.

Performance Qualification (PQ)

 System meets expectations over an extended number of runs in the normal operating environment.

Summary

- In practice the IQ/OQ/PQ may be a single validation activity.
- Document Document Document
 - Have the acceptance criteria and specifications defined *prior* to the validation activity.
 - The validation activities must be relevant; ie test cases must map back to your system specifications.
 - Document all adverse events and their disposition preferably in the validation report.
 - The validation may serve as the "system" document or a separate tooling document may be used.

Common Industry Symbols

- Serial Number, Lot Number, Expiration Date, Single Use Only, ETO, Manufacturing Date, Sterile, Caution, Instructions for Use, Use by Date, Storage Temperature, Notified Body CE Marks, Do Not Re-Use, RTTE, Green Dot
- Sources: EN980 and ISO 15223
- Symbol Examples



Multiple Language Labeling Issues

- First determine language requirements for all the markets being distributed to.
- What are the space issues related to language requirements determined?
- Identify options for saving space
 - Combine variable information together, symbols together, and multiple language text together in separate locations on the label
 - Group specific languages together on multiple labels.
 This involves increased configurations per model/product but allows more text or symbols to be included without having so much of a space constraint

Multiple Language Labeling Issues (cont.)

- Develop new symbols for common text. En980 and ISO 15223 are guides but nothing stops manufacturers from creating symbols and submitting them for approval as long as they can be explained in the IFU. Development of new symbols that can be used by the industry are encouraged and should be apart of labeling submissions if they are created.
- Remember to allocate time for translations
 - Depending on size and scope three months is normal
- Allocate time for affiliate approval
 - Again, three months is normal overlapping with the translation process

Advantages of Using Symbols

- Reduced translation time and cost
- Space saver and visual enhancements to the external label
- Allows for the addition of many languages without potential redesign to labeling firmware or label stock.
- Additional information can be added to labeling that previously would not have fit.

Work Item Initiatives

- Bar Coding
- Regulatory
- ♦ Validation
- Symbols & Languages



Contributing Members

Dave Olson Web Label

Brent Lother Medtronic

Dean Nivala Medtronic

Marilyn Heckley Smith Deltec

Mark Andersen Boston Scientific Corporation

> Gerry Gunderson, CPP Quality Tech Services



3

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Opening Slide 2

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