MPD Training Course: Labelling Requirements

AGENDA

9.00	Introductions, Aims and Objectives
9.15	EU Regulatory Environment Current Directives and Future Regulation • The regulatory basis for labelling • EU • USA
10.00	Brexit Challenges and Authorise Representatives
	Group Discussion Workshop - Labelling Strategies
10.30	Refreshment break
10.45	UDI Data Content and Label Requirements • Implementation of UDI
11.30	• EUDAMED • Required Data elements
12.00	**Lunch & Networking**
12.30	E-Labelling, Websites and Website Content • Review of EU Requirements • Configuration Management and Document Control
	Group Discussion - Examination of Sampole Labels and Labelling
13.30	The Link to Human Factors Considerations • Risk Management • Examples of Poor Labelling
14.15	**Refreshment Break**
14.30	Label Content Control • Maintenance of Technical Documentation • PMS
14.45	Labelling Systems Procurement and Validation • Types of Printers • Vaildation Considerations
	Group Review and Questions
16.00	**Event Close**

DID YOU KNOW?

The definition of 'label' has, in the past decade, expanded to include items such as multi-language booklets and Instructions for Use (IFUs). EU MDR introduces new rules around these crucial materials. But what does it mean for the sticky label itself? EU MDR introduces additional information that needs to be included on labels, forcing organisations to design new label templates that make room for data not previously part of the labelling system. It's both a design and a data challenge, and they must quickly be addressed to avoid a sticky situation.

Some of the most impactful changes include:

- **UDI applied in Europe**
- **More serial and lot numbers**
- **Highlight authorised EU representatives**
- **Label spacing differences**
- **Gluing it all together**

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