



Accurate labelling in paper and digital formats

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Look below,
can you spot where the
the mistake is ?

1, 2, 3, 4, 5, 6, 7 , 8, 9, 10

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Unavoidable errors can lead to expensive recalls!

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- ▶ **According to a 2023 FDA report**
 - ▶ **25% of Medical Device recalls are due to Mislabelling**
 - ▶ <https://www.qualityze.com/blogs/medical-device-recall-management-guidelines>

What can go wrong in labelling

- ▶ Missing regulatory update
- ▶ IFUs and Manuals are loooooong
- ▶ Translation error
- ▶ Manual error by graphic designer
 - Deleted / repeated / modified / moved text
- ▶ Word to PDF conversion issue
 - Wrong font used
 - Old InDesign/Illustrator version
- ▶ PDF to paper printing issue
 - Technical issue in the printing process
- ▶ Word to XML conversion issue
 - Unapproved conversion process
- ▶ Wrong IFU / Manuals with the device at production!
- ▶ ...

Online Labelling PDF considerations

- ▶ PDF must have **selectable text** (searchable!)
- ▶ PDF must have valid **Unicode fonts** for the languages used (also applicable for paper)
- ▶ **Reading order** of PDF content needs to be **technically accurate** for reading it out loud for visually impaired patients
 - Visit Daisy Consortium for accessibility & readability recommendations <https://daisy.org/>

Online Labelling considerations

- ▶ PDF
- ▶ MS Word .doc, .docx
- ▶ XML formats
 - DITA: Darwin Information Typing Architecture
 - GS1: Global Standards
 - PLA: PharmaLedger Association
 - FHIR: Fast Healthcare Interoperability Resources

- ▶ How do you maintain **accurate content**?
- ▶ How do you ensure correct **PDF or XML conversion**?

Simplified labelling workflow for accuracy



