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Webinar On

A Regulatory Puzzle: Writing for the Medical Device Industry

Speaker

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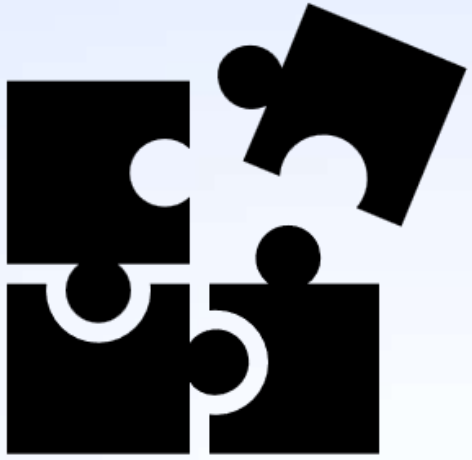
Overview



- ✓ How regulatory bodies shape your content
- ✓ Conflicting interests: who are you writing for?
- ✓ Embracing IFUs as multipurpose documents

What are regulatory bodies?

Medical Device Regulation (MDR)

FDA

Medical Device Single Audit Program (MDSAP)

Other regulations, standards, etc.

How regulatory bodies shape content

- Specific IFU requirements: does one size fits all?
- What happens if there’s a mismatch?
- Is parallel documentation bad?
- What about other standards and requirements?

Who is your audience?

Regulatory & testing houses

Product users

Competitors & hackers

Does your IFU have conflicting interests?

And, if so, can you please everyone?

A strategy for mismatch containment

Things you might NOT control

One document, or many?

Overall IFU organizational strategy

Things you might control

Order / organization

Headings and titles

Terminology

Index terms

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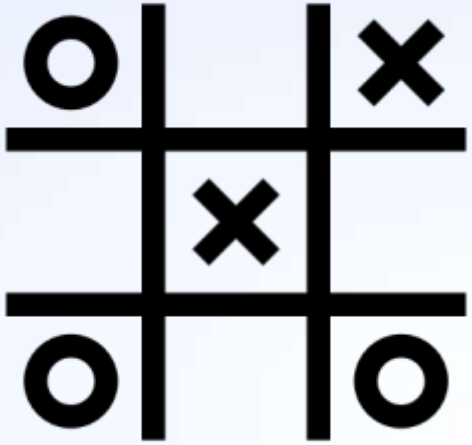
Embracing IFUs as multipurpose documents



- What do you lose?
- What do you gain?
- What opportunities does this create?

* AI-generated content may be incorrect

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What really matters

- ✓ Every medical device must meet regulatory requirements for each market it is sold in
- ✓ YOU can create coherent, useful IFUs that reach multiple readers simultaneously
- ✓ YOU can (and should!) embrace IFUs as multipurpose documents

Questions?

Thank You!