

19th Annual Pharmaceutical and Medical Device Compliance Congress

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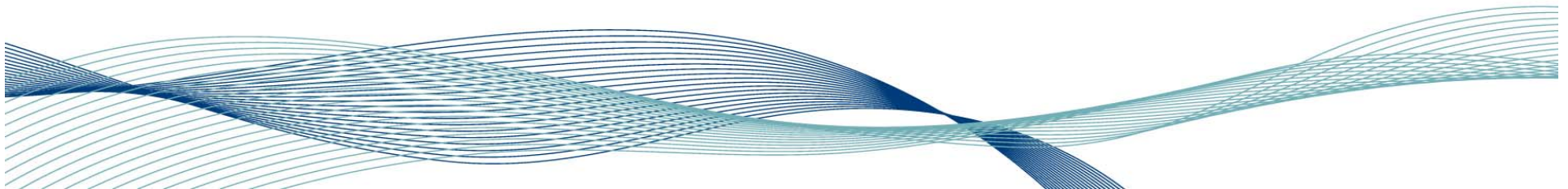
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Global Documentation: Practical Strategies for Implementing an Effective Framework for Global Policies and Procedures

Pharmaceutical and Medical Device Compliance Congress
November 8, 2018



Introductions



Jon Wilkenfeld (moderator)
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Director,
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Agenda

- Introductions
- Global Documentation Framework
- Topics of Discussion
- Conclusion
- Q&A

Do your employees say this?

“I love this policy. It includes exactly the information I need as an MSL in Spain. It didn’t go into any Sales or HQ Medical content. I also didn’t have to read about MSL rules that only apply to the US market. And, the content was written in easy-to-understand Spanish!

Furthermore, the content was 100% consistent with the SOP and computer-based training. It’s easy to access on my iPad or laptop, and I am notified whenever there are any major changes.

Why not?

- Variety of audiences
- Constant changes
- Different reader/writer preferences

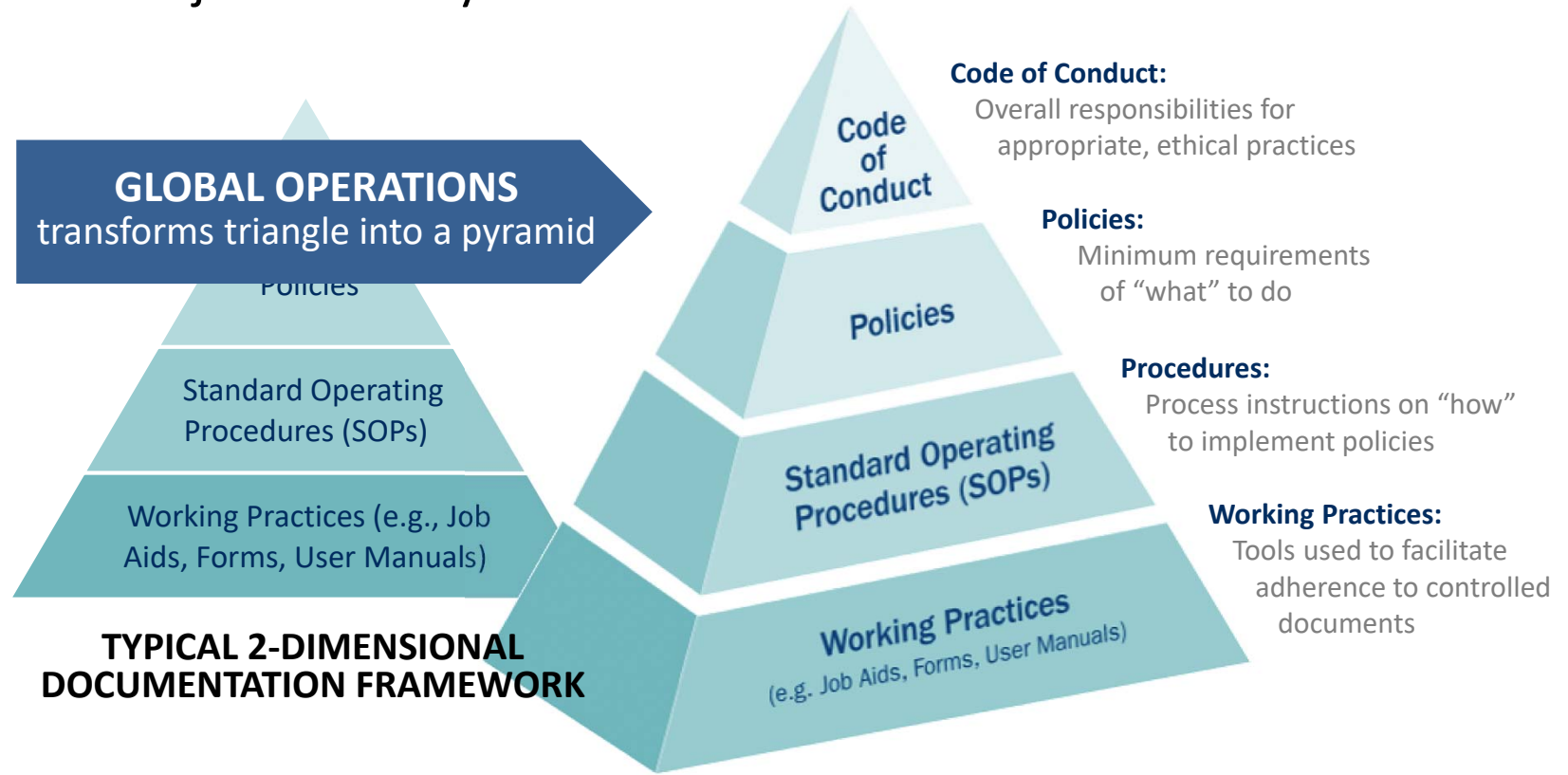
What are the constraints?

- Not enough time / budget
- Lack of expertise
- Long review cycles
- Internal Audit nitpicks

What is a “Global Documentation Framework?”

Definition: Hierarchical method of organizing compliance documents across markets or entities/affiliates

> More than just a “Policy on Policies”



What is Often Covered by a Documentation Framework?

Requirements:

- Governance
- Document Structure(s)
- Authorship Requirements
- Approvals
- Translation Requirements
- Training Requirements
- Storage
- Expiration and Re-Review Cycles

Resources:

- Blank templates by document type
- Examples of “best practice” documents



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There is No “One Perfect Answer”

- It is important to remember that each organization is different
- There is no one correct answer
- Our goal: Be intentional

**“Right Answer”**

Topics of Discussion

1. Governance
2. Audience and Scope
3. Structure
4. Style / Tone
5. Authorship Process
6. Training and Implementation

Conclusion

Important things to remember:

- The goal is to ensure compliance and reduce risk
- Not one approach will work for all companies
- Consider the end user(s)
- Be intentional

Questions / Contact Information

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