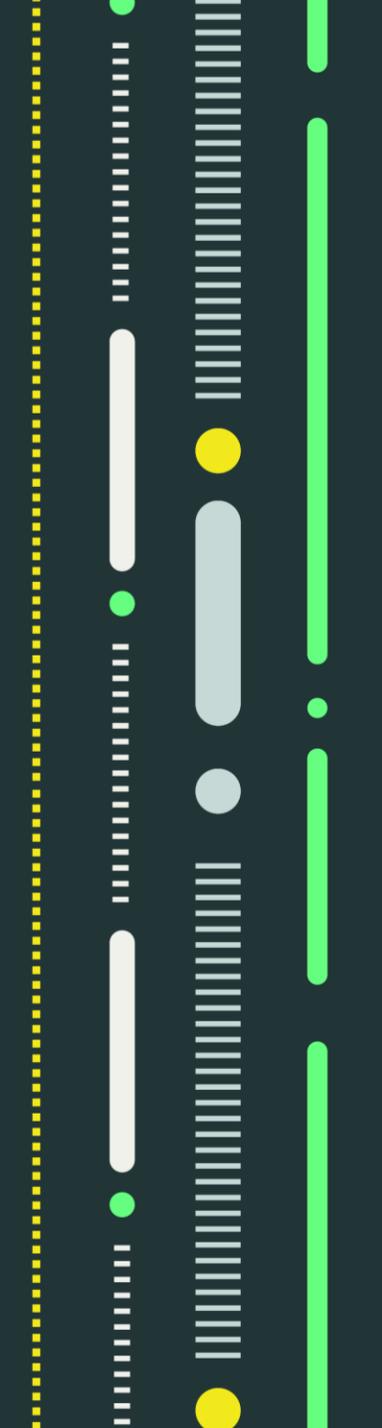




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What's on File Could be on Trial

Mastering Document Risk Part II: *The Files Strike Back*

When Bad Documentation Undermines Good Companies

Tuesday, May 13, 2025



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Presenter Introduction



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David Graham is an experienced litigator known for his success in high-profile cases related to food, medical devices, and pharmaceuticals. He has substantial expertise in defending companies against product liability claims and regulatory challenges, particularly concerning FDA and USDA regulations.

With a focus on strategic thinking and negotiation, David is dedicated to achieving positive results for his clients.



Agenda

 Recap Part I: Documenting with Discipline: Legal Foundations and Best Practices

 Introduction to the Rules of the Road

 Bad Document Creation Practices & Conduct

 Good Document Creation Practices & Conduct

 Organizational Avenues for Reporting

 Questions

Introduction to the Rules of the Road



Nothing is in a vacuum, and you are not alone



Assume someone that is not the intended recipient of the communication will read it



Write to achieve a business goal- what are you intending to say?



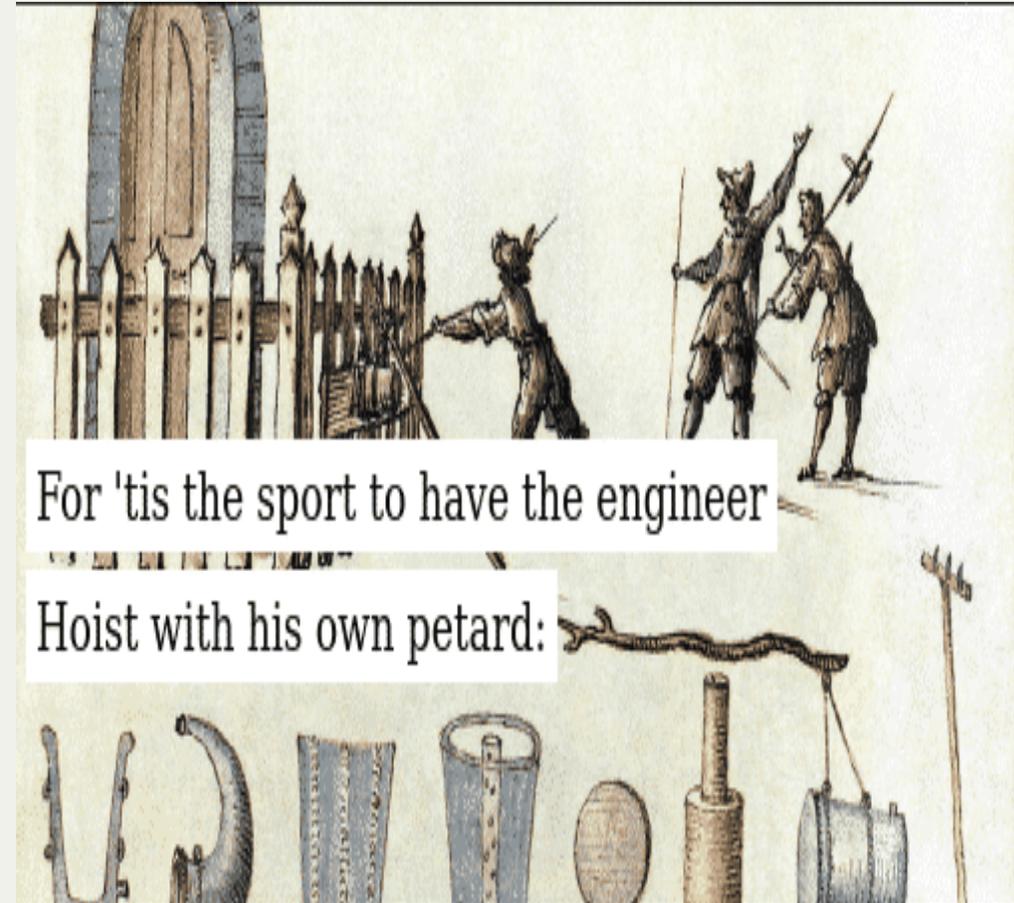
Assume the document will be evidence in a legal proceeding



Do not put safety or liability in monetary terms

Bad Document Creation Practices/Conduct

- What these have in common:
 - The Jail House memo
 - The Hangman's Noose memo
 - The "This is a disaster of epic proportions" memo
- 48-hour rule
- Writing instead of talking
- Writing before you are sure what you want to say or understand the facts
- Making conclusions without knowing the facts



Bad Document Creation Practices/Conduct

- Poor nomenclature-language that negatively mischaracterizes a situation or event—e.g. *risk*, *defective*, *unethical*, *injury*, *fault*
- Not paying attention to privilege, privacy, confidentiality and document retention rules
- Being personal in a negative manner
- Assuming your document is confidential



Good Document Creation Practices/Conduct



The communication is necessary, i.e., it meets a business need



Understandable-use plain language and include important context



Accuracy-True and fair



Concise-be succinct and do not include extraneous information that may be confusing to later readers



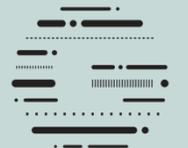
Appropriate-beware of humor and sarcasm and inflammatory opinions



Delivered correctly-only to those who need the communication

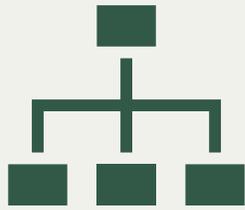
Good Documentation Practices/Conduct (cont.)

- ✓ Do not use personal accounts
- ✓ Do not do what you do not understand or disagree with
- ✓ If you feel uneasy, do not write
- ✓ Stick to the facts. Imagine you are being deposed. What do you really know?
- ✓ Always appropriately respond to and record complaints



Organizational Avenues for Reporting

Whom can I talk to in the company?



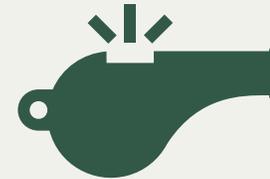
Manager



Legal



Designated
reportees



Whistle blower
options



Trusted
confidant

What do the company policies say you should do?





Questions?



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