

# *What is Good Evidence?*





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## *This Presentation Covers ...*

- Types of Evidence
- Qualities of Evidence
- Traps and Anti-Patterns

## *Why I Care, and Why You Should*

- Civil and Criminal Courts
- Credible and Persuasive Story-of-Testing

# TYPES OF EVIDENCE

## *Sources*

- FDA's 21 CFR Part 11 – Electronic Records
- FDA's Good Manufacturing Practices
- (Adjust for your context)

## *Records versus Testimony*

- Speaks for Itself
- Cross-Examination

# QUALITIES ...

## *Clear*

- To Whom?

## *Objective*

- To What Degree?

# ... QUALITIES ...

## *Authentic*

- Originals or Copies?
- Resistant to Falsification?

## *Integrity*

- Protected from Damage / Deterioration?
- Can not be Readily Repudiated?

# ... QUALITIES ...

## *Readable*

- Human and Machine?

## *Changes*

- Do Not Obscure Previous Information?
- Single line-out, initial, date, reason?

# ... QUALITIES ...

## *Attributable*

- Do we know the Specific Person?

## *Contemporary*

- Created At-The-Moment?
- Are Not Recollections?

# ... QUALITIES ...

## *Audit Trail*

- Is there a Chain-of-Custody?
- Is there a Revision History?

## *Retrievable*

- Is this stored where I can Access it?



# ... QUALITIES

## *3<sup>rd</sup> Party Review / Reconstruction*

- Minimal Outside Assistance?
- Reach the Same Results & Conclusions?

# TRAPS, THREATS AND ANTI-PATTERNS

## *Deficient Qualities*

- *Leads to Feebleness*

## *Feebleness*

- Leads to **Unpersuasive Stories**
- Maybe a **Systemic Risk** smell?

# "PASS-As EXPECTED" CHECKBOXES

## *Fear potential False-Positives*

- The danger of the **Green-Bar**
- Falsification versus Confirmation

## *What you Intended to do*

- Not what you Actually Did

# LULLABY LANGUAGE

## *Shuts-down Conversation*

- *Discourages feedback*
- *Promotes **Shallow Agreement***
- **Lulls your mind into a False Sense of Security**

## *Styled Ceremony and Ritual*

- *To provoke a behavior, not inform a decision*

# ... VERSUS LEAN'S GENCHI GENBUTU

*“... It's Lies! All Lies!”*

- *Metrics and reports are just maps ...*
- *Get out of your office*
- *Go observe where the work happens*
- *Take your own measurements*

# EFFICIENCY AND TIME PRESSURE

## *Biasing and Priming the Subject*

- Over-Scripting over-focuses attention
- The “Moon-Walking Bear” problem
- Target Lock-On

## *Unringing the Bell*

- The button story and pixel-drop out

# SUMMARY ... A

## *Recognize the Different Qualities*

- Clear, Objective, Authentic, Integrity, Readable, Changes, Attributable, Contemporary, Audit Trail, Retrievable, Reconstructable

*How is your evidence deficient?*

# SUMMARY... B

## *Recognize the Traps*

- Pass-As-Expected
- Lullaby Language
- Moon-Walking Bear

## *Go Observe the Work*



# QUESTIONS AND STORIES

*What is Good  
Evidence?*



*Thank you for attending this session.*

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