Rooted in Quality – Preventing Deviations Before They Sprout

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Outline

Introduction and Background

Why Deviations Happen

Examples

Practical Guidance for Deviation-Resistant Protocols and SOPs

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Introduction

Some deviations can't be avoided, no matter how much you plan.

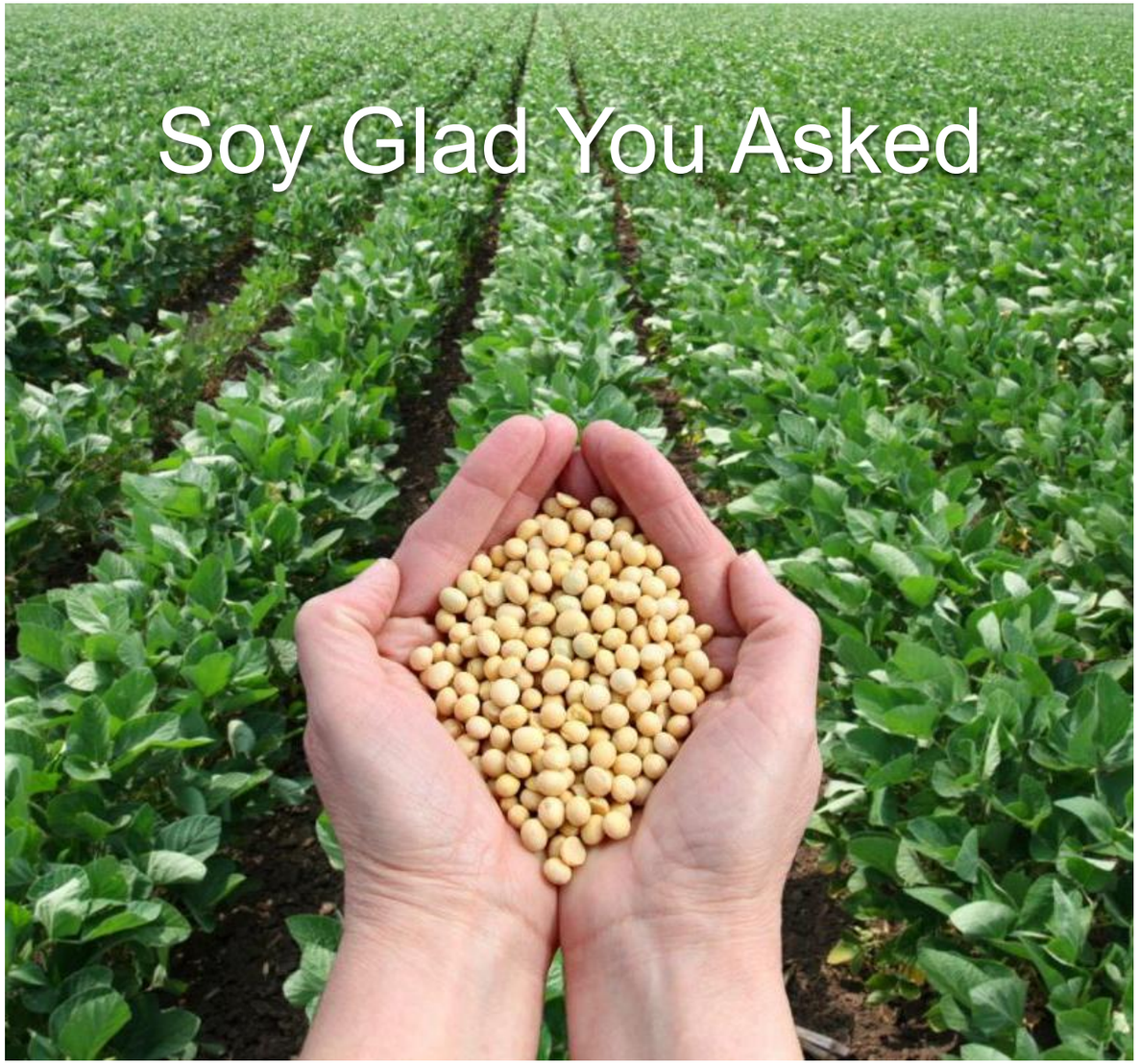
Many other deviations arise from well-intentioned but poorly designed protocols and SOPs.

- Can have an undesired impact on study results
- Even if minor, costs time and money to properly document

How do we proactively avoid these types of deviations?

Why Deviations Happen

- Ambiguity
- Assumed Knowledge
- Mismatch with Reality
- Unverifiable or Unmeasurable Steps
- Conflicts between Protocol and SOPs



Why Deviations Happen: Ambiguity

Ambiguious instructions create room for different interpretations

Examples

- “Mix the solution thoroughly before application.”
- “Use appropriate PPE when handling chemicals.”

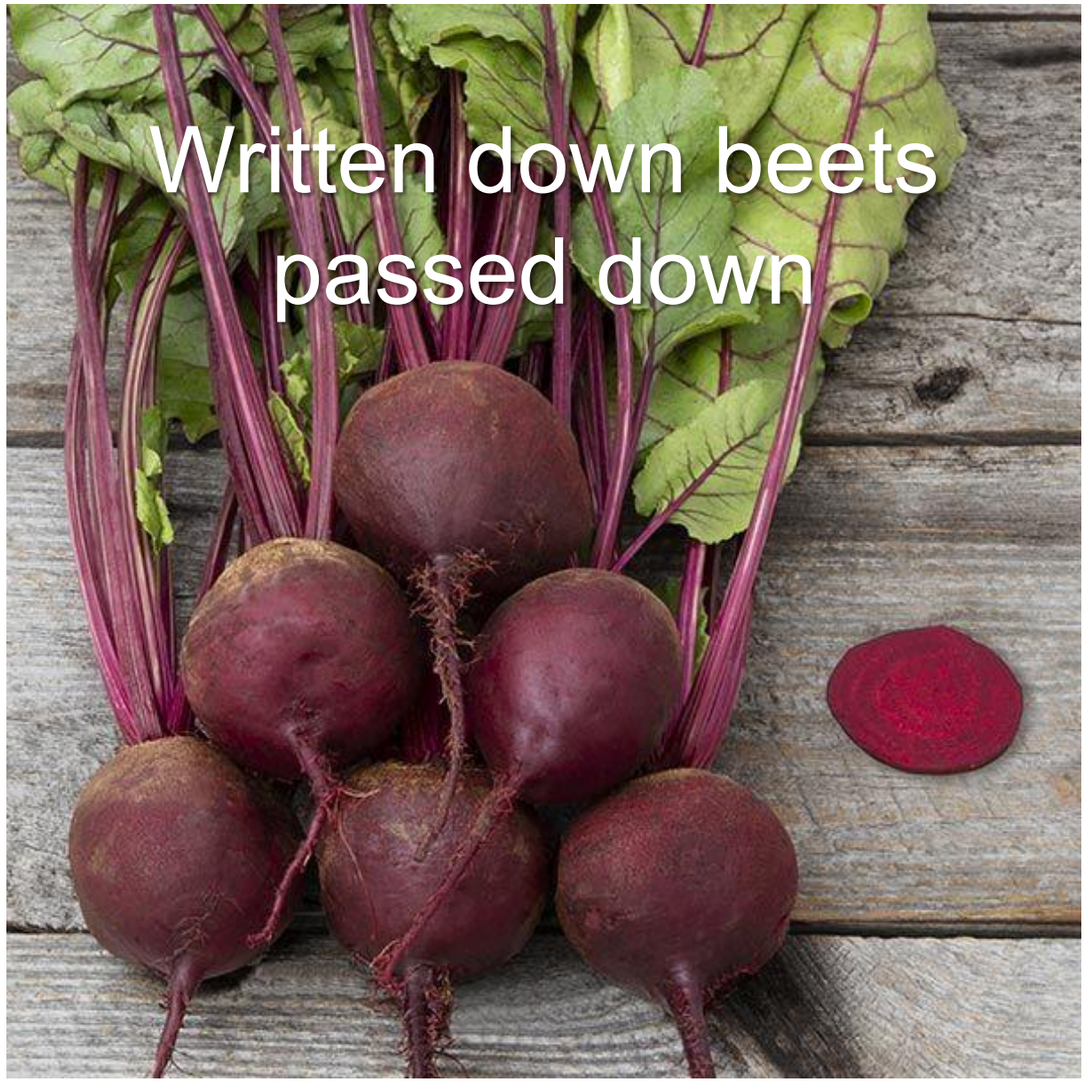
Why Deviations Happen: Assumed Knowledge

Masks gaps in understanding

- Experienced staff may be able to fill in details from memory, but new staff can not
- New or seasonal staff may miss critical steps or perform tasks incorrectly.
- Can lead to deviations and increases training burden

Example

- SOP-123 includes detailed directions for performing sprayer verification using SpotOn calibrators but includes the statement “alterative measuring devices such as graduated cylinders may be used.” There are no detailed procedures for using graduated cylinders to perform verification.



Why Deviations Happen: Mismatch with Reality

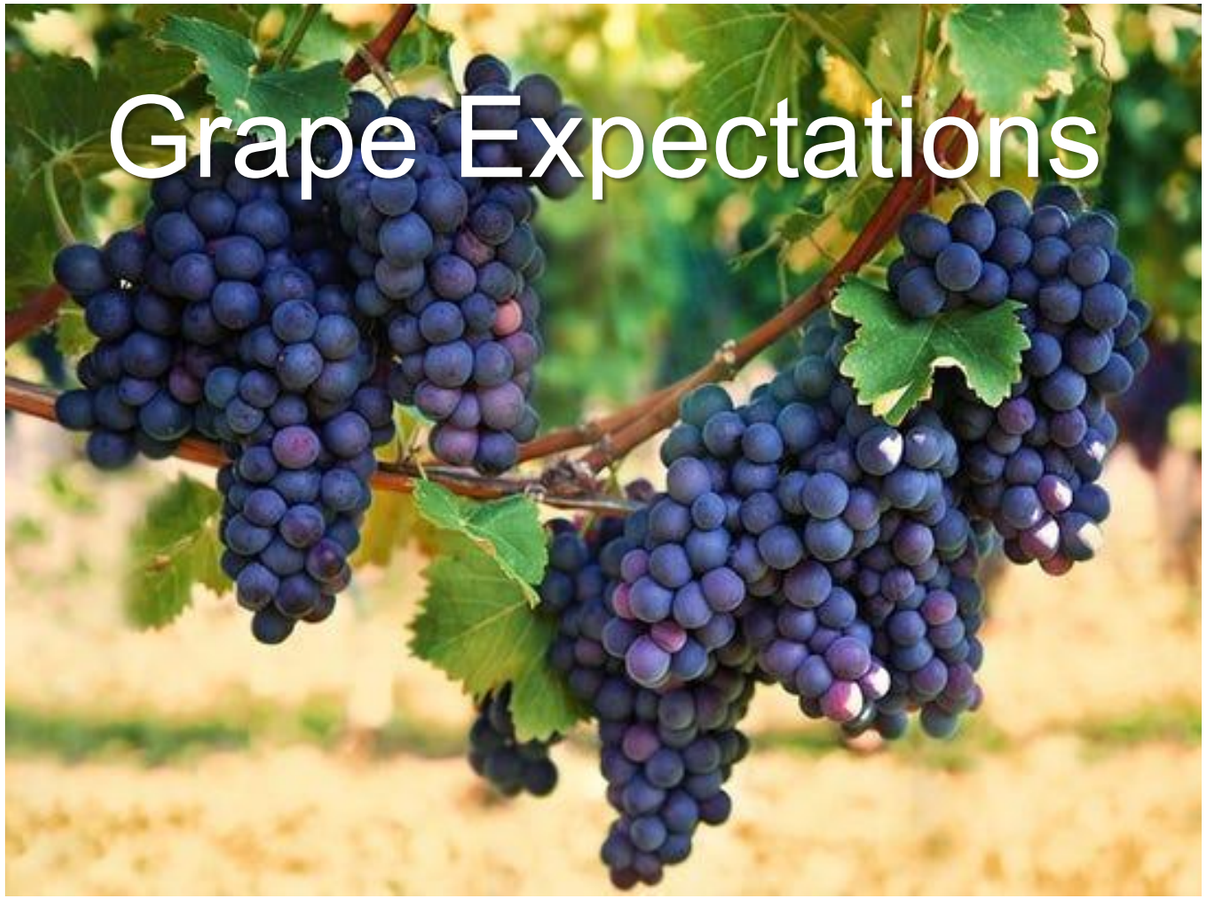
Field work has unique challenges that sound good on paper but may not be feasible.

- Weather
- Timing

Field constraints force workarounds

Examples

- “Collect all samples within one hour of application.”
  - Reality: samples take 5 minutes each to collect and there are 20 samples…cannot meet one hour requirement.



Why Deviations Happen: Unverifiable or Unmeasurable Steps

QA can't confirm compliance without objective evidence

- If requirements aren't measurable, compliance gets explained after the fact instead of demonstrated → GLP deviation.

Examples:

- "Ensure wind speed is within label limits."
- "Confirm no rain occurred within 72 hours of application."

Without appropriate GLP-compliant meteorological data these are unverifiable.

Why Deviations Happen: Conflicts Between Protocols and SOPs

Conflicting instructions can lead to deviations even if staff follow one document correctly.

- Protocols supersede SOPs but staff need to be aware there is a difference

Example

- SOP states that gloves will be changed after sampling all deposition locations along a single transect.
- Protocol states that gloves will be changed after collection of each sample

Communication is critical!

Guidance for Deviation-Resistant Protocols & SOPs

Make Instructions Clear, Specific and Verifiable

- Use action verbs (record, verify, photograph, measure)
- Avoid “should,” “may,” “approximately” and vague phrases
- Provide acceptance criteria whenever possible

Example

- “Confirm sprayer output using SOP AG-204; acceptable if within ±5%.”

Why it works

- Avoids ambiguity and enables clear verification by providing acceptance limits

Guidance for Deviation-Proof Protocols & SOPs

Write for the Actual User

- Aim for clarity for field staff
- Ensure steps can be executed in real world field conditions (dust, gloves, time pressure)

Example

- “Spike mylar cards with 10 µL of the solution prepared in Step 1. Record start and end time in seconds.
  - Note: Work in a team of two to spike and collect the samples. One team member should be responsible for spiking samples and recording the start time. The second team member should be responsible for collecting the early time interval samples and recording the end time.”

Why it works

- Acknowledges the time constraint of a single sampler spiking and collecting samples and noting start/end times.

Guidance for Deviation-Proof Protocols & SOPs

Reduce Cognitive Load

- Chunk long steps
- Bulleted/numbered lists are easier to read
- Illustrations provide visual guidance
- Use consistent formatting so users know where to look for critical info

Example

- “Assemble PUF cartridge filter assembly per the diagram below.”

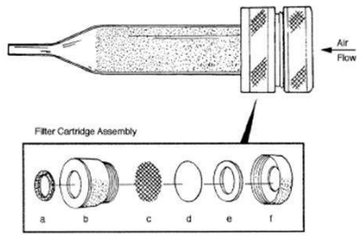
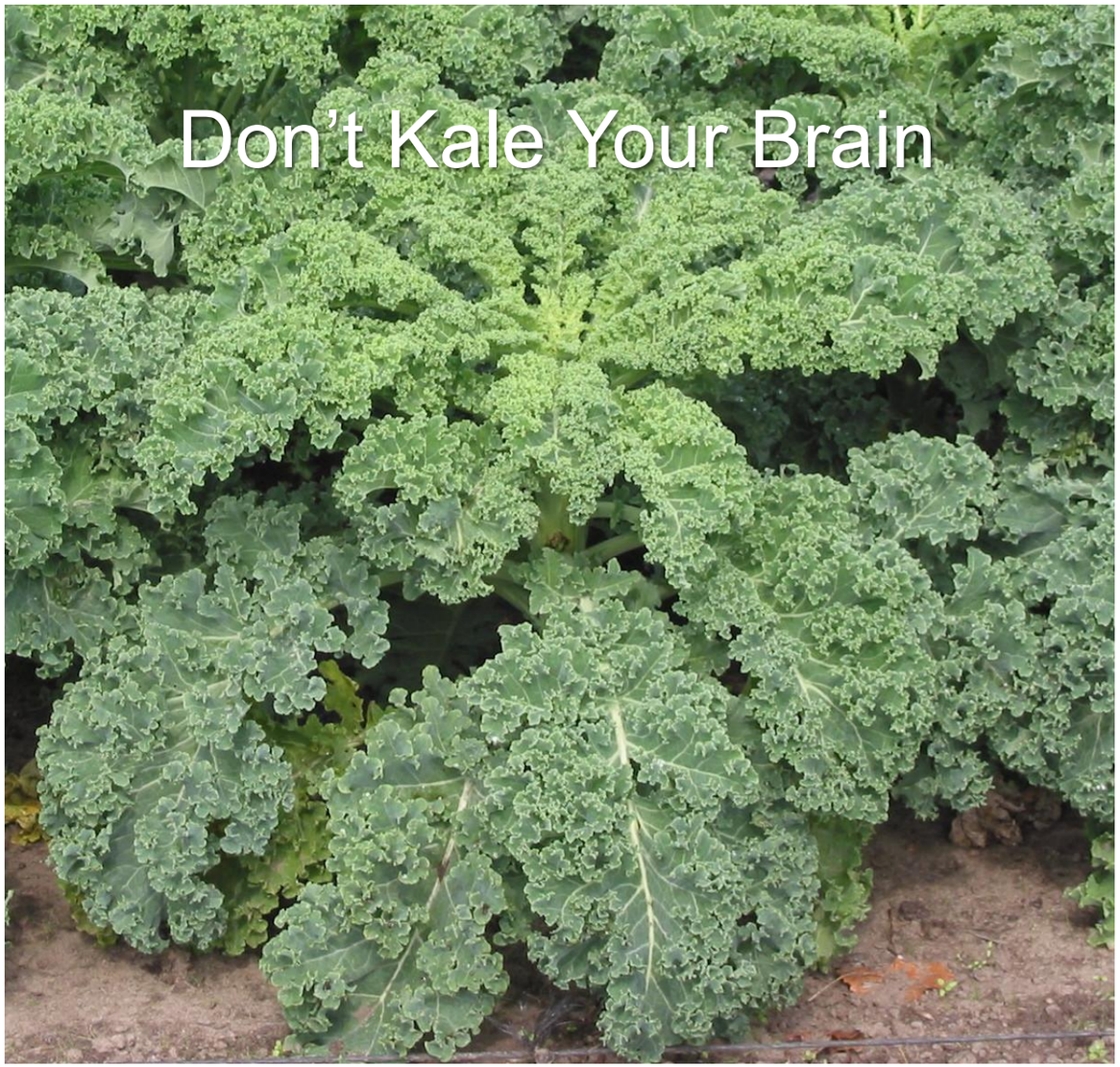


Figure 3. Open-face filter assembly attached to a PUF cartridge: (a) Inner Viton® o-ring, (b) filter cartridge, (c) stainless steel screen, (d) quartz filter, (e) filter ring, and (f) cartridge screw

Why it works

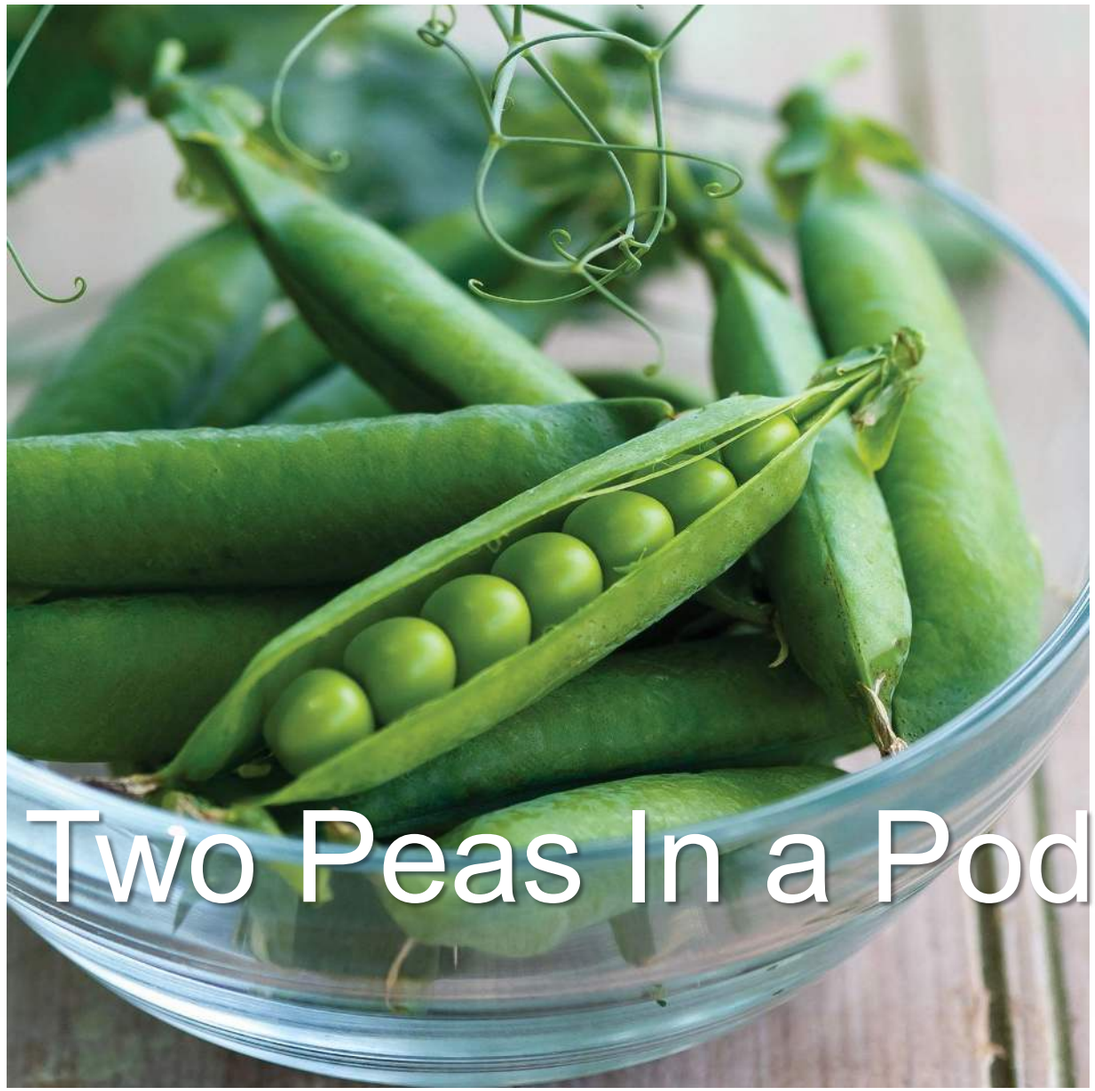
- Diagram provides visual reference



Guidance for Deviation-Proof Protocols & SOPs

Align SOPs and Protocols

- SOP = “how we do it”
- Protocol = “what we’re doing for this study.”
- Neither exist in a vacuum, they need to support one another.
- **If there are discrepancies between the two, communicate clearly to field staff ahead of time.**



Guidance for Deviation-Proof Protocols & SOPs

Example

- Drift deposition SOP can provide general details.
  - Align downwind transects perpendicular to the zero line at distances specified in protocol.
- Protocol will provide exact plot layout and sampling locations.
  - Three transects spaced 10m apart
  - Downwind sample locations at 0, 2, 4, 8, 16, 32, 64, and 100m from zero line.

Why it works

- SOP details how we do it, protocol provides study-specific details.

Document Review Tips That Prevent Deviations

Scenario Testing

- Pretend you're new; follow it step-by-step.
- Highlight anywhere two reasonable interpretations exist.
- Sanity-check to confirm process can be executed under real world conditions.
- Are all materials, tools, and data readily available?

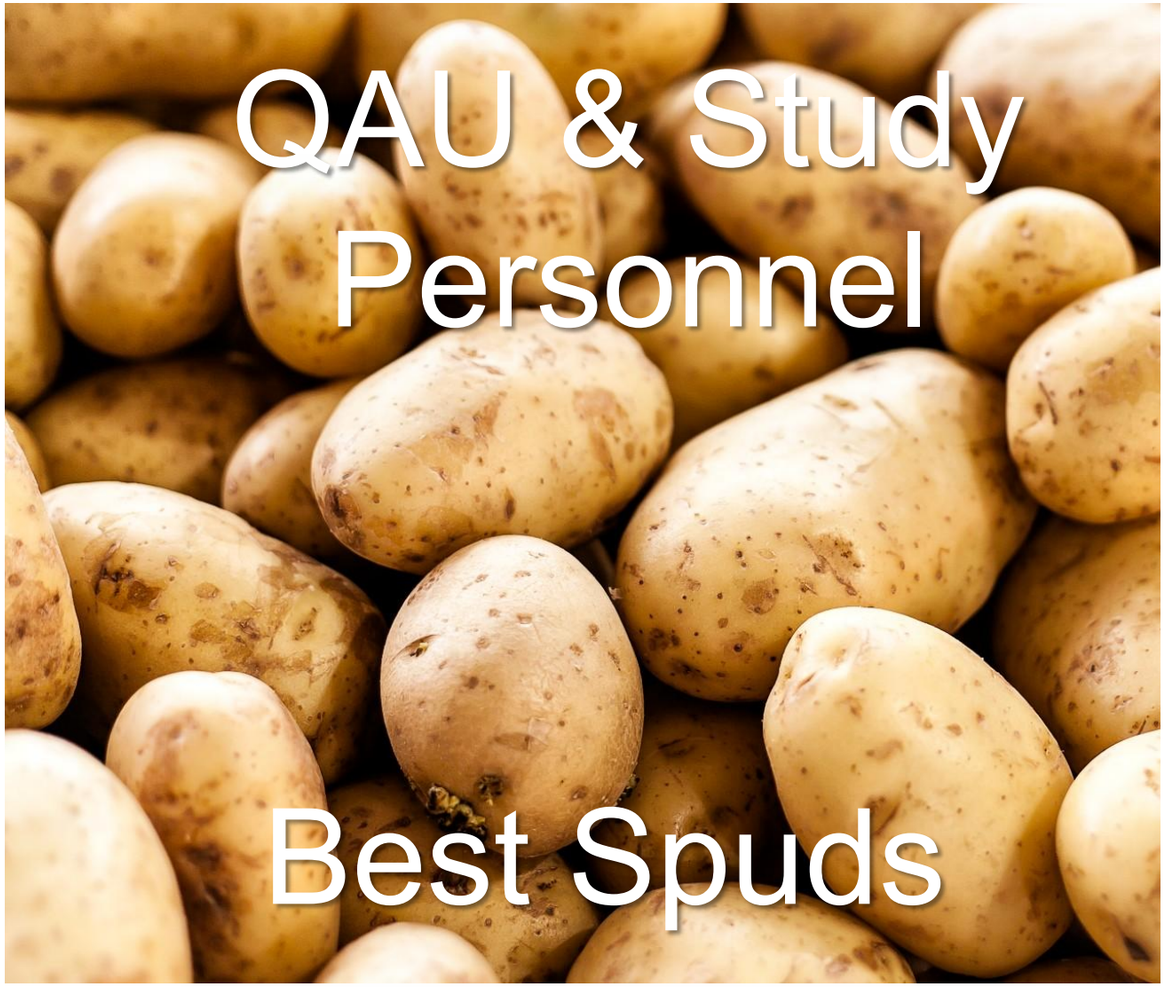
Audit Lens

- Can this be documented/verified?
- Is there a defined method if an alternative is required?
- Would two trained staff do it the same way?
- What record proves this requirement was met?

TL;DR

- Deviations happen; many are preventable
- Common causes include ambiguity, assumed knowledge, unmeasurable steps, mismatched reality, and conflicts between protocols and SOPs.
- Deviation-resistant SOPs and protocols are clear, concise, and realistic for field execution.
- Scenario testing and an audit perspective help identify gaps before the study begins.

Proactive collaboration with QA and study personnel drive quality and compliance and avoid unnecessary deviations.



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Thank you. Questions?

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