



# CAN REGULATIONS AND SCIENCE COEXIST?

Establishing a Quality Culture

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# THE SIMPLE ANSWER

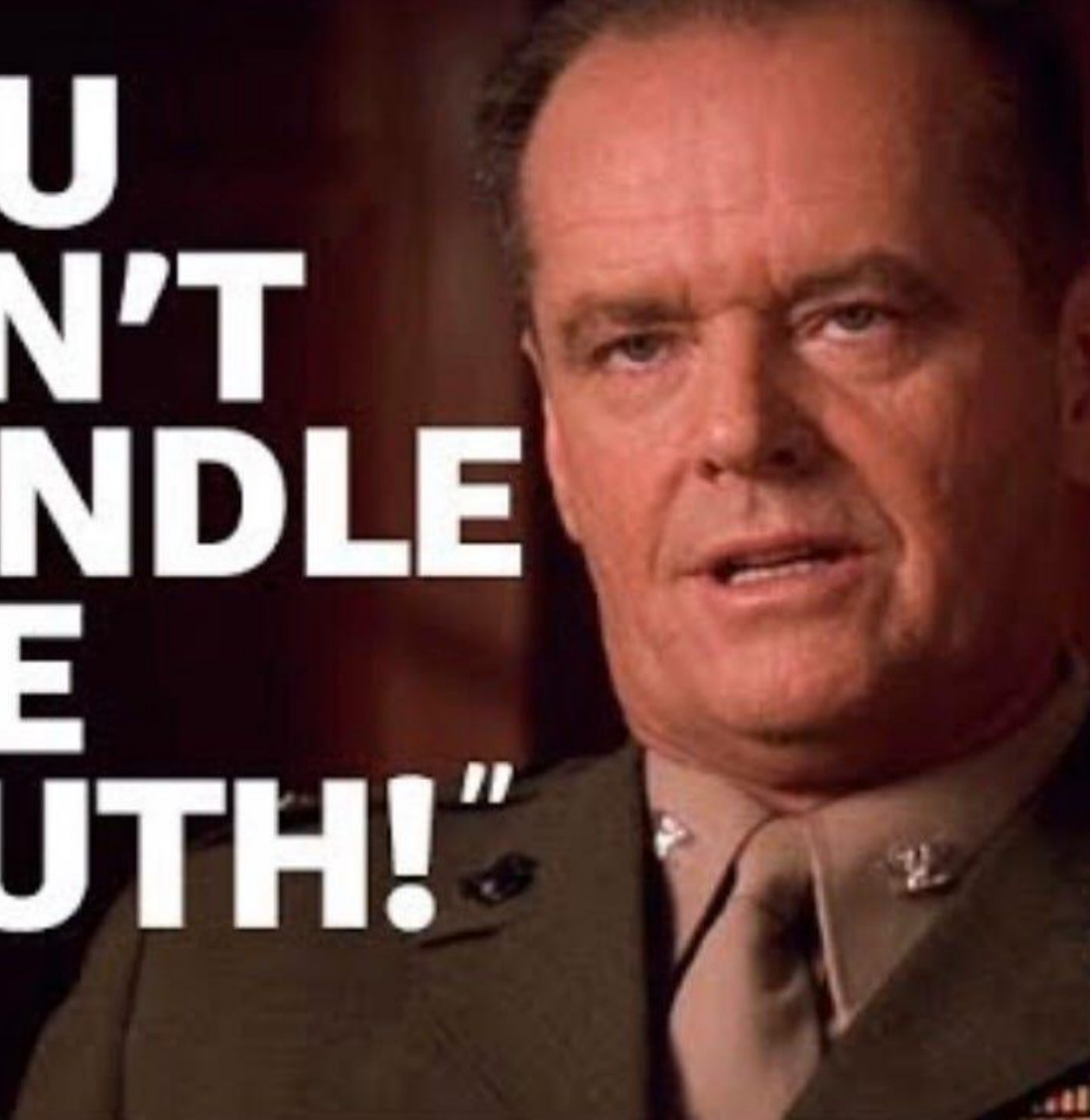
- Yes.
- They have to!
- The regulations came about because of bad scientific method.
- If you can master good documentation, you can master GLP compliance.



# SCIENCE VS. COMPLIANCE

- Science is reality
  - Investigations are designed to be unbiased
  - Scientific method holds up to scrutiny
  - Good science is the truth
- Compliance is the construct
  - Arbitrary rules to comply with
  - Documentation of how/what/where/who/when
  - Records the science, it does not improve it

**"YOU  
CAN'T  
HANDLE  
THE  
TRUTH!"**



# WHAT MAKES GLP COMPLIANCE

- Structured Personnel
  - Management
  - Study Director
  - Quality Assurance
  - Trained Staff
- Operational Documentation
  - Standard Operating Procedures
  - Training Files
  - Equipment Records

# WHAT MAKES GLP COMPLIANCE

- Study Design Documentation
  - Protocols
  - Changes to Protocols
    - Amendments
    - Deviations
    - Unanticipated Events
- Results Reporting
  - Key results must be reported
  - Adverse events
- Retention



**IT'S NOT WHAT YOU KNOW**

**IT'S WHAT YOU CAN PROVE**

# THE PROCESS

- Decide on what path your CRO will follow:
  - GLP
  - GLP-like
  - Non-GLP
- Start some place, just start.
  - Begin drafting one SOP
    - Get the core procedures covered
    - Sign off to approve (you can change later if necessary)



# THE PROCESS

- Decide on data capture
  - Paper
  - Electronic
  - Mix
- Design forms
  - Prompt for critical info
  - Organize data
  - Provide consistency/uniformity

# THE PROCESS

- Qualify Electronic Systems
  - Be Logical
  - Be Practical
  - Be Thorough
- Start Training
  - Know the Regulations
  - Know your SOPs
  - Document, Document, Document

# SECRETS TO SUCCESS

- Know your limits
  - Stay in your lane
- Embrace documentation
  - Come to terms early that you'll write a lot
- Research is a team sport
  - It takes a village
- Don't fear the reaper
  - Mistakes happen

# SECRETS TO SUCCESS

- Stretch
  - Be flexible; respond to last minute changes
- Strength of the Pillar
  - Build the program organically, from the ground up
- Find your Way
  - GLPs offer room for interpretation
- Don't reinvent the wheel
  - Get Professional Help



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# CONSULTING

IF YOU'RE NOT A PART OF THE SOLUTION,  
THERE'S GOOD MONEY TO BE MADE IN PROLONGING THE PROBLEM.