

# GLP Compliance Assurance vs. Quality Assurance

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## Quality Beyond GLP Compliance

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# Outline

- ❑ Why QAU is here?
- ❑ Quality Assurance beyond GLP Compliance
- ❑ Expanding Quality throughout the Testing Facility
- ❑ Benefits of a Quality System

# Why QAU is here...a GLP Requirement

## ❑ GLP requirement

- ❑ EPA: 40 CFR 160.31 (c) *Testing facility management shall assure there is a **Quality Assurance Unit** as described in 160.35*
- ❑ OECD GLP 1.1 (f) *Testing facility management should ensure that there is a **Quality Assurance Programme** as described in 2.*

## ❑ **Quality Assurance Unit must be present to monitor study compliance to the regulations.**

- ❑ QAU responsibilities as stated in 40 CFR Part 160.

## ❑ **Compliance to the GLP regulations is study specific...GLP provides a framework for generating **reliable, reconstructable, and retrievable data.****

# GLP Compliance Assurance...

## QAU Responsibilities



❖ QAU Responsibilities as stated in 40 CFR Part 160.

# QA's Role...

## *Beyond Compliance to the GLPs:*

- ❑ Provide Quality and Compliance Oversight and **Guidance**
- ❑ **Interpretation of the regulations**
- ❑ **Collaborate** to understand and influence industry standards
- ❑ Participate in collaborative **process improvement**
- ❑ Maintain a **perspective** of the **business needs**

# A Successful QA Incorporates

- ❑ Growing **Technical Knowledge**
  - Ongoing **Training**; Both QA and Study Personnel
- ❑ Building effective **relationships** and effective **communication**
  - **Soft skills** to influence quality culture
- ❑ **Proactive** approach rather than a reactive
- ❑ **Collaboration** with stakeholders



# Quality Assurance

## Building a Culture of Quality Beyond the GLPs



□ Leveraging our successes as QA professionals to **expand the culture of quality throughout the Testing Facility**





# Expanding a Quality Culture throughout the Testing Facility

- Drive Continuous Improvement
  - Improvement is a permanent objective
  - Implement KPIs (key performance indicators) & Metrics
  - Proactive approach
  - Benefit :
    - Effective and efficient processes
    - Cost reductions
    - Decisions based on data

# Expanding a Quality Culture throughout the Testing Facility

- Take a process approach
  - Evaluate each process independent of the study
    - Examples: A risk based strategy for auditing data.
    - Implementation of LEAN / 6 Sigma philosophies to gain efficiencies.
  - Benefit:
    - Shortened audit timelines leads to faster product approvals.
    - Quality is built in the processes; rather than a list of requirements to complete a study.

# Expanding a Quality Culture Throughout the Testing Facility

- Make Quality is everyone's responsibility
  - Set quality goals
  - Shared responsibility for quality initiatives throughout your testing facility
  - Benefit:
    - Quality is way of life
    - Involvement of people at all levels including management

# Expanding a Quality Culture Throughout the Testing Facility

## □ Focus on the customer

- Understand customer needs

- Benefits:

- Meet and Exceed Customer expectations

- Minimizing rework / repeats

# Quality Assurance

## Culture of Quality Beyond the GLPs



# Summary

## □ Adopt Quality as a Business Advantage

- Business approach to quality not just a approach to completing a study.
- Benefit:
  - An Agile Business with consistent quality practices
  - Competitive advantage.





# Questions ?

## THANK YOU



# BACK UP SLIDES



# GLP and ISO 9001 together

## GLP

- Study workflow
- Test system
- Master schedule
- Study director, Principle Investigator, Archivist
- QA Unit
- Chain of custody

## Shared

- Management
- Training
- Reference materials
- Equipment & maintenance
- Reports
- Sampling
- Audits
- Corrective actions
- Method Validation
- Quality control

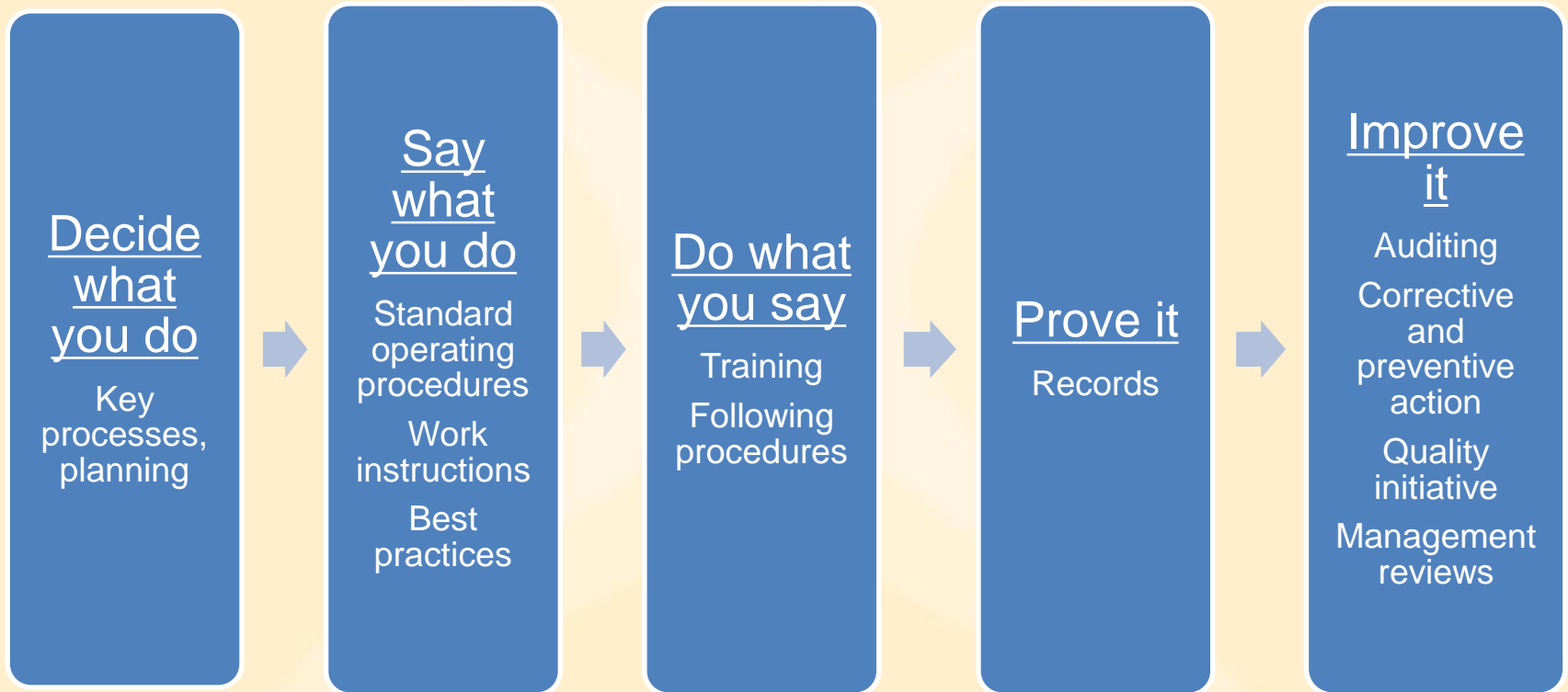
## ISO 9001

- Preventative actions
- Continual improvement
- Focus on the client
- Customer Feedback



# ISO 9001 in Brief

Focus on Customer & Compliance Requirements



We already do all of this...some may be more informal processes



# What ISO 9001 is about:

- ❑ Keep things systematized
  - Interlinked processes
  - Understand how these work together to accomplish desired results
- ❑ Keep things standardized
  - Capture in simplest form sufficient for the need
  - Share best practices and building on history
  - Don't reinvent wheel
- ❑ Keep system sustained
  - Audit for compliance
- ❑ Keep things relevant, current, and fresh
  - Management review system to maintain alignment with visions
  - Determine actions, changes, and resources needed for relevancy
  - Audit for opportunity
  - Continual improvement

