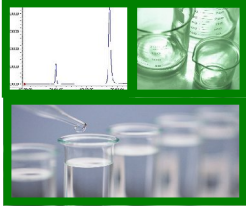


Excerpts from **The Brass Tacks of GLP**

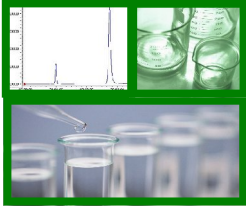
GLP Training Workshop – March 2010
Presented by Celeste Rose, RQAP-GLP
RoseTECH Consulting, Inc
www.rosetechconsulting.com

*This training workshop is sponsored in conjunction with the
FDA compliance learning community of enKap www.enkap.com*



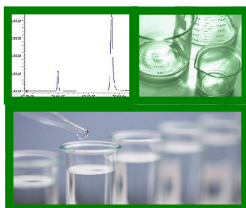
Fundamental Approach

- What is the intention of GLP regulations
- What are premises of GLP fundamental principles
- Why is GLP also GBP (good business practices)

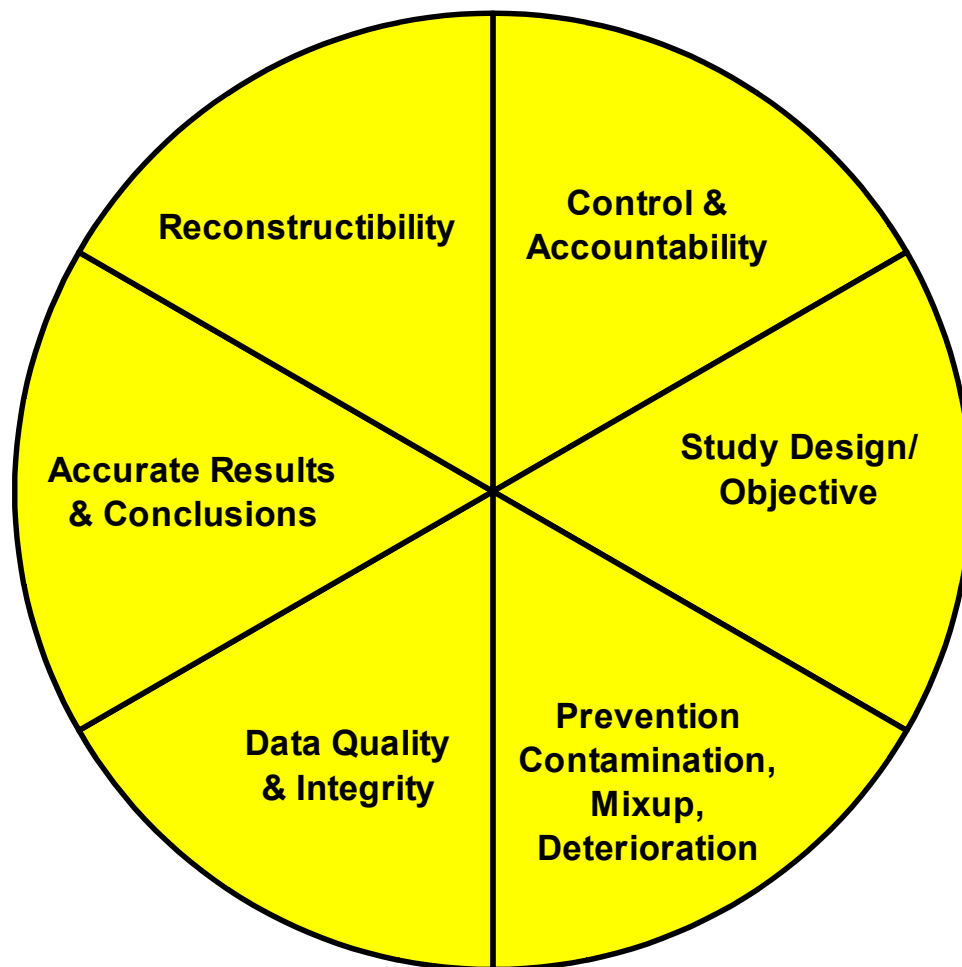


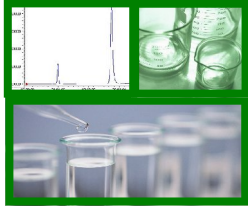
Workshop Goal

- What to gain from this workshop
 - Instinctive understanding of GLP and good business practices
 - Incorporation into everyday practices and functions



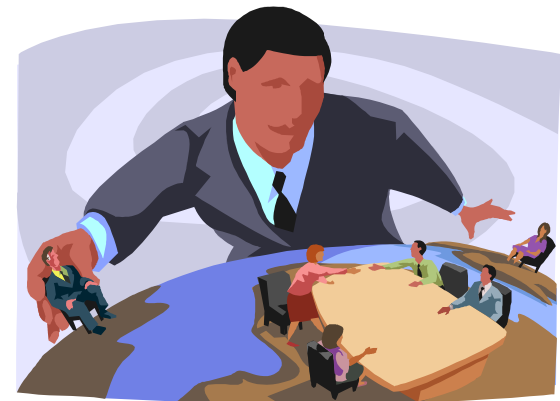
GLP Compliance

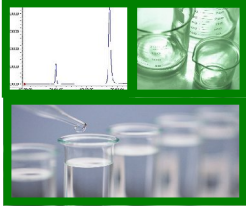




Management

- Mgt responsibilities
 - Sufficient # of qualified personnel
 - Personnel understand assigned functions
 - Documentation of qualification, training, JDs
 - Designate/replace qualified individual as SD/PI

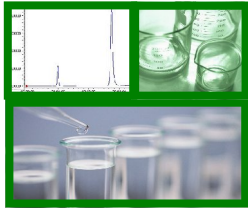




Single Point of Control

- One Study Director – for a study at any given time
- Ultimate responsibility of Study Director cannot be delegated



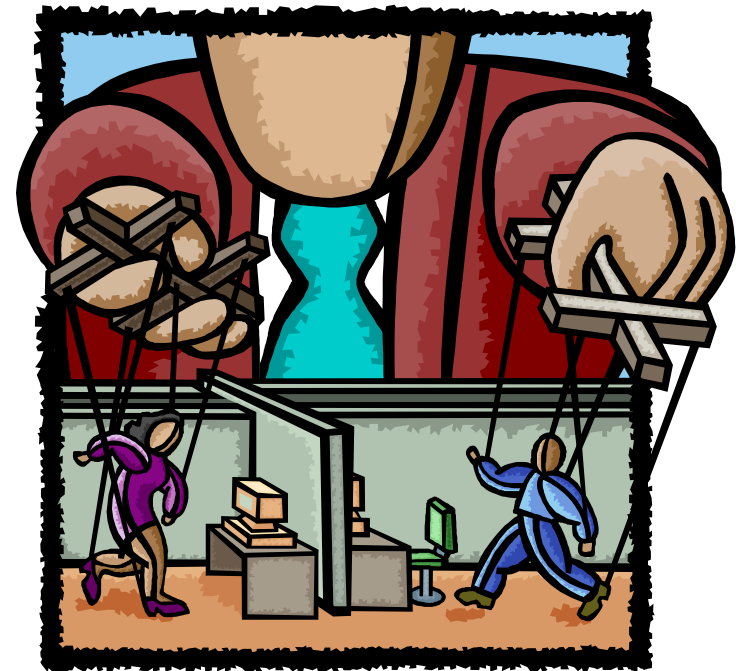


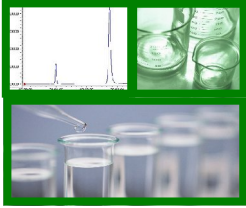
Control vs. Responsibility

The Study Director Disconnect

Generally do not have “business” control of studies

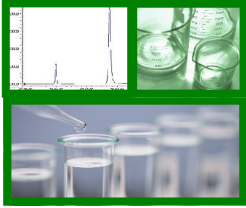
- Personnel management
- Resource allocation
- Prioritization





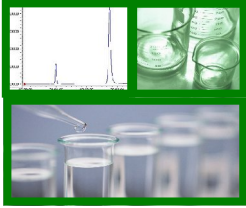
Study Director Roles & Responsibilities

...it's not just 58.33



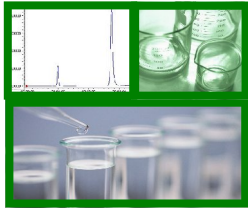
Technical

- Formulate the pre-study plan
- Design the study plan/protocol
- Initiate study meetings
- Oversee data collection, analysis, documentation
- Interpret the data
- Report study results
- Derive study conclusions



Delegation

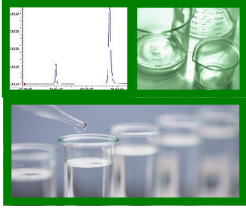
- The ability to:
 - See the big picture
 - Allocate & effectively use resources
 - Be innovative when resources are short
 - Be perceptive to strengths & limitations
 - Use strengths & limitations accordingly
 - Make & execute critical judgment calls



Protocol

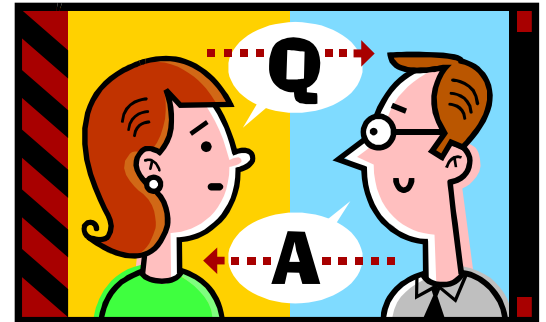
- The protocol is used to
 - Ensure properly planned study design
 - Establish how study shall be done
 - Eliminate bias in study conduct and reporting of results

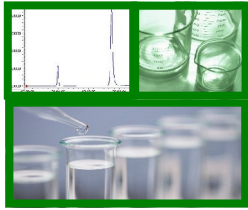




Plan for the Best/ Prepare for the Worst

- Meet pre-study, in-study, post-mortem
 - Discussion is good error prevention
- Well-assembled study file
 - Enables staying aware of study progress
 - Facilitates data review, evaluation, and report

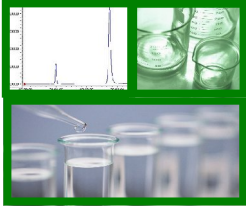




Study Integrity

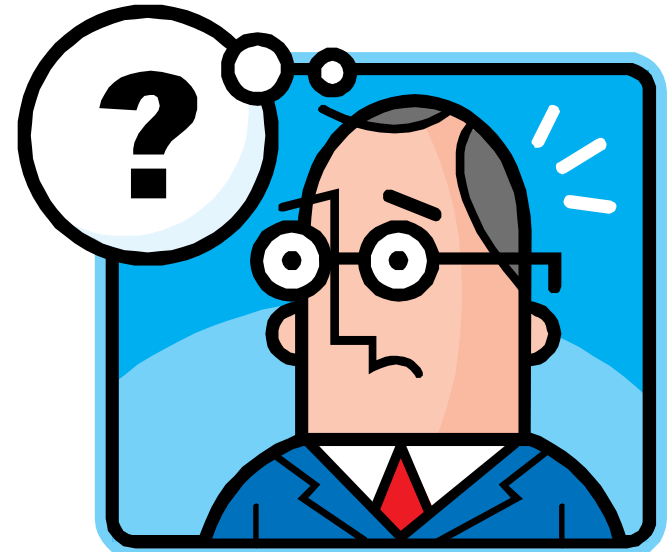
- Study Integrity is dependent upon
 - Qualifications of personnel
 - Test/control material integrity
 - Test system integrity
 - Lab operations & procedures
 - Equipment fitness for use
 - Study file organization

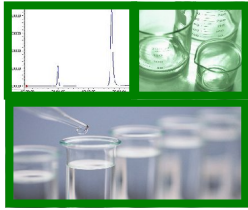




Point to Consider

- *Isn't the integrity of a reference material as important to the integrity of the study as the integrity of the test and control materials?*





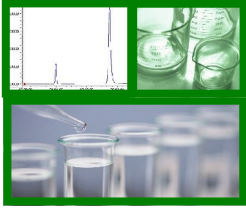
Raw Data

GLP Definition of Raw Data

1. Any worksheets, records, memoranda, notes, or exact copies thereof,
2. Result of original observations & activities of study

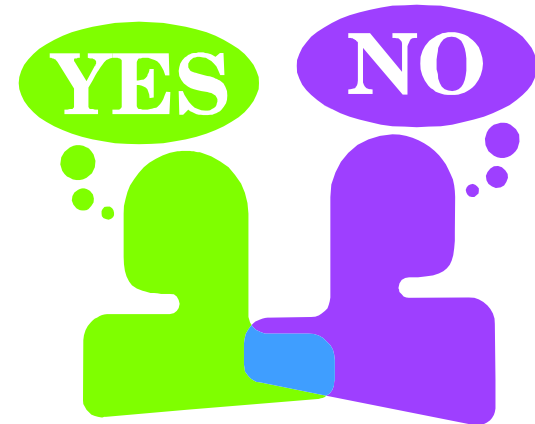
AND

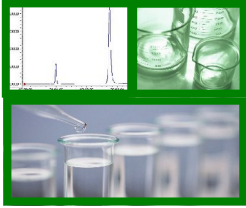
3. Necessary for the reconstruction and evaluation of the study report



Fact vs. Opinion

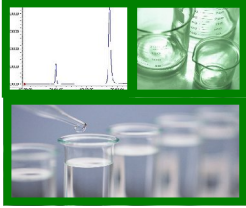
- Accurate, complete content
 - Factual, based on the data
 - Clear, concise
 - Do not over claim conclusion
 - Clearly state any assumptions or unknowns
 - When results are inconclusive, state so





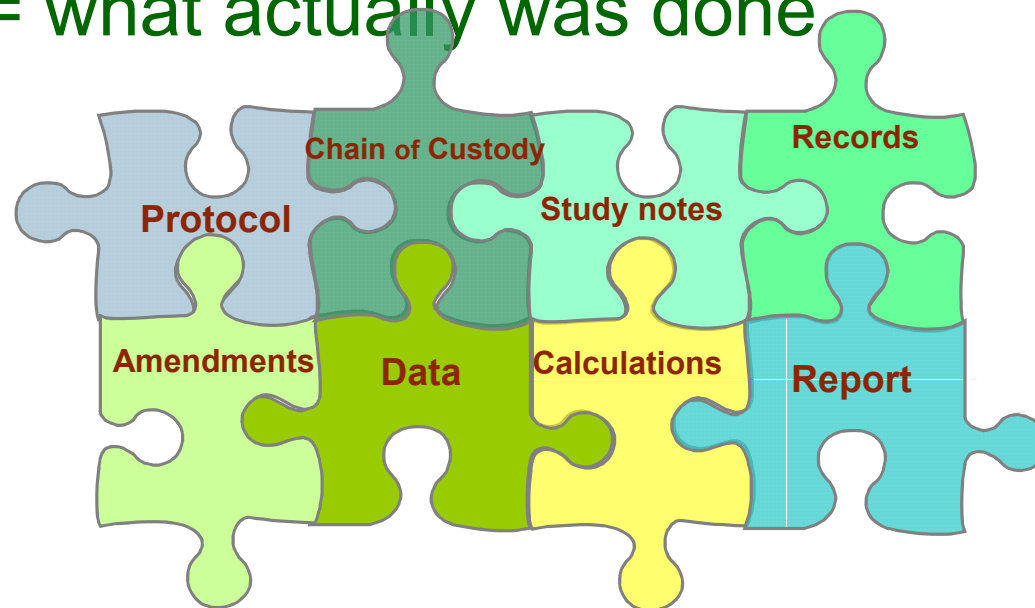
FDA 483 Findings

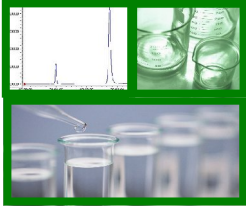
- Study Reports 58.185
 - Did not contain data required in the protocol
 - Did not accurately describe procedure used
 - Data did not substantiate report
 - Did not report changes to protocol



Reconstructibility

- Protocol = what shall be done
- Study File = what actually is done
- Final Report = what actually was done





Summary

- Brass Tack Fundamental Elements
 - Background on why GLP exist
 - Familiarization of regulations/standards
 - Understanding of GLP requirements
 - Respect for importance of GLP principles
 - Sources of information/resources
 - Knowledge applicable to job function
 - Soft Skills