

# Laboratory Quality Quiz (Take One)

- Quiz Utility:
  - Help laboratory staff have goals of continuous improvement!
  - Give clients of laboratories questions to determine if a laboratory can support basic research, drug development, or assist with release assays.
  - A range of responses is expected!
  - Very few academic laboratories will have to meet these standards of quality.
  - cGMP laboratories must meet these standards and more.
- How do you rate?

# Laboratory Quality Quiz

- Do you have a notebook or computer data base to track incoming samples?
- Do you record all sample preparation steps in a traceable manner?
- Do you document the status of each sample from entry into the lab until it is dispensed according to client's wishes?
- Do you monitor the temperature of the cold box or other equipment for sample and reagent storage and record dated values for future reference?
- Have you installed temperature monitoring instrumentation for sample and reagent storage equipment?
- Do you store temperature data in a controlled location for integrity and future reference?
- Do you date arrival and mark out dates on reagent bottles when they arrive in the lab?
- Do you keep a good reagent inventory list?

# Laboratory Quality Quiz

## continued...

- Are all instruction and reference manuals available in a known referenced location for check out by staff?
- Have you written procedures for the operation of your equipment and instrumentation?
- Have you placed these procedures in a controlled location?
- Do you have a mechanism to know if someone in your lab changes the procedures?
- Do you have a mechanism to control these changes and alert all of your staff to the changes?
- Is appropriate laboratory equipment and instrumentation in your laboratory on routine preventative maintenance schedules?
- Do you have a maintenance and repair log for each appropriate piece of equipment and instrumentation?
- Is appropriate laboratory equipment and instrumentation in your laboratory on routine documented calibration schedules?

# Laboratory Quality Quiz

## continued...

- Are the steps of performed and written raw data placed in a notebook?  
Bound?                      Signed?                      Dated?                      Witnessed?
- Do you have efficient procedures to ensure and document that your staff is appropriately trained?
- Do you follow validated method protocols?
- Do you record and explain each deviation from the protocol?