Management Responsibilities with Respect to GLP Regulations & QA

Kathryn Hackett-Fields,
RQAP-GLP IR-4 Project Headquarters

Who is “management”?

- Simple: The person or entity responsible for allocation of resources necessary to carry out facility operations .
- Is it really that simple?

Let's consider some details -

- A crop sample freezer is *controlled* by thermostat. It is monitored by equipment-generating records. These are to be downloaded & printed.
- A person initials and dates them, and the records are filed. The monitoring devices are periodically calibrated, and *those* records are filed. Later, everything is archived.
  - That's just for one freezer! Where are the GLP concern points?
- Facility, equipment, protocol requirements, personnel, training, data management & archival.

What are the overall expectations?

- Subpart B is a good starting point. 160.31
  - planning, organizing and delegation,
  - selection & replacement of appropriate staff,
  - coordination of systems, schedules, equipment,
  - personnel management – highest % of budget,
  - and specific requirements for the facility and type of test system(s) in use.
- GLP knowledge is fundamental to success – how naturally do *you* “think GLP” ?

An early conclusion:

- Management is the setter of standards and expectations for the whole organization.
- GLP requirements force more attention to:
  - details, as we saw in the freezer example,
  - daily operations, including security issues,
  - control of variables. Always *sounds* easy, right?
- Delegation is a management tool, but the final responsibility cannot be transferred.
  - Be careful when assigning to your support staff.
  - You must follow up, coach, communicate clearly.

Unpacking the expectations

- Personnel section of GLP, Subpart B 160.29
  - Selection, training, prior education = records.
  - Who needs it? Study conduct or supervision.
    - Study Directors, technicians, field workers need education, training and experience for the performance of assigned functions.
    - What about: QA, technicians, archivist, the person in charge of test substance intake & sample shipment?
    - Who takes care of critical equipment?
  - In short, be sure all the bases are covered by GLP and other training specific to their functions.

Unpacking the expectations, continued

- Early, FDA GLP concerns with the vivarium show a focus on *diseases* and transmission.
- But field work is not exempt from risk and hazard
  - What are the risks for your work?
  - Many focus on harvest…but what is the protection during the growing season?
    - Management decisions regarding field or site access, who should operate certain equipment, disaster recovery.
  - Worker safety and worker contamination issues in field, irrigation canals, chemical handling, crop sampling.
  - Are there any county or State-specific requirements that should be built into your SOPs?

Unpacking the expectations, continued

- Appropriate clothing, changed as often as needed to prevent contamination.
- "All personnel shall be instructed to report…any health or medical conditions that may reasonably be considered to have an adverse effect on a study."
  - What about medications that can cause inattention?
  - Illegal drug or alcohol use on the job?
  - What are other ways that your staff could be reduced? Is any backup help needed? Where will it come from, and how will training be handled?

Unpacking the expectations, continued

- Study Director (SD) interactions, 160.33
  - Management must "identify" the SD most qualified to control the study – prior to study initiation.
    - What is your procedure for this? For replacement?
      - SD on vacation is not "replaced" but back-up given.
  - First line of GLP compliance is the SD
  - Note the extensive list of SD responsibilities, and plan to monitor and assess them.

Unpacking the expectations, continued

- QA interactions
  - This group "assures" you of…what?
    - So, their scope is similar to that of Management:
      - "Facilities, equipment, personnel, methods, practices, records and controls"
    - QA personnel require specific, continuous education
      - Attend yourself from time to time, so you can appreciate their perspective, learn what's new or being planned by the government.

SOP Points for Management

- What SOPs would *you* require for QA?
  - Compare your list to that in the GLPs
  - What is a “control” in your facility?
- What are your methods and practices?
  - Related to SOPs, policies and even personnel records to some extent.
- With regard to both QA and other personnel, what is the role of the job description?
  - A prime point of inspection by regulatory agencies!
  - Be sure communication and reporting expectations are described for all personnel.
- Set up a simple system for review of SOPs

When quality is not assured

- Remember the GLP focus on “studies” and be sure specifics are documented.
- Is it a study or facility-related problem?
  - What is the cause? Could it happen again?
  - Personnel issue? Be careful to get all details to asses the situation fairly & take action.
- Did this problem impact a range of studies?
  - Might need to back-track, get dates or times, put a team on the problem if necessary.

Yet another area for Management…

- Test, Control and Reference substances
  - A critical responsibility, but often you are without authority to control. What will you substitute?
  - Reliable chemical sources? COA format?
    - What regulations were in force for characterization?
  - Documentation – where is the characterization raw data, and a retention sample of the lot, to be archived?
    - Final report information and/or EPA inspections
  - Communicate your needs and maintain a good relationship with suppliers.

Pulling it all together:

- In a sense, Management has a parallel to Study Directors – the point of control.
- How do you communicate with all staff?
- Evaluation, improvement, assessment and adjustment systems:
  - Personnel – make the annual review “2-way”
  - SOPs – is this procedure currently adequate?
  - Equipment life & replacement schedules
  - Data storage, with particular challenge for electronic data’s long-term storage needs

It's a big job, but you can excel!

Make sure you're a familiar, approachable figure around the facility. Bee around!

Don’t be a drag on operations…

- Assess things fairly, but don’t postpone making changes as you see needs arise.

Closing advice -

- Pick one area that got your attention today and begin thinking, planning and acquiring what will be needed for success.
  - Repeat as necessary
- In the next few months, dismantle at least one “wall” that stands in the way of better communication. Celebrate!
- Accept that change is hard, not always welcome, but if Management doesn’t take charge, somebody else will!