
Management Responsibilities with Respect to GLP Regulations & QA



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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” ?
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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.
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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.
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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?
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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?
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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
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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 assess 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.
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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.
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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
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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!
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