Departmentalization Coordination: A Team Approach

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ABSTRACT

For most large laboratories, functional departmentalization, i.e., grouping of activities by functions performed, provides multiple advantages by placing employees with technical expertise and process experience into distinct operational units throughout an organization. However, separation of functional units can lead to a loss of awareness of the diverse requirements that related departments must meet as well as the overall corporate goal. As QAU auditors or mock-agency inspectors, we often see this illustrated during facility visits in the form of conflicting SOP instructions, overlooked SOP responsibilities, lack of process understanding by study personnel, and documentation of unnecessary procedure deviations. To address the challenges resulting from departmentalization, this poster explores how to implement functional teams that cross over traditional department lines to coordinate operational requirements.

DEPARTMENTALIZATION

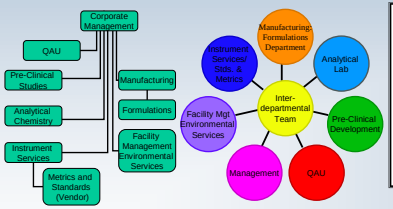
Definition: Functional departmentalization is the business practice of allocating activities to personnel work groups according to functions they perform.

Application: For quality assurance professionals, this translates most commonly to separation of laboratory activities linked to equipment calibration and maintenance, environmental and storage unit control monitoring, and information technology tasks.

Advantages:
- Department can be staffed by experts with specialized training
- Consistency among departments for repetitive activities (i.e., balance calibration)
- Human resource balance among functional operations
- Shared management responsibility
- Supervision is facilitated
- SOP economy
- Coordination within the department is easier

Disadvantages:
- Personnel unfamiliar with procedures performed in their department by others
- Inter-department documentation of activities is often not accessible
- Delays when there are problems
- "Layered" SOPs sometimes contain contradictory instructions
- Decision making becomes slow and bureaucratic
- Lose sight of organizational goals/issues
- Accountability and performance are difficult to monitor

Departmentalization to Coordination



QAU ROLE: AN OPPORTUNITY

Although a departmentalized management approach makes sense in larger organizations, resulting coordination challenges among separate but related functional groups must be addressed pro-actively. Several management theorist authors (Drucker, 1954; Koontz & O'Donnell, 1964) emphasize the need for establishing "control systems" that serve the purpose of facilitating decentralized decisions, while still aligning all sub-units to the overall goals of the organization. More modern authors use "coordinating" in place of "controlling" to more accurately describe the collaborative effort. In the Quality Assurance world, the QAU has a unique opportunity, with management buy-in, to assist and promote team building across departments to solve communication and operations challenges. In addition to a leadership role, the QAU acts in an advisory capacity and as a regulatory resource. Department staff designated as equipment officers, SOP advisors, and/or interdepartmental liaisons can successfully overcome problematic issues that are not only visible to outside sponsors and clients, but negatively affect the quality standard of research to which all staff are committed.

INSPECTION SCENARIOS / THE PROBLEM DEFINED AND ITS IMPORTANCE / POSSIBLE SOLUTIONS USING CROSS-DEPARTMENT TEAMS

Conflicting process descriptions in SOPs:

The Formulation SOPs require that the deionized water system be serviced by facility maintenance personnel on a biannual schedule. However, the General Facility SOPs require that all facility deionized water systems be inspected and serviced by an approved outside vendor on an annual basis.

The Formulation Lab procedure is not consistent with the facility over-arching SOP designating who performs the water system maintenance and how frequently the maintenance is required. This problem is often seen in organizations that have SOPs describing similar tasks in related departments or when there is a hierarchy system for written procedures, designed with increasing levels of detail. In this document structure, high level SOPs can be referred to as "policies", documents describing general department tasks are "SOPs", and detailed steps are described in "Work Instructions". Regardless of document structure design, departments run the risk of SOP deviations when procedures from different departments are not coordinated.

People: Cross-Department Teams

Separation of functional units gives rise to the need for cross-department coordination to provide control over related processes. This control can be accomplished by designating specific individuals within related departments to participate in interdepartmental teams which would routinely review SOPs pertaining to related processes, in this case the deionized water system maintenance. The conflicting policies would be resolved and SOPs revised to reflect the actual practice.

Management Support

Cross-departmental coordination needs to have upper managerial support as directed by the complexity of the organizational chart. Typically, the more separated the lines of authority are, the more difficult communication and collaborative decisions among departments become.

Cross-Department Team Tasks
- Review related tasks among the departments.
- Ensure that organizational activities are consistent.
- Review and contribute to SOP writing/revision.
- Ensure that department staff are trained in relevant SOPs from other departments.
- Provide feedback on proposed changes in processes.
- Aid in Decision-making.
- Facilitate communication among departments that have a common organizational goal.

Outside Vendor Considerations
- Make sure tasks performed meet all departments' objectives.
- Use a team effort for routine reviews.
- Verify that documentation practices are sufficient to meet regulatory expectations.
- Liaise with the QAU for periodic quality inspections.

Absence of documentation and Lack of knowledge by study personnel:

Equipment maintenance and calibration logs for freezers had no entries. The only documentation of calibration is the calibration stickers on the units. When interviewed, staff did not know how often freezers were calibrated or how the procedure is documented.

This is an example of an organization in which equipment calibration and maintenance are the responsibility of one or more departments other than the labs in which the equipment are used. Therefore, the SOPs governing procedures affecting laboratory processes are maintained by separately managed groups of personnel. As a result, lab personnel do not have custody of storage unit maintenance and calibration documentation. Laboratory management, study directors, and the QAU must be assured that regulatory-required processes and scientifically sound controls of test article and study sample storage are in place so that data generated during study conduct are reliable. In addition, lab staff should be aware of critical processes affecting study-related activities and documentation practices should meet standards of accessibility and uniformity.

Tools: Equipment Policy Handbook

An equipment policy handbook is one tool that a department could employ to consolidate equipment maintenance and calibration procedure information from various other department SOPs and/or outside vendors. This handbook would be a useful reference for study staff, study directors, lab management, sponsor representatives, and QAU.

Logistics

The handbook can be a written document or electronic. It can provide brief information, such as an interdepartmental SOP list indexed by task, or provide abbreviated descriptions of equipment practices. An equipment officer is designated to oversee this document and to participate in the inter-department team discussed under the SOP scenario. Coordination with other team members would eliminate duplicate instructions and clarify procedures. Ongoing maintenance and update of the handbook becomes an integral part of cross-department team tasks.

Topics
- Glossary of terms (annual, biannual, biennial, semiannual, etc.)
- Equipment inventory
- Vendor identification and contact information
- Equipment life cycle (installation, validation, retirement)
- Procedures for malfunction and repair (emergency back-up, disaster recovery)
- Maintenance (scheduled, non-scheduled)
- Calibration (intervals, basic procedure, and failure contingency)
- Equipment relocation (re-validation)

Example of Equipment Handbook Contents
- For each topic, the following information should be summarized or the appropriate SOP referenced as applicable:
- What department/vendor is responsible
- Who to contact
- Procedure overview
- Frequency of task (validation, calibration, maintenance)
- Access to documentation
- SOP reference

QAU unaware of other department SOP responsibilities:

Drug Development Services department SOPs described review activities to be performed by the organization's Quality Assurance Unit (QAU). QAU personnel were not trained on these SOPs and were unaware of the activities required by the Drug Development Services SOPs.

The departmentalization approach can reduce communication between departments and create a narrow perspective; employees may lose sight of what other departments need to know to meet procedural expectations. This scenario points to lack of staff training, SOP deviations, inefficiencies, and failure of the critical review activities, directly impacting data quality.

Team Support: QAU Team
- Summary reference of non-QAU SOPs that involve action by QA.
- Departments referenced in SOPs are informed at initial approval and revision of SOPs.
- Master listing of SOP training requirements.
- SOP Responsibility Table

Other QAU team support tasks:
- Vendor audits
- Interdepartmental inspections
- Review of maintenance/calibration documentation during lab inspections
- Conduct personnel interviews
- Implement an internal inspection program with adequate intervals to be effective

SOP RESPONSIBILTIES

Department	SOP# and Responsibility			
	1	2	3	4
Study Personnel	X		X	
DDS		X		
QA			X	X
Formulations		X		

SUMMARY

Interdepartmental teams with the responsibility of overseeing related tasks, responsibilities, and SOPs can solve problematic issues that arise as a result of departmentalized management. QAU has an opportunity to participate in an advisory role in these teams to maximize coordination of operations, documentation, and staff awareness.

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