Case Studies in Laboratory Management

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Objectives

- Discuss considerations for several business/management decisions that might impact the management of Laboratory Operations and Compliance
  - Describe options for tools to help expedite processes
- Share experiences between attendees

Case 1-
Organization, Financial & Business Needs

- CEO wants you to implement an outreach program and he wants it done in record time
- Target=local medical groups
- Test Menu includes the spectrum of testing in terms of complexity as well as new LDT molecular testing
- Multiple sample types
- You've never done this….where do you start?

Considerations-Case 1

- SWOT?
- Risk Analysis?
- Both?
- What about Project Planning
  - Resources
    - Implementation vs. Maintenance
  - Pre Analytic
  - Analytic
  - Post Analytic
  - IT needs
  - Who's selling; what are they saying?
  - Who's collecting the sample?
  - What else should be considered???

SWOT Analysis

Considerations-Case 1

- SWOT Approach
  - (maybe fold in the Risk Analysis at the same time?)
- Strengths
  - Increased volume/revenue
  - Increases support of physicians
- Weaknesses
  - Insufficient testing capacity with existing staff
  - Need new testing platforms
- Opportunities
  - Ability to position lab as center of excellence
  - Ability to partner with local hospitals in terms of ACO management
- Threats
  - Budget (more instruments, staff, inventory)
  - Staffing (CLS shortages; potential need for multiple shifts

Case 2-Organization & Personnel

- 2 colleagues assigned to new Committee and provided with several deliverables related to
- Neither has the time for such assignments
- One took a positive approach and managed to create some (but not all) of the deliverables
- The other took what appeared to be a more negative approach. with reduced productivity and a perceived change in attitude (for the worse)
- What's a Manager to do?

Considerations-Case 2

- Negative feedback vs. Constructive feedback
- Drive by process
- Define targets for excellence and personal accomplishment
- Ongoing feedback/meetings
- Still may need to escalate if issues continue

Case 3-
Process Management & Business Practices

- This same CEO in Case 1 decides that management is not moving faster
  - Can't understand why new molecular assay can't be "ready for prime time by the end of the week (and it's late on Tuesday)
  - Individual believes that talking louder will help get things done faster
  - What to do?

Considerations-Case 3

- Project Schedule Illustrating Tasks?

Scheduling Tool

- Existing processes signed off by Medical Director?
- Compliance requirements
  - What if it's FDA cleared/approved?
  - What if it's an LDT?
- Transparency for Timelines
  - Management Challenges often (but not always) remedied with increased transparency

Case 4-Information Management

- A small local laboratory at a clinic is going to come under your management
- This laboratory actually has quite a large client base with multiple interfaces
- Your due diligence finds a lack of validation data for the Information management component of your Quality system
- You have neither the resources or time to perform a full validation of the system
- What do you do?

Case 4 Considerations

Investigation

- Location of customers?
- Already interfaced?
  - Can existing interfaces be used?
- Who draws the samples?
- Who processes the samples?
- Sample Transport already in place?
- What else should be considered?

Validation Planning

- Retrospective OK?
- What to validation?
- Critical Control Point Strategy?
  - http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm
- Scheduling Tool AND Validation Checklist??
  - Something else??

Case 5-Assessments and LDT Internal PT

- Your Quality Assurance Program requires an internal audit of your entire Quality System ever 12 months
- You offer a Laboratory Developed test that has been available for 5 years both from your lab and several others
- A review of the validation documentation shows a complete set of data in alignment with CLIA and Quality requirements
- The audit findings show that the "owner" of the assay who was responsible for conducting the internal proficiency testing (PT) has left the laboratory and the transition to the next internal PT event was less than smooth
- You find out about this at month 7 when you get a complaint from one of the other labs who states: our PT is failing because of your test
- What do you do?

Considerations-Case 5

- What are the requirements/options for LDT PT?


Document

- What are the challenges with LDT PT?

Investigation SOP/ Form

- How to address the look back investigation of the original finding?
- How to take a lessons learned approach regarding the next time key personnel decide to leave the laboratory?
- What are some potential solutions?

Case 6-
Business, Financial & Document & Records

- You've gotten approval for an electronic document management system, but have been told by your IT group that they want nothing to do with it.
- What type of approach might be a fit?
- What are some of the items that might go into your RFP
- What do you look for?
- How to you assess the appropriate # of licenses?
- Who are your internal key stakeholders?
- How might the access/rights to a system differ from an environment governed by the FDA?

Considerations-Case 6

- Where might "ownership" reside?
  - Source of Management tools?
    - Internal vs Vendor
- Hosted vs. Software as a Service?
- Full Configurable "out of the box"?
- Type and number of licenses?
- How are updates handled?
- Document Collaboration/Review Online or Offline?
- Other modules attractive (training, CAPA, forms, etc)?

Case 7-Method Validation

- Company X is marketing a breath test for H. Pylori
  - The assay requires the patient blow into a baseline bag which is put aside
  - The patient then drinks a solution, waits a defined time and then blows into a second bag (different color), the breath now containing a tagged metabolite
  - Both bags are transferred back to the library
- You have a physician who is very interested in the assay
- The salesperson assures your that "breath is a non-regulated, special sample" and everyone who is running just "turns on the assay"
- You call one of the users, who verifies this approach

Considerations-Case 7

- You are short on labor, but have 2 interns
- The current controls are internal and electronic
- You are accredited by COLA
- What is your plan for assay implementation?

Document

New Method Checklist

Wrap Up

Self-Assessment Questions

- Utilization of Project Mgt Tools can help manage expectations
  - **True**
  - False
- Purchase of an Electronic Document Management System should include the following number of licenses:
  - 1 for each user (100%)
  - Licenses equal to half the number of users (50%)
  - **Licenses equal to 1/10 the number of users (10%)**
- The Critical Control Point strategy validates specific parts of a workflow, with the assumption that "everything upstream will be defacto validated"
  - **True**
  - False

Any Questions???

THANK YOU!!!