FOCUS AND PURPOSE

• Focus: evolution of our quality control plan
• Who we are and what we do – service offerings
• Baseline standard practices
• Identified need for an enhanced system
  • Communication mediums
  • Staff involvement
  • Change and continual improvement
Technical offerings
• STR
• Y-STR
• MiniSTRs
• mtDNA
• 2 extraction chemistries – 3 robotic systems
• 4 quantification kits
• 8 amplification kits

Operations Team Makeup
• Growing staff of 90 analysts and technicians
• 2 shifts implemented
• 1 pre-amp and 1 post-amp laboratory

2014 Throughput
• 16,000 forensic cases (~48,000 samples)
• 80,000 database samples

Client Base
• 50+ clients across our operational teams
CURRENT PROCESS

BASELINE STANDARD PRACTICES

- Maintain staff and visitor database
- Use batched sample processing to visualize trends in reagent and substrate control
- Repurpose existing computer programs to detect sample comparisons within a data tray
- Engage client and manufacturer relationships to optimize laboratory procedures
• Compartmentalized group structure similar to the discipline separation in a traditional crime laboratory
• Ineffective hard copy notification process
• Inability to determine trends that happen across teams, reagents, laboratory spaces, shared equipment and/or personnel

**We needed a culture change:** we needed more transparency between groups and real time error identification/tracking system!
HOW CAN WE ENHANCE OUR QUALITY PLAN?

INCREASE TRANSPARENCY

• Big question – how do we increase transparency across our operational teams?
  • Take a look at how we could improve or implement various methods for communication

• GOAL: simple and cheap!!
  • Compliance management software
  • Social business enterprise system
  • Meetings: Huddle format/traditional
  • Email
• Pre-existing system - 

• Central repository of information; email notifications of document changes; electronic workflows instead of paper forms and manual processes; data reporting

• Electronic workflow feature: trend analysis
  • Equipment status (e.g. out of service)
  • Non-conformance process
Out of service workflow process

- Instrument Error
- Out of Service Workflow Initiation
- Service/Performance check completion
- TL, Lab Director, QA notification
- Instrument back into service

Equipment - Out of Service/Retire
ID 89749
Current State is Completed
Initiated by Naem Khan
Out of Service by Naem Khan on 5/4/2015 10:50:33 AM
In Service by Naem Khan on 5/13/2015 9:23:23 AM
File by Amanda Thomas on 5/27/2015 11:10:40 AM

Completed

CE Number
CE-A006

Serial Number
1586-030

Out of Service Date 5/4/2015

Reason Placed Out of Service
Provide short description of why unit is being placed out of service. Engineer is performing preventative maintenance. NK050415

Released Back into Service Date
When applicable, calibration/performance verification must be completed prior to 5/13/2015
**Non-conformance reporting process**

1. Non-conformance occurs; workflow initiated
2. TL, Supervisor, Lab Director and QA notified
3. TL feedback on planned actions
4. Analyst verifies actions completed and submits follow up workflow
5. TL and QA review for completion or additional actions required
• A robotic instrument sporadically failed to elute purified extracts or failed to elute the total volume of expected purified extract across multiple shipments from multiple clients. This issue spanned for 8 months.
  • 31 identified non-conformances, 7 client projects
• Troubleshooting and investigations were ongoing from the initial occurrence leading up to the resolution of the identified issue.
• Resolutions: software upgrade, validation, process change
COMMUNICATION MEDIUM #2
SOCIAL BUSINESS ENTERPRISE SYSTEM

• Project management website –

• Real time “Facebook” feed with conversation threads; dedicated project pages and associated tasks for management; direct tagging of individuals to call attention to topics; automatic weekly task summary via email

• Groups/project team members (manager based/project owners) assignments determine who sees what, but allows information to be “publically” available to all associated individuals; maintains historical thread; allows for document storage

  • Client specific: expected volumes, potential issues

  • QA topics: corrective action process
COMMUNICATION MEDIUM #2
SOCIAL BUSINESS ENTERPRISE SYSTEM

<table>
<thead>
<tr>
<th>Activity</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Client communication</strong></td>
<td></td>
</tr>
<tr>
<td>Send initial notification email</td>
<td></td>
</tr>
<tr>
<td>Investigation status update to clients</td>
<td></td>
</tr>
<tr>
<td>Add Task</td>
<td></td>
</tr>
<tr>
<td><strong>NCR Submission</strong></td>
<td></td>
</tr>
<tr>
<td>Submission of NCR by analyst</td>
<td></td>
</tr>
<tr>
<td>Add Task</td>
<td></td>
</tr>
<tr>
<td><strong>Investigation</strong></td>
<td></td>
</tr>
<tr>
<td>Root Cause Analysis</td>
<td></td>
</tr>
<tr>
<td>Add Task</td>
<td></td>
</tr>
<tr>
<td><strong>CAR Write Up</strong></td>
<td></td>
</tr>
<tr>
<td>Draft Copy Completed</td>
<td></td>
</tr>
<tr>
<td>Draft routed for review</td>
<td></td>
</tr>
<tr>
<td>Upload final document to CAR follow-up workflow for e-signature</td>
<td></td>
</tr>
</tbody>
</table>
Traditional meeting plans

- Set agenda
- Less frequent

- Email
  - User notification system
  - Team huddles have reduced traffic
## STAFF PARTICIPATION

<table>
<thead>
<tr>
<th>Participation Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCR submission and remediation follow up</td>
</tr>
<tr>
<td>Permission to initiate edits/updates for procedures and documents</td>
</tr>
<tr>
<td>Huddle interactions</td>
</tr>
<tr>
<td>Training updates and training effectiveness reviews</td>
</tr>
<tr>
<td>Shipment or case processing updates/progress</td>
</tr>
<tr>
<td>Qualifications maintenance: continuing education, etc.</td>
</tr>
<tr>
<td>Testimony, client contact</td>
</tr>
<tr>
<td>Focus groups</td>
</tr>
</tbody>
</table>
STAFF PARTICIPATION

Overall, the key is active engagement at all levels

Operation Bodemization

If you would like to become a part of a focus group to tackle laboratory efficiency improvement with Lean Six Sigma approaches please let Amy Jeanguenat know. She is currently identifying 4-7 people who would like to dedicate 30-60 minutes every day (incremental acts) and up to 4 days a month to participate in laboratory efficiency improvements. If you are interested in being a part of this focus team please let Amy know your interest level how you plan to handle the time commitment.
Avenues for change

• Determination of validation needs
  • Contract/client driven
  • Required for efficiency purposes
• Process evaluation as weaknesses are identified
  • Preventive actions
  • Streamline as much as possible (e.g. new hire process, electronic templates)
• Management review
  • Summary review of quality actions within previous ~6 month time period
  • Outlines future initiatives for process and/or procedural updates or improvements
• Performance evaluation process enforces commitment to quality goals
• Client feedback (regular communications/site visits)
  • Additional 100% technical review performed by client laboratories
  • Fosters discussions regarding laboratory practices such as interpretation guidelines and identifies ways to clarify procedures
CHANGE
CONSTANT IMPROVEMENTS

Qualtrax – documents edited

Qualtrax – documents published
SUMMARY

• Started with a solid standard baseline in terms of quality
• Increased scrutiny within the field and increased surge of cases/people forced the need to identify different avenues for quality improvement and constant monitoring
• Created a transparent management system and required staff to be part of the solution through active engagement
• Error detection practices and quality applications can be used as a model across the field and applied to challenges faced in cross-discipline situations
Natalie Morgan  
Director, Forensic Casework  
Bode Cellmark Forensics  
natalie.morgan@bodetech.com  
703-646-9793

Thank you!  
• Amanda Thomas, Director of Compliance & QA  
• Amy Jeanguenat, Laboratory Director  
• Karin Crenshaw, Technical Leader  
• Entire Bode Cellmark operations staff!