Supercharging Histology Workflow

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September 2009

Today's Learning Objectives

• Be able to pinpoint patient safety RISKS in your AP lab
• Understand how your AP lab can unlock major GAINS with Lean methodologies
• Explore value of automation and workflow changes in the AP lab – a CASE STUDY
• Discover new solutions to move from planning to execution to create the AP lab of the FUTURE
Ventana Medical Systems, Inc.

Born from a relentless search to find a better and faster way to diagnose the patient

- Over 1,200 employees across North America
- Fully integrated commercial operations, manufacturing, research and development in Tucson, AZ
- 95 patents issued and pending
- 6,000+ systems installed in 2,000+ labs across 33 countries worldwide
- 24% annual growth
- Acquired by F. Hoffmann-La Roche in early 2008
- A division within Roche called Roche Tissue Diagnostics

Ventana Leads in Tissue-Based Diagnostics

- Superior workflow solutions in both automation and information systems
- A proven track record of innovation, execution and patient centricity
- Strong research and development investment
- World class capabilities in core technologies
- Unparalleled partnerships for next generation companion diagnostics
- Passion for improving standard of cancer patient care

"We will not rest until every cancer patient receives the access to information, therapy options and individualized care we know is possible."
- Dr. Thomas Grogan
Vantage & Advanced Workflow - Powering the Total Solution

The only complete lean workflow solution that maximizes lab productivity and patient safety
• Turnkey lab improvement solution, including lean six sigma consulting
• Streamlines laboratory workflow
• Provides positive identification, with one label for the entire lab
• Enables advanced, active tracking and reporting
• Integrates Ventana products, multiplying customer value

Risks of Status Quo
High Potential for Human Error

• Overcalling
• Missing diagnosis
• What do you see in your lab?

High Potential for Human Error

• Misidentification of slides/cases
• Tissue floaters
• Redundant data entry
• Handwritten logs/manual information collection
• Labeling/re-labeling
• Batch processing
• Non-standard work practices
Journals Focus on Lab Safety

2-week study in histology:

- Nearly 30% of cases had manual rework: 159 hours; 1.3 FTEs
- 89% of defects were made in the analytic phase
- 2% misidentification rate; 67% of those in slide labeling
  - All could have been avoided with an integrated identification system

Source: Am J Clin Pathol 2007; 128 p423
Market Forces

- Declining reimbursement
- Staffing shortages
- Increasing regulatory requirements
- Mounting competition from consolidation
- Consumer demand for rapid turn on results
- Higher test volumes; more diverse test mixes

Getting It Right...
Lean Methodologies Unlock Major Gains

Lean Moves Labs to the Next Level

• Improves patient safety
  – Reduce errors

• Improves efficiency and reduces costs
  – More capacity
  – Better staff productivity
  – Reduce wasteful activities
  – Save time and steps
  – Happier staff

• Improves experience for your cancer patients
  – Faster turnaround times
  – More reliable results
Case Study - A Midwest Reference Lab

Workflow Consulting Solutions is a catalyst for change. Assessment tool measure dimensions for change management.

- How big is this change for the organization culturally and in general? (Day to day work activities, Decision making, Logistically)?
  - Major Changes: 7
  - Minor Changes: 3

- What is the level of severity if the change fails? (Strategic Alignment, Lost Opportunity, Loss of Credibility)
  - Very Severe: 7
  - Not a Big Deal: 3

- How widely acknowledged are the risks of the status quo? (Quality, Patient Safety, Productivity)
  - High Recognition: 7
  - Low Recognition: 3

- How much are the benefits of this change recognized by those involved in the change? (Cost Reduction, Employee Satisfaction)
  - High Recognition: 7
  - Low Recognition: 3
Case Study - A Two Way Partnership

• 80+ hours on-site with team
  – Involve leadership and establish accountability
  – Observation and determine current state baseline
  – Identify opportunities via Voice of Customer

• High level of engagement to ensure team embraces change

• Leverage expertise across Ventana

Steps to a Safe, Efficient, Effective Lab

1. Observe and record
2. Reduce or eliminate non-value added activity by mapping the flow of work through the lab
3. Map current workflow process and design future state
4. Engage team in change management to implement improvements
5. Prioritize opportunities for continuous process flow improvements
Case Study - Current State Process Flow

Facts:
- 1000+ slides/cases per day
- 17 FTEs
- 3 shifts

Case Study - Future State Process Flows

Initial opportunity:
- 26% of TAT - reduce non-value adds
- 20.57 hrs - reduce manual logging
- $174,613 potential savings
Case Study - Identify Value System

Use Lean and Six Sigma tools to systematically uncover non-value added activity/ways to maximize lab productivity and safety

Case Study - Streamline Movements

Current State Floor Plan

Assumption: 17 people
25 movements per person per day

Totals:
~ 58,125 ft / day
~ 11.1 miles / day
~ 3,176.6 miles / year
Case Study - Future State Histology Lab

Cut miles/yr in half!

Case Study - Reduce Manual Log Creation

<table>
<thead>
<tr>
<th>Work Station</th>
<th>Hours</th>
<th>Associated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessioning</td>
<td>3.97</td>
<td>$34,062</td>
</tr>
<tr>
<td>Grossing</td>
<td>2.77</td>
<td>$23,737</td>
</tr>
<tr>
<td>Embedding</td>
<td>1.30</td>
<td>$11,154</td>
</tr>
<tr>
<td>Microtomy</td>
<td>0.87</td>
<td>$7,464</td>
</tr>
<tr>
<td>H&amp;E Staining</td>
<td>2.98</td>
<td>$23,681</td>
</tr>
<tr>
<td>Immuno Staining</td>
<td>2.30</td>
<td>$19,447</td>
</tr>
<tr>
<td>Special Staining</td>
<td>1.00</td>
<td>$8,580</td>
</tr>
<tr>
<td>Case Assembly</td>
<td>5.38</td>
<td>$46,188</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>20.57</strong></td>
<td><strong>$174,613</strong></td>
</tr>
</tbody>
</table>
### Case Study - Reduce Cycle Time

<table>
<thead>
<tr>
<th>Process Steps</th>
<th>Current State</th>
<th>Future State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessioning</td>
<td>53.6 minutes</td>
<td>11.5 minutes</td>
</tr>
<tr>
<td>Grossing</td>
<td>18.6 minutes</td>
<td>31.8 minutes</td>
</tr>
<tr>
<td>Tissue Processing</td>
<td>7.2 hours</td>
<td>7.2 hours</td>
</tr>
<tr>
<td>Embedding</td>
<td>10.6 minutes</td>
<td>5.7 minutes</td>
</tr>
<tr>
<td>Microtome</td>
<td>52.6 minutes</td>
<td>18.6 minutes</td>
</tr>
<tr>
<td>H&amp;E Staining</td>
<td>16.9 hours</td>
<td>46.3 hours</td>
</tr>
<tr>
<td>IHC Staining</td>
<td>426.0 hours</td>
<td>410.8 hours</td>
</tr>
<tr>
<td>Special Staining</td>
<td>133.1 hours</td>
<td>117.9 hours</td>
</tr>
<tr>
<td>Case Assemble</td>
<td>253.7 hours</td>
<td>188.9 hours</td>
</tr>
<tr>
<td>Total Time</td>
<td>2067 minutes</td>
<td>1620 minutes</td>
</tr>
</tbody>
</table>

Cycle Time saved: 447 minutes = 7.4 hours

$63,492

Case Study - Reduce Overtime

**Improvement Gains**

- **Current State** Cycle Time in Accessioning: 29 minutes
- **Future State** Cycle Time in Accessioning: 11.5 minutes
- **May Eliminate Over Time**: 65.5 hours /pay period or $51,090/yr
Case Study - Improve Patient Safety

Akro-Mils Bins with Intersecting Dividers

Bar Coding

Case Study - Improve Patient Safety

Optimize workspace to reduce crowding

Automation
Case Study - Voice of the Customer (VOC)

- Total Personnel Interviewed: 11
- Key Themes Reported in order of popularity with staff
  1) Workflow assessment (across total flow and individual work cells) for alignment of Lean processes
  2) Tracking/bar coding need (internal and external)
  3) Leadership involvement and communication increase
  4) Redundant/excessive paperwork
  5) Space increase needed

Staff need more efficient workspace, better communication from management, more physical space in which to work, and less turnover in key roles.

Case Study - Impact Summary

<table>
<thead>
<tr>
<th>No.</th>
<th>Process Improvement</th>
<th>Process Step</th>
<th>Priority</th>
<th>Lean Improvement Concept</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Elimination of Handwritten slides</td>
<td>Microtome</td>
<td>High</td>
<td>Waste Reduction</td>
</tr>
<tr>
<td>2</td>
<td>Bar Code Tracking, Data / Quality Management</td>
<td>Histology</td>
<td>High</td>
<td>Waste Reduction</td>
</tr>
<tr>
<td>3</td>
<td>Eliminate / reduce log creation and management of paper work</td>
<td>Histology</td>
<td>High</td>
<td>Waste Reduction</td>
</tr>
<tr>
<td>4</td>
<td>Redesign of laboratory</td>
<td>Histology</td>
<td>High</td>
<td>Visual Workplace, Workcell design</td>
</tr>
<tr>
<td>5</td>
<td>Improved Automation of H&amp;E Stainer -</td>
<td>H&amp;E</td>
<td>High</td>
<td>Wait Time Reduction</td>
</tr>
<tr>
<td>6</td>
<td>Install Metric Board - Key Performance Indicators</td>
<td>General</td>
<td>High</td>
<td>Visual Workplace</td>
</tr>
<tr>
<td>7</td>
<td>Additional Tissue Processors</td>
<td>Tissue Process</td>
<td>Medium</td>
<td>Wait Time Reduction</td>
</tr>
<tr>
<td>8</td>
<td>Review/Update Standard Work</td>
<td>Grossing, Microtomy, Distribution</td>
<td>Medium</td>
<td>Standard Work</td>
</tr>
<tr>
<td>9</td>
<td>Courier Routing Optimization</td>
<td>Receiving and Distribution</td>
<td>Medium</td>
<td>Wait Time , Batch size Reduction</td>
</tr>
<tr>
<td>10</td>
<td>Initiate 5S Concept</td>
<td>Histology</td>
<td>Low</td>
<td>Visual Workplace</td>
</tr>
<tr>
<td>11</td>
<td>Runner to transport resources in the lab</td>
<td>Histology</td>
<td>Low</td>
<td>Wait Time Reduction</td>
</tr>
</tbody>
</table>
Case Study - Reference Lab Opportunity

- Reduce TAT 26%
- Logging Savings $174,613
- Bar Coding Savings $63,492
- Overtime Savings $51,090

Annual Savings $289,195

- Improved safety
- Higher employee satisfaction
- Better patient experience
- More competitive lab

Using Lean to Create the Lab of the Future
Lean Transforms AP Lab Performance

- Better quality
- Quicker response
- Greater flexibility
- Increased value

Lean & Six Sigma

Lean Keeps Focus on Execution

- Lean Six Sigma is established as a continuous, cohesive way of working (not a project)
- Leadership is on board and governance is in place; both are aligned to systematically review and improve business process
- Lab staff participate in establishing accountability and chain of command at the onset of Lean Six Sigma
- Teams are focused on business process, not just tools for improvement
- Emphasis is on culture change to sustain improvement
Greatest Challenge is Execution!

**Process improvement leads to cost reduction...**

**Execution** leads to quantum leaps in competitive advantage and long-term financial benefits

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Future Lab – Safe, Effective, Efficient

- Better equipment
- More Sophisticated Testing
- Improved Patient Safety
- More Reliable Information
- Automated Work Processes
- Greater Efficiency, Effectiveness
- Financial Stability
- Competitive Advantage
The First Step…Map Out Your Plan

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