# of Implementing New Equipment into Histology

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Lab Quality Confab 2012

Credentials

Quality Management

2001 - 2003

BD

BD MPD Program™

Measure, Predict, Deliver

Global Solutions Optimizations Specialist

since 2012

Leica MICROSYSTEMS

6σ

Six Sigma Black Belt

2003-2005

Workflow Consulting

2009 - 2012

DBSL

2005 - 2009

- Whodunit?
- Motivation for Change
- Due Diligence
- Implementation

Mystery # 1

Cast

3 Pathologists
1 Lab Manager
2 IHC Techs
4 New Automated Advanced Stainers

Plot

- ✓ Pathologists decide to purchase a new advanced staining platform and replace the old instruments
- ✓ Evaluation of various platforms and decision for one of them
- ✓ IHC techs love their old platform and are not willing to convert to the new technology
- ✓ Lab Manager goes ahead with project and decides on laboratory layout modifications to fit the new instrumentation into the old space and a delivery date.

Mystery # 1

Resolution

- ✓ Lab Manager is “powerless” convincing the Techs to accept the new instrumentation
- ✓ Instruments being shipped back to vendor
- ✓ Construction in laboratory and validation of new equipment delayed for months
- ✓ Lab Manager is being replaced

Root Cause

Top Down Approach without getting buy-in from laboratory staff

Mystery # 2

Cast

1 Lab Manager
1 Histo Tech
1 New Automated Microtome

Plot

- ✓ Histo Tech develops carpal tunnel using an old microtome with non-disposable blades
- ✓ Lab Manager decides to purchase an automated microtome to avoid this in future
- ✓ Several instruments from different vendors are being evaluated, the Tech picks the one she likes the best
- ✓ Manager buys that particular microtome
- ✓ Old microtome stays in laboratory as back up

Mystery # 2

Resolution

✓ Tech sets it up besides her old microtome but decides she still likes her old microtome better and does not use the new automated microtome

Root Cause

The old instrument is still in place and fully functioning and as the tech is more comfortable with it, it is primarily used

Mystery # 3

Cast

1 Lab Manager
1 Purchasing
2 Cyto Tech
2 Pathologists
Various Cytology Equipment

Plot

- ✓ Lab Manager decides to introduce 2nd platform
- ✓ Pathologists have not been part of the decision making process
- ✓ Techs get training on the new instrumentation and start to use it

Mystery # 3

Resolution

- ✓ Pathologists notice an increase in unsatisfactory results
- ✓ Amount of slides to be reprocessed increases and the workflow slows down
- ✓ Laboratory manager decided to convert all test back to original platform

Root Cause

Bottom Up approach – not all stakeholders involved in decision making process

Mystery #4

Cast

1 Lab Manager
2 Molecular Techs
2 New Automated Molecular Analyzers

Plot

- ✓ Lab Manager purchases 2 automated molecular analyzers
- ✓ Lab Manager flies to vendor facility to be trained how to use the analyzers
- ✓ Lab Manager instructs Techs how to use the equipment
- ✓ Techs struggle how to enter the tubes into the analyzer software

Mystery # 4

Resolution

- ✓ Techs enter all tubes manually into the software and complain that this is too cumbersome
- ✓ Managers asks the vendors application specialist to visit his laboratory and fix the equipment so that tubes can be scanned

Root Cause

Techs did not receive the same thorough training as the Lab Manager

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Mystery # 5

Cast

1 Lab Manager
3 New Rapid Processors

Plot

- ✓ Lab Manager purchases rapid tissue processors and implements them successfully into the laboratory workflow

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Mystery # 5

Resolution

- ✓ The laboratory runs out of storage room for bulk reagents
- ✓ The amount of bulk reagents to be discarded increase drastically

Root Cause

Lab Manager did not adjust the amount of bulk reagents to be purchased to the usage of the new instruments

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Mystery # 6

Cast

New Equipment
Old Layout

Plot

- ✓ Place new equipment wherever you find space for it

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Mystery # 6

Resolution

Root Cause

Necessary layout changes to place equipment according to process flow were not made

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Motivation for Change

Quotes

- ✓ **"Manage staff shortages"**
- ✓ **"High lab costs compared to benchmark"**
- ✓ **"Increase capacity without increasing costs"**
- ✓ **"Improving turn around times"**
- ✓ **"Reducing errors"**
- ✓ **"Improving working conditions"**
- ✓ **"A new lab facility on the horizon"**

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Due Diligence – the key for successful implementation

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Evaluate your needs

Process needs	→	error reduction, TAT
Growth prediction	→	increase throughput, laboratory acquisitions/mergers
List Stakeholders	→	list all parties impacted by change

Shape a vision – create a goal

What do you want to achieve with the new equipment?

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Predicted Impact on your Laboratory

- Process changes
  - smaller batch flow possible
  - same day processing
- Layout changes
  - equipment dimensions
  - changed workflow
- Staffing changes
  - skill sets
  - hours
  - job tasks
- Consumable and Supply utilization
- Ergonomic Changes / Safety
- Software Infrastructure

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Equipment Evaluation

- ✓ Demonstration
- ✓ Understand all Implications
- ✓ Involve all stakeholders
- ✓ Tap into the experience of your peers in other laboratories (e.g. Histonet)

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Equipment Evaluation - Benefits

- “We listened to our staff and they know they are supported”
- “Involved technical staff in instrumentation selection and the development of SOP’s”
- “Instrumentation upgrades complimented AP LEAN Redesign”
- “We knew our instrumentation was to be layered over a new computer system”
- “We had relationships with our vendors – instrumentation verification and validation”

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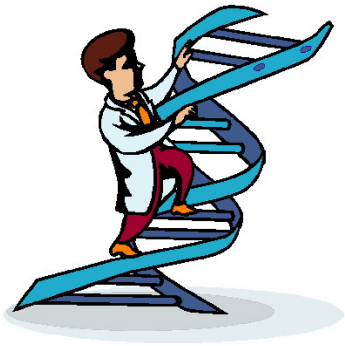
Implementation Step by Step



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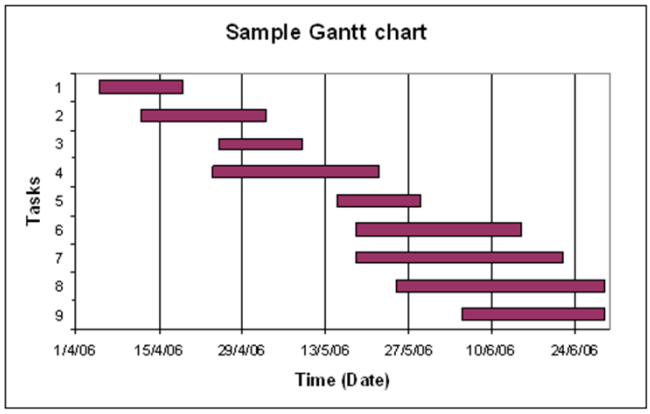
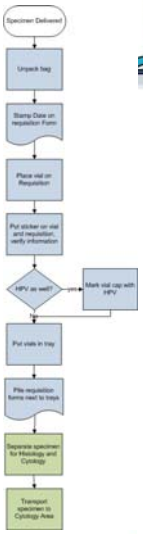
Draft action plan / Gantt chart for implementation



Process changes

- ✓ Do Process changes occur with the new equipment?
- ➔ Map your current process flow and highlight all changes the new equipment will require



Example Delivery Process

Process Mapping 101

- ✓ Start with the input that initiates the process 
- ✓ Ask the question, “What happens next?”
- ✓ Record each step in post-it note boxes flowing left-to-right, or top-to-bottom. 
- ✓ Insert arrows to show the direction or flow of the process.
- ✓ When the flow can go in two directions, turn the post-it to a diamond for a yes/no question and put in two arrows to show the two directions. 

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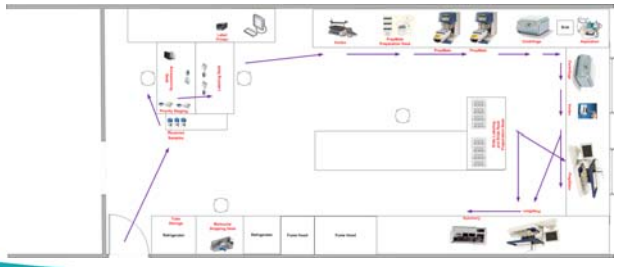
Layout changes

- ✓ Do Layout changes occur with the new equipment?

➔ Draft a spaghetti diagram of new process flow in laboratory and incorporate new equipment where it fits into the flow



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How to create a spaghetti map

1. Follow the specimen through the laboratory according to your process flow
2. Mark the movement with numbers on your layout
3. Connect the numbers with lines

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Ergonomic Changes / Safety

- ✓ Do you need additional ventilation? Water? Sinks? Plugs?
- ✓ Are there chemicals that require waste disposal?
- ✓ Do you need more space for Flammables?
- ✓ Do you need to adjust countertops or storage space?
- ➔ Involve Waste Management in your facility if necessary
- ➔ Discuss possible changes with the “facilities manager”
  - ➔ Additional fume hoods or ventilation
  - ➔ Additional or less storage space for consumables and supplies
  - ➔ Changes with regards to furniture

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Software / Hardware Requirements

- ✓ Are you planning to interface your new equipment?
- ✓ Does your new equipment require any hardware or software upgrades?

- ➔ Involve IT as early as possible to communicate with vendor
- ➔ Evaluate time needed to prepare laboratory software for possible changes
- ➔ Explore opportunities to upgrade existing hardware or software to fully explore all features of new equipment
  - ➔ bar-coding slides and cassettes
  - ➔ reporting
  - ➔ remote care

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Training Requirements

- ✓ Does the new equipment require additional training?

- ➔ Evaluate skill sets needed
- ➔ If training occurs at your facility
  - ➔ Train all employees that will use equipment
  - ➔ Appoint one employee as “key user” with the responsibility to troubleshoot
  - ➔ Obtain training materials (written or as CD)

- ➔ If training occurs at vendors facility
  - ➔ Send employees that will use the equipment on a daily basis
  - ➔ Send 2 employees to back each other up

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Equipment Validation

✓ Does the new equipment require validation?

➔ Appoint at least one employee to oversee validation process

➔ Plan validation timeframe and work involved

➔ Document validation

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Summary

- ✓ Know your Drivers for change
- ✓ Due Diligence
  - ✓ Process Needs
  - ✓ Growth Prediction
  - ✓ Identify Stakeholders
- ✓ Predict Impact on your laboratory
  - ✓ Processes
  - ✓ Layout
  - ✓ Staffing
  - ✓ Consumables and Supplies
  - ✓ Ergonomic / Safety
  - ✓ Software Infrastructure
- ✓ Evaluate
- ✓ Thorough Implementation - Step by Step

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QUESTIONS ?

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