THE IMPORTANCE OF STRATEGIC PLANNING IN LABORATORY INFORMATICS PROJECTS

RANDY HICE

MANAGING DIRECTOR

JUNE 6TH, 2019



PRESENTER



Developed laboratory workflow analysis in 1988 while at Digital Equipment Corporation

Techniques have been presented at various conferences in North America, Europe, Asia, and South America

Scientific Computing Magazine monthly columnist and editorial board 1996-2016

More info? Google Randy Hice Workflow Analysis



WHAT YOU WILL TAKE AWAY FROM THIS WEBINAR

- The criticality of understanding the current state of your company's processes for good or ill
- Why most internally-produced process flowcharts are not useful in deployment projects
- How future state process flows can save time, money, and careers
 How to derive system requirements from workflow maps
 Benefits of and best practices for site harmonization



ASTRIX 2018 LIMS SURVEY

- This year's survey was completed by 100 R&D professionals across a wide variety of industries.
- Over half of the respondents were from companies with greater than 500 employees.
- 79% of respondents indicated that at least one LIMS is being utilized by their company.
- Nearly half of respondents reported that their LIMS had either a net neutral effect or actually decreased work efficiency in their laboratory.



In Resource Library at **astrixinc.com** <u>https://astrixinc.com/2018-lims-market-</u> <u>research-report-by-astrix/</u>



In companies reporting a LIMS deployment, only 27% of respondents (21 out of 79) indicated a high level of satisfaction with their LIMS, while 18% reported that their LIMS was cumbersome to use.



How satisfied are respondents with their LIMS?

14 respondents (nearly 18% of companies that reported a LIMS deployment) felt that their LIMS is cumbersome to use.

Very satisfied		21%	21
It's OK, gets the job done		50%	50
Not satisfied, cumbersome		14%	14
Next question		15%	15
TOTAL			100



ASTRIX 2018 LIMS SURVEY

Likely cause for lack of enthusiasm with LIMS deployments:

Yes

No

Don't know

TOTAL

Yes

No

Don't know

TOTAL

Did the LIMS implementation team conduct Business Process Analysis (BPA) to develop optimized futurestate laboratory workflows prior to selecting the LIMS?

Only 50% of companies that reported a LIMS deployment (39 out of 79) indicated that they conducted BPA prior to selecting their LIMS.



Did the implementation team develop functional and technical requirements prior to selecting the current LIMS?

71% of organizations that reported a LIMS deployment indicated that they developed functional and technical requirements prior to selecting their system.







Over budget

Behind schedule

Poor execution

User dissatisfaction





PRIMARY CAUSES OF PROJECT FAILURE

Poor Planning
Poor Requirements
Unrealistic Expectations
Lack of Investment *Poor Communication*



DEPLOYMENT PROJECT PROBLEMS ARE PREVENTABLE





BUSINESS PROCESS ANALYSIS



POOR REQUIREMENTS



Aim for nothing and you'll hit it every time

A shocking number of companies do not define success metrics



POORLY-DEFINED TARGETS ARE NEVER HIT



Nebulous Targets	Defined Targets		
	Roll Out Sites by Functional		
Replace Current System by October	Groups in 60-day Cycles		
	Improve Monthly Sample		
Improve Lab Efficiency	Turnaround by 15%		
	Implement ESIGs and Audit Trails		
Improve Compliance	Division-Wide		





BUSINESS PROCESS ANALYSIS OBJECTIVES



What results is a project with precise scope and cost



Current state (AS-IS) process maps identify inefficiencies and wait states

AS-IS maps serve as the underpinnings for the future (TO-BE) state



TO-BE state maps project process improvements and optimized environments agreed to by all stakeholders
TO-BE state maps specifically define system requirements
System requirements become vendor requirements and are constrained to business improvements, not bells and whistles



ENTIRE OPERATION REPRESENTED ON ONE PAGE



- Detail level unsuitable for process improvements or meaningful requirements
- Author assumes intuitive knowledge



WHAT A CURRENT STATE SHOULD REALLY LOOK LIKE





A CLOSE LOOK AT A SPECIFIC NEED





TO-BE FLOW REFLECTS SIMPLER, IMPROVED PROCESSES

BASELINE Chemistry Testing, TO-BE





Version 0 – To Be Customized for Customer – DO NOT DISTRIBUTE

HOW TO-BE PROCESS FLOW BECOMES SYSTEM REQUIREMENTS



LIMS Sample Runs

- System must provide a selection of primary instruments from a pull-down list of all available instruments on the LAN
- System must all a selection of samples to be included in the run from a shared laboratory workgroup backlog
- System must allow the inclusion of QC samples to be sequenced in the run list

Run Information

. . .

- System must allow inclusion of equipment IDs in the format defined in appendix section 121.b
- Consumable IDs and quantities required must be selected from an inventory screen and all amounts decremented from inventory

Worklist (Run Sheet) Generation

- Worklist must include all sample and consumables bar codes
- Run list must be formatted as per instrument interfacing requirements section 154.c



REQUIREMENTS NOT CAPTURED AT CORRECT LEVEL

The vast majority of requirements documents we see are too high level



The primary issue is that requirements documented at the wrong level cannot differentiate one system from the next, so the system selection becomes more visceral than grounded in logic



PROCESS IMPROVEMENT OPPORTUNITIES OVERLOOKED

"Electrifying" a poor process yields a faster-moving poor process







FROM PROCESS MAPPING TO BUDGET SAVINGS

• Current state flows a snapshot of reality **Current State Process Flows** • Future state flows reflect Best-in-Class **Developed from SME interviews** technology and functionality • Vendors must demonstrate fluency with functions derived from agreed-upon business needs Project Dollars Dedicated to Agreed Future State Developed Off Site **Requirements Focused on Upon Functionality Process Improvements**

Laser-focused Requirements

SITE HARMONIZATION



Accurate Requirements Build the Foundation for a Successful Project that provides real business value

Step 1: AS-IS Workflow Analysis

Comprehensive model of all customer workgroups developed. Wait states and process impediments identified for future state correcttion

Step 2: Future State Model

Future state reflects process improvements and best-practices for employing informatics software. If multi-site, harmonization occurs here

Step 3: Requirements Extracted

Requirements are derived from agreed-upon future state model. Process improvements made

Step 4: Vendor Selection

Vendors must demonstrate fluency with future state functionality and not demo superfluous bells and whistles

Step 5: Project Design

Project design constrained to first implementing functionality agreed upon to bring material benefits

HARMONIZATION

Harmonization is a BPA Benefit for multi-site projects





HARMONIZATION





HARMONIZATION





THE POLITICAL CHALLENGES OF HARMONIZATION





THE POLITICAL CHALLENGES OF HARMONIZATION



Harmonization often is more a political exercise rather than a technical one:

- NIH Not Invented Here
- "Doing it your way makes <u>me</u> look like an idiot."
- Just because you live in XXX, it doesn't mean you understand how we work in YYY



THE IMPORTANCE OF STRATEGIC PLANNING IN LABORATORY INFORMATICS PROJECTS

RANDY HICE

MANAGING DIRECTOR

JUNE 6TH, 2019

