

Lean in BioPharma

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Lean in BioPharma

Agenda

- What is Lean
- Rational for Lean in BioPharma
- Lean Examples & Impact in BioPharma
 - Employee Engagement
 - Workplace Organization
 - Flow Efficiency
 - Healthcare
 - Bio 5 Label & Pack
 - SLR Solution Lot Record Reviews
 - Impact Summary
- Next



Why Lean?



Company



Customer



Process

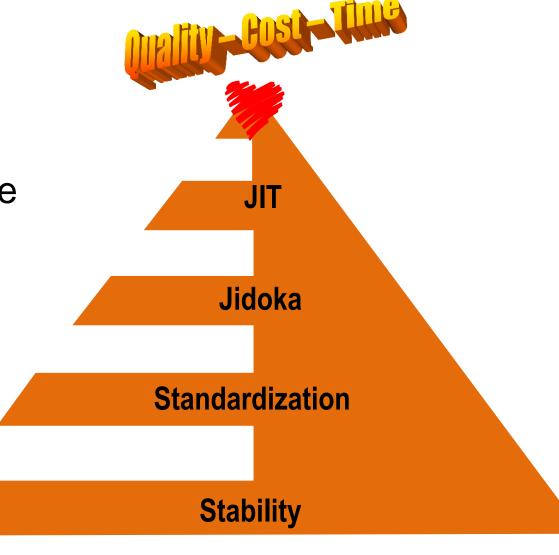


Employees



What is Lean?

 An approach to business which strives to maximize value to the customer by maximizing the value of employees.





Lean – The Big Picture

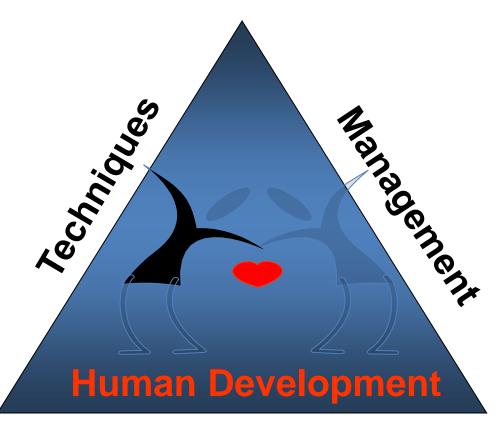
10% Techniques & 90% People

Before strategy there is Philosophy.

Techniques are the means, not the ends

Management must lead.

At the center is **Human** Development.





Philosophy

Operational Excellence

Lean & Six Sigma Integration, plus People

 $Y = f(x_n)$

Find the significant X's vs. the trivial x'



GOAL: Perfect the Process Step thru Variation Reduction

- Data Collection & Statistical Analysis
- Root Cause Analysis
- Optimization



Lean: Broad & Shallow



- 2. Map / Stream
- 3. Flow
- 4. Pull
- 5. Perfection

GOAL: Eliminate Waste & Create Flow:

- Culture of Respect
- Stability & Standardization
- Organization & Visual Management
- Value Stream Mapping
- Changeover / Level Loading / Pull
- Total Productive Maintenance





BioPharma Examples

- Employee Engagement GRIP
- Workplace Organization Beyond 5S
- Flow in L&P / Kitting
- Extend Flow to DS Mfg

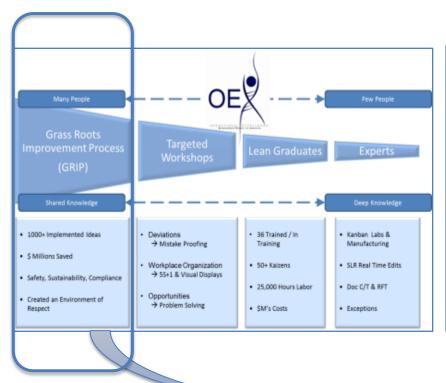


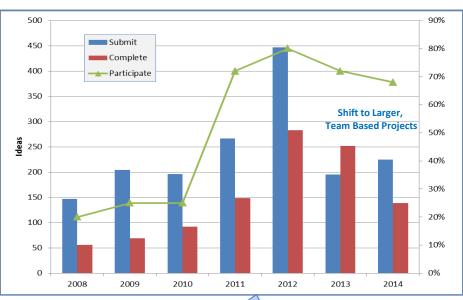


Grass Roots Improvement System

- Front Line Owned an Managed
- Focus: Safer <u>Easier</u> Better Faster Cheaper









GRIP: Tubing Holder

Jason Sullivan / Robert DeCoste

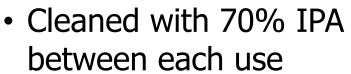
Current Situation:

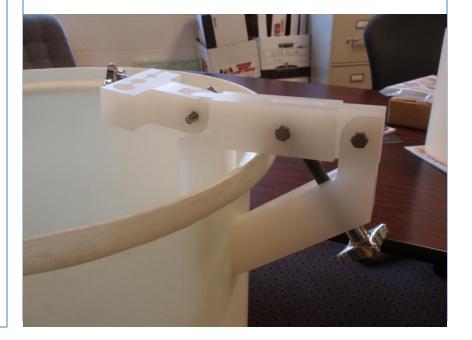
- Pumping GMP liquids:
- Concerns: spills, slippery, caustic, foaming, hose "whipping", keep the line above the fluid level.

Proposed Solution:

 Prototype tubing holder was obtained & tested with 100% success.











BioPharma Examples

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Workplace Organization Elements





GRIP

Kanban

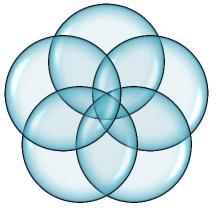


Readiness Checklists Kits / Carts Layouts SOP / WI



Standard Work

5S+1

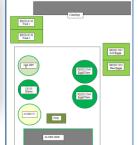


Visual Management











- Efficiency: What, When & Where You Need It!
- Abnormality Detection
- Hu / Error Free / Safe
- Inspection Ready



Laboratory Kanban Project

BEFORE AFTER





























GRIP: Making Life Easier, One Idea at a Time

Pump Carts and Welder / Sealer Carts

Robert Simoneau, Larry Visco, Hector Resillas Brian Blair, Doug McKay and Kevin Homer

Prior Situation:

- Parts are spread out, hard to find
- No dedicated location for parts
- Multiple cords running all over
- Hooking everything up
- Lifting Heavy Pumps

Implemented Solution:

- Mobile & nimble, designed to be used & moved as a <u>SINGLE</u> <u>UNIT</u>
- ONE power cord in the back
- NO heavy lifting & looking for a storage spot



DOWNTIMES Wastes

- □ DEFECTS
- □ OVERPRODUCTION
- ✓ WAITING
- ✓ NON UTILIZED TALENT
- ✓ TRANSPIRATION
- □ INVENTORY
- ✓ MOTION
- □ EXTRA PROCESSING
- ✓ SAFETY



After

















BioPharma Examples

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- Flow in L&P / Kitting

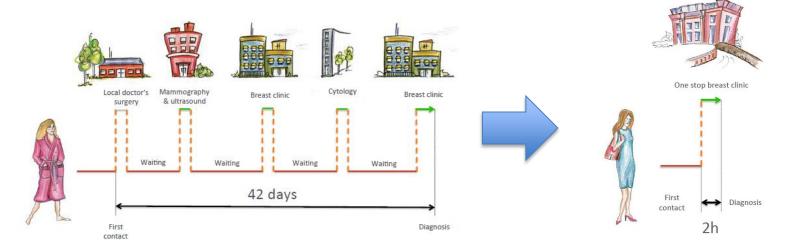
FLOW

Extend Flow to DS Mfg



This is Lean: Resolving the Efficiency Paradox

Alison thinks she has cancer



What is the difference?



Ref: This is Lean, Resolving the Efficiency Paradox Niklas Modig, Par Ahlstrom

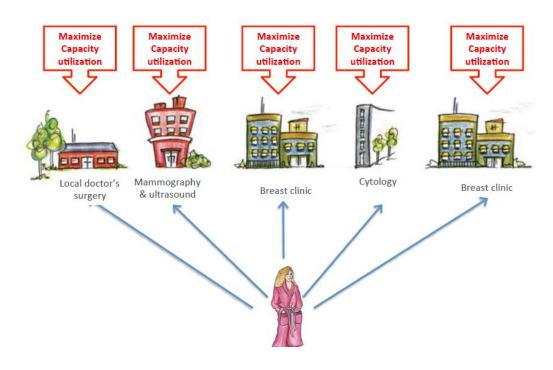
500 times faster



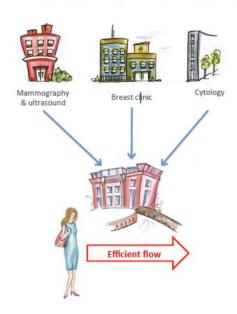


This is Lean: Resolving the Efficiency Paradox

Resource efficiency = to utilize resources



Flow efficiency = to fulfill needs



Ref: This is Lean, Resolving the Efficiency Paradox Niklas Modig, Par Ahlstrom



This is Lean: Resolving the Efficiency Paradox

Taking care of receipts

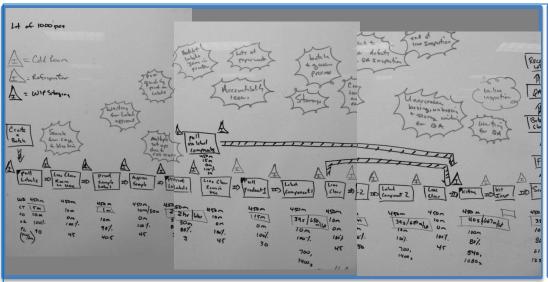
Routine	4 times / year	2 times / week
Analysis period	3 months	3 months
Number of activities	1	$2 \times 4 \times 3 = 24$
Number of receipts	App 400 receipts	App 400 receipts
Total time	8h	2h 13min
Time per receipt	72 sec	20 sec
Through-put time	Max 3 months	Max 3 days
Number of receipts	400	17
Number of restarts / receipt	3-4	1
Superfluous work	Structure	
	Sort	"Free capacity"
	Search	Tree capacity
	Waste	
Value-adding time	Filing	Filing

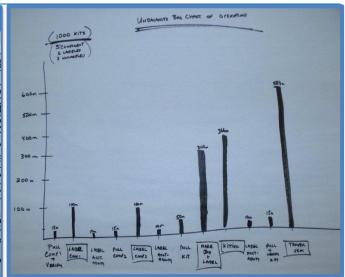
www.hankensse.fi/lean

www.tataonlean.fi



Biogen Idec Examples







Mfg Associate Observations:

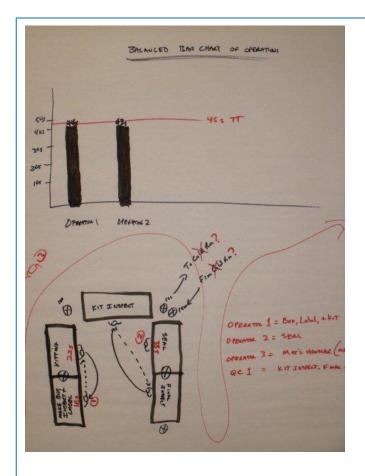
- Too much walking
- Too much movement
- Mountains of WIP
- Takes too long
- Unbalanced

Methods Used:

- VSM
- Line Balance Charts
- Observation
- Spaghetti Diagrams
- Standard Work



Biogen Idec Examples



Focus on Flow Efficiency Also found Resource Efficiency Plus a Change in Mindset



Measure	Resource	Flow	
Walking	14k Ft / 4 hrs	0 ft / 0 hrs	
Time to 1st Kit	2 hrs 43 min	44 sec	
Operators	4.5	2.5	
Kits / Hr / Op	30	56	
Associate designed production of kits			



BioPharma Examples

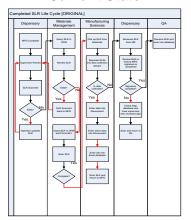
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Flow in Doc: Solution Lot Records

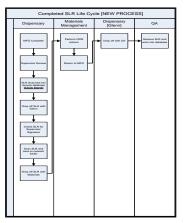
1st Transition

Current State

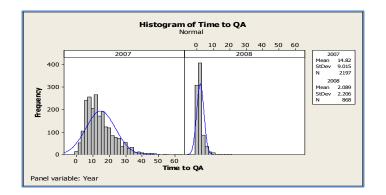


- 25 Steps,
- 5 Decisions
- Target: 85% / 7 Days
- Actual: 19% / 15 Days

Future State



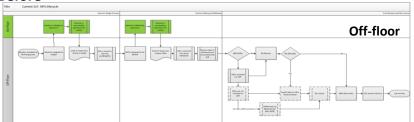
- 11 Steps,
- 0 Decisions
- Target: 85% / 7 Days
- Actual: 97% / 2 Days



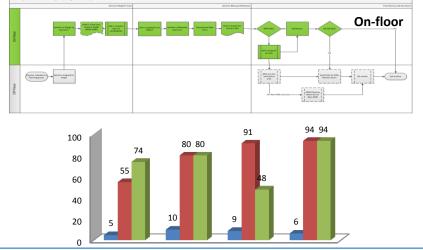
2nd Transition

- Goal: Real-time review & edits
- · Results: within shift rectification
- Real Time Data Entry

Before



Now Title Proposed SLR 8





2007 2008 2014

14 days 2 days

2-3 hours

Overall Impact

- Drug Substance Mfg
 - Tripled capacity in the past 6 years
- Finished Goods Mfg
 - Tripled capacity in the past 6 years
- Contributors
 - Creativity GRIP
 - Direct Observation Flow & Layout
 - Continuous Improvement Projects
 - Technology Equipment, Automation
 - Innovation Single Use Components



Next

Create and *Biotech Operating System* to handle increased mfg velocity and engage the organization further with daily problem solving

Elements:

- Visual Performance System
- Leader Standard Std Work
- A3 Thinking & PDCA





Thank You

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