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.
Before strategy there is *Philosophy.*

Techniques are the means, not the ends

*Management* must lead.

At the center is *Human Development.*
**Operational Excellence**

Lean & Six Sigma Integration, plus People

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**GOAL: Eliminate Waste & Create Flow:**
- Culture of Respect
- Stability & Standardization
- Organization & Visual Management
- Value Stream Mapping
- Changeover / Level Loading / Pull
- Total Productive Maintenance

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**Six Sigma: Narrow & Deep**

- GOAL: Perfect the Process Step thru Variation Reduction
  - Data Collection & Statistical Analysis
  - Root Cause Analysis
  - Optimization

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**Lean: Broad & Shallow**

- Y = f(x_n)
  - Find the significant X’s vs. the trivial x’

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1. ID Value
2. Map / Stream
3. Flow
4. Pull
5. Perfection

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**Step 1** Waste
**Step 2** Waste
**Step 3** Waste
**Step 4** Waste
**Step 5** Waste
**Step 6** Waste
**Step 7** Waste
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 and Managed
- Focus: Safer Easier Better Faster Cheaper
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.
- Autoclave-able
- Cleaned with 70% IPA between each use
BioPharma Examples

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

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

GRIP
Kanban
Visual Management

5S+1

Readiness Checklists
Kits/Carts
Layouts
SOP/WI
Laboratory Kanban Project

BEFORE

AFTER

Summary of Benefits

RECOVER >66+ WORK-DAYS / YR
SPENT IN ORDER MGMT

Replenishment

Inventory

Locations

Best-in-Class Lab Materials Mgmt

>$310K EXCESS INVENTORY

> 830 ft² UNDER-UTILIZED SURFACE AREA
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 SINGLE UNIT
- ONE power cord in the back
- NO heavy lifting & looking for a storage spot

Impact: Safety $ Time – waiting, looking, connecting... AND... Easier!!!
BioPharma Examples

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This is Lean: Resolving the Efficiency Paradox

Alison thinks she has cancer

What is the difference?

42 days 24h = 1008h

2h

500 times faster

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

<table>
<thead>
<tr>
<th>Routine</th>
<th>4 times/year</th>
<th>2 times/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis period</td>
<td>3 months</td>
<td>3 months</td>
</tr>
<tr>
<td>Number of activities</td>
<td>1</td>
<td>2 x 4 x 3 = 24</td>
</tr>
<tr>
<td>Number of receipts</td>
<td>App 400 receipts</td>
<td>App 400 receipts</td>
</tr>
</tbody>
</table>

Total time
- Time per receipt
- Through-put time
- Number of receipts
- Number of restarts/receipt

8h 72 sec Max 3 months 400 3-4

Superfluous work

Structure
- Sort
- Search
- Waste

Value-adding time

Filing

“Free capacity”

www.hankensse.fi/lean

www.tataonlean.fi
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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Resource</th>
<th>Flow</th>
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</thead>
<tbody>
<tr>
<td>Walking</td>
<td>14k Ft / 4 hrs</td>
<td>0 ft / 0 hrs</td>
</tr>
<tr>
<td>Time to 1st Kit</td>
<td>2 hrs 43 min</td>
<td>44 sec</td>
</tr>
<tr>
<td>Operators</td>
<td>4.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Kits / Hr / Op</td>
<td>30</td>
<td>56</td>
</tr>
</tbody>
</table>

*Associate designed production of kits*
BioPharma Examples

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

Histogram of Time to QA

![Histogram of Time to QA](attached)

<table>
<thead>
<tr>
<th>Year</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>2008</td>
</tr>
</tbody>
</table>

Panel variable: Year

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to QA (Days)</td>
<td>14 days</td>
<td>2 days</td>
<td>2-3 hours</td>
</tr>
</tbody>
</table>
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
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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