Managing Change for Continuous Improvement in a Regulated Industry

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“It is not necessary to change. Survival is not mandatory.”

W. Edwards Deming
Why Change?

• To generate a benefit for one or more of the stakeholders.
  – Financial benefit (higher price, lower cost, better quality, lower inventory...)
  – Avoid regulatory intervention (fines, registration suspension, recall...)
  – Safety
  – Environment
  – Reputation
Why Change?

• *Because everything else will!*
  – Your competitors will change;
  – Your customers will change;
  – Your business environment will change;
  – Your suppliers will change;
  – Your employees will change.

• *And you want to survive!*
Why to Manage Change?

• Outcomes of an Ineffective Change Process
  – Unpredictable process outcomes;
  – Unplanned nested changes;
  – High percentages of non-conforming product;
  – High waste and rework levels;
  – No traceability of product affected by changes;
  – Product or process history might not be available;
  – Cost!!!
Code of Federal Regulations
Examples of Federal Regulations Requiring Change Management

OSHA
29 CFR 1910.119
Process Safety Management of Highly Hazardous Chemicals

30 CFR 250.1912
Oil and Gas and Sulphur Operations in the Outer Continental

40 CFR 68.75
Chemical Accident Prevention Provisions

21 CFR 820.20/70
Quality System Regulation
Regulated Industry

• For businesses covered by those pieces of regulation, Change Management is mandatory.

• In 2013, out of 2201 FDA inspections, 3534 Form-483 observations were issued;
• 113 were change management related – 3.2%.
• Revisions to 21 CFR 820 covering CGMP - June 1997

• 820.30(i) - Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

• 820.70(b) - Production and process controls. Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40.
History

• Historic focus on change control;
• Heavy documental emphasis and approval requirements;
• Disincentive to change;
• Reduce regulatory risk by limiting change;
• Focus on individual changes;
• Highly reactive:
  – Changes driven by equipment obsolescence, raw material vendor changes...
History

- Static manufacturing can create, or is a result of, a mind-set that “the product is approved and validated – do not change.” Innovation and Continuous Improvement in Pharmaceutical manufacturing, FDA
## Pharmaceuticals Compared to Others

<table>
<thead>
<tr>
<th>Measure</th>
<th>Pharma</th>
<th>Auto</th>
<th>Aero-space</th>
<th>Computer</th>
<th>Consumer Packaged Goods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Equipment Effectiveness</td>
<td>10% to 60%</td>
<td>70% to 85%</td>
<td>50% to 70%</td>
<td>80% to 90%</td>
<td>70% to 90%</td>
</tr>
<tr>
<td>Annual Productivity Improvement</td>
<td>1% to 3%</td>
<td>5% to 15%</td>
<td>5% to 10%</td>
<td>1% to 3%</td>
<td>5% to 15%</td>
</tr>
<tr>
<td>First Pass Yield</td>
<td>60%</td>
<td>90% to 99%</td>
<td>70% to 90%</td>
<td>90% to 99%</td>
<td>90% to 99%</td>
</tr>
<tr>
<td>Production Lead Times in days</td>
<td>120 to 180</td>
<td>1 to 7</td>
<td>7 to 120</td>
<td>5 to 10</td>
<td>3 to 7</td>
</tr>
<tr>
<td>Finished Goods Inventory in Days</td>
<td>60 to 90</td>
<td>3 to 30</td>
<td>3 to 30</td>
<td>5 to 50</td>
<td>10 to 40</td>
</tr>
<tr>
<td>Labor Value-add Time</td>
<td>20%</td>
<td>60% to 70%</td>
<td>60% to 70%</td>
<td>60% to 70%</td>
<td>60% to 90%</td>
</tr>
<tr>
<td>Direct/Indirect Labor Ratio</td>
<td>1:1</td>
<td>10:1</td>
<td>10:1</td>
<td>10:1</td>
<td>10:1</td>
</tr>
</tbody>
</table>

Consequences of Change Control

• Hindered innovation and continuous improvement;
• Lower productivity;
• High percentages of non-conforming product;
• High waste and rework levels;
• High inventory levels;
• Cost!!!
Transition to Change Management

• The FDA recognized the need for a change in focus
• Flexibility and change are the precursors to improvement; Change process should support continuous improvement;
• Developing good process understanding to support a sound risk assessment and change evaluation plan
• Oversight of the change process instead of restriction change
• Focus on planning and managing multiple changes at once
Balance your approach

- COMPLIANCE
- DOCUMENTATION
- PEOPLE
- ASSESSMENT
Documentation

• *If you can’t prove it, it never happened!*  
• Should include essential fields;  
• Complex documents tend to increase the regulatory risk;  
  – Mistakes filling;  
  – Stimulate undocumented changes;  
• Complex documents also tend to disincentive changes.
Documentation

• Automate and coordinate your documents as much as possible;
  – Critical statements should be linked to radio buttons for example.
  – Minimize the chance of unnecessary comments
• Customize forms to your business;
• Should serve as a road map for the approval and evaluation of the change.
• Some companies use the risk assessment to determine level of documentation.
Assessment

• Known impacts
  – List benefits and how they can be measured;
  – Create risk assessment based on process knowledge and develop test plan accordingly;

• Unknown impacts
  – Test plan should be robust enough to catch side-effects not-listed as part of the initial assessment;
  – Some impacts will appear over long periods of time;
  – Careful with biased evaluations and simultaneous changes.
People

- Provide training to all employees expected to participate in change management;
- Employees should understand the FDA requirements; eliminate *fear of the unknown*;
- Make it easy for people to follow the process;
  - Simplify forms to contain the essential information;
  - Automate critical repetitive steps;
  - Test requirements and amount of documentation should reflect risk assessment.
Minimize approval lead-times (people’s times should be spent in planning, testing and implementation of the changes)

Incentive employees to ACTIVELY look for changes that could lead to significant benefits to the business;
Other Considerations

• Clearly define a change
  – Definition of like-for-like;
  – Existence of a design space;

• Account for emergencies and temporary changes.
Leadership Role

• Support continuous improvement and innovation;
• Never use the change management process as a punishment;
• Share the benefits of important changes with employees to break resistance to change.
Conclusions

• An ineffective change management process can lead to a chaotic manufacturing environment and the side-effects can be summarized by an increased operational cost.

• A number of different titles of the Code of Federal Regulations require change management. As a consequence, businesses regulated by those have to have a robust change management process.

• Traditionally, those requirements have been interpreted as a command to control changes or to limit the changes to the absolutely necessary. That interpretation also led to additional operational costs as it hindered innovation and continuous improvement;
Conclusions

• Even some regulatory agencies (like the FDA) started to understand the importance of continuous improvement and innovation. As a result, the focus shifted from change control to a fully functional change management.

• The implementation of a change management process requires a better balance between compliance, documentation, assessment and people.