Quality Management Systems Can Be Lean in a Highly Regulated Industry

Jennifer Rodriguez
Corporate quality systems manager at QuVa Pharma
Key Takeaways …

- How to evaluate your system to identify non-value-added activities.
- How to set up a lean improvement project for success.
- Benefits of choosing a validated QMS.
- Go from a “just OK” to a “value-added” QMS.
Jennifer Rodriguez

- Corporate quality systems manager at QuVa Pharma.
- Over 15 years as a quality professional in highly regulated industries (oil, gas and pharmaceutical).
- Expertise extends across multiple capacities, including lead auditor, project management, root cause investigation and validation.
  - Skillfully integrates IT systems with management applications, ultimately replacing paper-based systems.

Bachelor’s degree in engineering with a minor in systems engineering from Javeriana University in Colombia.

Professional certifications:
- Pharmaceutical Validation Management.
- Computer System Validation.
A “Just OK” QMS is Not Enough
Using a Value-Added QMS in a Regulated Environment

- Creates a culture focused on product quality, safety and efficacy.
- Drives out waste (non-value-added activities).
- Ensures data integrity.
- Facilitates more efficient manufacturing.
A Value-Added QMS is Expected

- Accurate and reliable data is the expectation.
- End users and patients depend on companies adhering to this concept.

**SWOT ANALYSIS**

**Internal Driver**
Assurance of product quality and efficacy is a priority

**Removing Complacency**
“Just OK” QMS has passed inspections

**Risk Mitigation**
Opportunity to be proactive instead of reactive

**Industry Expectation**
Competition is moving from “just OK” to value-added
Confronting the Brutal Facts

Hedgehog Concept
Adapted from Jim Collins’ “Good to Great”
Hedgehog Concept

Greek Parable …

Foxes …
Know many small things.

Hedgehogs …
Know one big thing.

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Hedgehog Concept

All good-to-great leaders are hedgehogs!
Hedgehogs are the experts.
Foxes are the amateurs

Are our companies becoming IT amateurs?
Should our resources be invested in building a QMS?
What Is Your Passion?

Focus on what you’re good at – core product/service.
What Can We Be Best At?

And equally important …
What can we NOT be the best at?
How Can We Be Profitable?

What drives our economic engine?
Confronting the Brutal Facts

Hedgehog Concept
Adapted from Jim Collins’ “Good to Great”

Technology accelerators:
- Digitization
- Value-added QMS
Principles of Lean

Deadly Wastes: Lean Manufacturing

- Inventory
- Waiting
- Over Processing
- Human Potential
- Transport
- Motion
- Over Production
- Defects

Reduce waste by evaluating and eliminating 7 non-value-added activities - TIMWOODS
### “Just OK” vs. Value-Added QMS

<table>
<thead>
<tr>
<th>Just OK</th>
<th>Value Added</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Waiting</strong></td>
<td><strong>Instant Notification &amp; Electronic Approval</strong></td>
</tr>
<tr>
<td>▪ Long cycle time for doc revisions.</td>
<td>▪ Reviewers can complete task away from their desks.</td>
</tr>
<tr>
<td>▪ Processes wait to be improved.</td>
<td>▪ Reduced cycle time, more efficient collaboration.</td>
</tr>
<tr>
<td>▪ Documents wait on desks to be reviewed.</td>
<td><strong>Digitization</strong></td>
</tr>
<tr>
<td></td>
<td>▪ Documents readily accessible and easy to be found.</td>
</tr>
<tr>
<td><strong>Over Production</strong></td>
<td></td>
</tr>
</tbody>
</table>
## “Just OK” vs. Value-Added QMS

<table>
<thead>
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</thead>
<tbody>
<tr>
<td><strong>R</strong>ework or <strong>D</strong>efects</td>
<td><strong>C</strong>onnectivity</td>
</tr>
</tbody>
</table>
| - Same information entered in multiple places (multiple databases)  
  - QMS is spread across different systems. | - Modules/Processes are connected.  
  - Information can be transferred and linked. |
| **M**otion | **E**lectronic Workflows |
| - Employees walk from desk to desk dropping off and collecting paper copies of documents. | - Dynamic collaboration spaces.  
  - Automatic notifications. |
## “Just OK” vs. Value-Added QMS

<table>
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<tr>
<td><strong>Processing</strong> (over processing)</td>
<td>Validated System</td>
</tr>
<tr>
<td>• Duplicate validation efforts.</td>
<td>• Validation tasks are performed by the</td>
</tr>
<tr>
<td>• Users perform more testing than needed.</td>
<td>EQMS supplier.</td>
</tr>
<tr>
<td><strong>Inventory</strong></td>
<td>• EQMS supplier provides the tools for</td>
</tr>
<tr>
<td>• Stockpile of printed forms.</td>
<td>risk assessment.</td>
</tr>
<tr>
<td>• When doc is revised, all old versions</td>
<td><strong>Just-in-Time Forms</strong></td>
</tr>
<tr>
<td>become costly waste.</td>
<td>• Employee prints only what is needed.</td>
</tr>
<tr>
<td></td>
<td>• Latest version available.</td>
</tr>
<tr>
<td></td>
<td>• Electronic forms.</td>
</tr>
</tbody>
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“Just OK” vs. Value-Added QMS

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</thead>
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<tr>
<td><strong>Intellect</strong></td>
<td><strong>Electronic Batch Records</strong></td>
</tr>
<tr>
<td>§ Non-utilized talent, skilled employees</td>
<td>§ No need to print, sort, file, retrieve, etc.</td>
</tr>
<tr>
<td>§ reviewing basic criteria.</td>
<td>§ Error proofing is built in.</td>
</tr>
<tr>
<td>§ managing paper</td>
<td></td>
</tr>
<tr>
<td>§ Negative impact on employee morale.</td>
<td></td>
</tr>
<tr>
<td><strong>Transport</strong></td>
<td><strong>Instant Record Retrieval</strong></td>
</tr>
<tr>
<td>§ Records moved from cabinets to storage locations.</td>
<td>§ Immediate retrieval of quality event and training records for inspections, internal investigations, etc.</td>
</tr>
<tr>
<td>§ During inspection, records must be transported to location.</td>
<td></td>
</tr>
</tbody>
</table>
Reducing Defects – Human Error

Goals
1. Prevent errors.
2. Detect defects (not all errors can be preventable).
3. Reduce the severity of defects.
# Reducing Defects – Human Error

**Just OK – Least Effective**

<table>
<thead>
<tr>
<th>Paper Process Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Legibility issues.</td>
</tr>
<tr>
<td>▪ Initials are not easily identifiable.</td>
</tr>
<tr>
<td>▪ Operator can easily enter the wrong date.</td>
</tr>
<tr>
<td>▪ Verifiers can miss mistakes entered by operator.</td>
</tr>
<tr>
<td>▪ Empty fields can easily be missed.</td>
</tr>
</tbody>
</table>

**Value Added – Most Effective**

<table>
<thead>
<tr>
<th>Electronic Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ No legibility issues. All data is typed.</td>
</tr>
<tr>
<td>▪ System-generated dates.</td>
</tr>
<tr>
<td>▪ Mandatory fields.</td>
</tr>
<tr>
<td>▪ Automatic value verification.</td>
</tr>
<tr>
<td>▪ Standard workflow for documents ensures all applicable personnel review documents.</td>
</tr>
</tbody>
</table>
Start by Selecting the Right Tool

- Does it have all the modules you need?
- Can it communicate with other systems such as ERP and MES?
- Is it validated?
- How mature is the supplier?
- Does the supplier have experience in your industry?
- What certifications does the supplier have?
Supplier Profile

Statements taken from ISPE GAMP Good Practice Guide: Testing of GxP Systems ...

▪ “Suppliers who are experienced in the industry and who implemented appropriate quality practices generally produce products with a lower likelihood of containing undiscovered software defects.”

▪ “Users should seek to purchase products with a lower likelihood of undiscovered software defects.”
Compliance – Data Security and Accuracy

- Is the supplier at least ISO 9001:2015 certified?
- Does the supplier have a backup and restoration policy?
- Does the supplier have disaster recovery and business continuity measures?
- Is the supplier ISO 27001 certified?
Compliance – 21 CFR Part 11

Statements from Electronic Record and Electronic Signature (ERES) Assessment – 21 CFR Part 11 …

- “Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.”
- “Electronic signatures that are not based upon biometrics shall: Employ at least two distinct identification components such as an identification code and password.”
MasterControl Experience

- More than 25 years in Life Science.
- More than 1k global customers.
- Users can rely on the documented testing conducted by a mature supplier and won’t need to repeat testing.
- Expert validation team, controlled processes, development and test environments, etc.
- Users can minimize the amount of required testing by avoiding unnecessary customizations.
- MasterControl meets all requirements of 21 CFR Part 11.
- MasterControl is widely used in highly regulated industries.
Summary

- You cannot afford to wait – a “just OK” QMS is not enough.
- Identify your non-value-added activities and start the change.
- Choose the right tool from the right supplier.
Thank You!