Quality System Development: Strength, Compliance and Efficiency Through Value Stream Mapping

Philip Russ, President, ICGXP Inc.
Philip Russ Bio

- Mr. Russ is an experienced regulatory compliance and quality assurance professional with 20 years experience in the pharmaceutical, medical device and biologics industries.
- He has a record of success developing and managing efficient business processes and systems to support these organizations.
- Russ is the owner and principal consultant of IcGXP Inc. IcGXP offers a range of regulatory compliance and quality assurance services.
Course Outline

- Introduction
- What is Value Stream Mapping?
- Value Stream Mapping for Quality Systems
- Corrective and Preventive Action (CAPA) System Example
- Case Study for CAPA
- Q&A
The Climate of Process Improvement

• Organizations should continually strive for lean and efficient operations.

• Particularly in the current economic climate, your company may ask you to find opportunities for lean improvement in your department or area, so that you can deliver the same value at lower cost to your organization.

• However it may be a challenge to find improvement opportunity in quality systems without impact on compliance.
Change is a Good Thing?!?!?

- There is always room to make small improvements, challenge the status quo, and tune processes and practice on an everyday basis.
- One approach to continuous, incremental improvement is called kaizen.
- It originated in Japan and the word translates to mean change (kai) for the good (zen).
- Kaizen is based on the philosophical belief that everything can be improved: Some organizations look at a process and see that it's running fine; Organizations that follow the principle of Kaizen see a process that can be improved.
Process Improvement

- Process improvement is successful only when you address the underlying problem.
- A useful way of improving processes successfully is to use a lean manufacturing technique called Value Stream Mapping (VSM).
- VSM originated at car manufacturer Toyota, where they called it 'material and information flow mapping.'
- VSM is now widely used in a variety of industries as a way of identifying improvement projects.
What is Value Stream Mapping?

• The basic idea behind Value Stream Mapping is this: if the underlying process is right, the outcome will be reliable.
• To get the process right, you have to understand the sequence of activities that provide value.
• VSM looks at the full, end-to-end process. It helps you map visually how information and materials flow through all of the activities that occur.
• This information is documented on a map showing how decision-making and communication processes affect the whole flow.
VSM for Quality Systems

• Value stream mapping is a tool that helps you to see and understand the flow of information as a quality system deliverable makes its way through the process or “value stream”.
• It gathers and displays a far broader range of information than a typical process map.
• It tends to be at a higher level (5-10 boxes) than many process maps.
• It tends to be used at a broader level, i.e. from receiving of request to delivery of a final system output.
VSM for Quality Systems

• A Current State Value Stream Map (CSVSM) will be created based on...
  – Review of the current procedure(s)...
  – Stake holder surveys...
  – Audit of input and output process documentation.

• Information from these sources will also indicate potential improvements, efficiencies and missing process parts for consideration.
The Basics

• After the CSVSM is developed, a project team will,
  – Calculate an initial “Value Ratio”...
  – Brainstorm improved process elements...
  – Drive out inefficiency and non-value added elements..
  – Recalculate a “Value Ratio”.

We need to determine a “Value Ratio”
Elements of a QS Value Ratio

Quality System Value Ratio

Compliance

User Friendliness

Cycle Time
The Basics

• Upon completion of the Value Stream process work a Future State Value Stream Map (FSVSM) can be generated.

• This is the road map for development of new or revised procedures, training and roll-out plans.
Warning!!

• The FSVSM may not be the “World Class System” you’ve dreamed of...
  – This is a process of **continuous** improvement.
  – There may be resource needs to implement the efficiencies/improvements.
  – Supporting systems may also need to be Value Stream Mapped.

• The idea is to **increase** the “Value Ratio” incrementally with each attempt.

• This is the “kaizen” principal.
**CAPA Process Example**

- Determine overall process and cycle time.
- Determine the “value added” processes and cycle time.
- Determine improvements to the process that increase “value added” elements and reduce cycle time.
Information Needed on Inputs

1. What are the sources of product and quality data?
2. How the data are to be captured?
3. How the data are to be analyzed, including the method of analysis?
4. When the data are to be analyzed?
5. What steps are taken after analysis?
Root Cause and Corrective Action

**Supplier**
- Investigative Process Owner
- “CAB”

**Input**
- Risk Assessment (High/Medium/Low)
- Decision to open a CAPA activity

**Output**
- Root Cause
- Justification for ‘No Escalation’ - In CAR
- Corrective Action – Non field
- Corrective Action - Field
- Action Plan Status Report
- Related documentation

**Customer**
- CAB
- Management Review
- CAB
- Action Owner (Mfg / R&D / ..)
- FDA
- Distribution
- Customer Service
- Management Review
- CAB

**Diagram Flow**
1. Prioritized Issues → Follow Investigation process
2. Document Investigation Results (Root Cause & CA)
3. Define Effectiveness Evaluation Criteria for CA
4. Is product in the field? (Yes)
5. Escalation Process
6. Implement Corrective Action
7. Review & Approve Corrective Action is implemented
8. Approvals
9. Feedback to Risk Management process
10. Implement Corrective Action
11. Assign Owners for different activities
Documenting the Current State

• A Current State Value Stream Map (CSVSM)
  – This map was created based on review of the current procedures
  – stake holder survey
  – and, an audit of input and output process documentation.

• Information from these sources indicated potential improvements, and missing process parts for consideration.
Enhancing the Future State

• Upon completion of the Value Stream process work a Future State Value Stream Map (FSVSM) can be generated.

• This is the road map for development of new or revised procedures, training and roll-out plans.
Defining Value

Value:
• As a current state baseline, each process element was assigned a “value” rating calculated using the following formula: (Cycle-time x User Friendliness Factor x Compliance Factor)

Cycle-time:
• Overall Cycle-time was to be used in the denominator of the “Value Ratio” calculation to normalize the value data. Overall Cycle-time was defined as an average of all the user response to cycle-times from the user group survey.
Defining Value

**User Friendliness:**
- **Easy:** Weighted at 100% (Value x 1)
- **OK:** Weighted at 75% (Value x 0.75)
- **Difficult:** Weighted at 50% (Value x 0.50)

**Compliance:**
- **High:** Fully Compliant to SOP and regulations. Weighted at 100% (Value x 1)
- **Medium:** All key elements in the SOP and regulation exist but could be enhanced. Weighted at 75% (Value x 0.75)
- **Low:** Key elements in the SOP and regulation are deficient or missing. Weighted at 50% (Value x 0.50)
Six (6) procedures were evaluated independently and with the core team.

Not all procedures completely detail needed key CAPA elements.

A composite of all business processes in the procedures was used to develop the CSVSM.
Stakeholder Survey

• Responses and comments from stakeholders indicated, the following areas be considered for CAPA process enhancement:
  – Making significant changes to the business process before implementing a software tracking solution.
  – Separate the CAPA system from the feeder stream systems of NCM, internal audit and deviation.
  – More training in CAPA business process.
  – Formalize methods for, and automate trending.
  – Reporting vehicle outside the system to facilitate trending.
  – Task notification system.
  – Better investigation training and resources for CAPA investigations
Output Review

• 29 CAPA package elements were reviewed independently based on requirements and expectations from CFR 820.100 and ISO13485.

• Compliance levels for the packages were rated based on the following definitions:
  – High: Fully Compliant to SOP and regulations. Weighted at 100% (Value x 1.0)
  – Medium: All key elements in the SOP and regulation exist but could be enhanced. Weighted at 75% (Value x 0.75)
  – Low: Key elements in the SOP and regulation are deficient or missing. Weighted at 50% (Value x 0.50)

• Compliance levels were rated as “Low”
CAPA Process
Value Stream Mapping
Brainstorm
CAPA VSM Process

- CAPA Streams
- Initiation
- Trending and prioritization
- Investigation
- Approvals
CAPA Streams
CAPA Streams

- Internal Audits
- External Audits
- Facilities
- Equipment
- Controls
- Calibration
- Laboratory Controls
- Receiving Inspection & Material Control
- Supplier Quality/OEM
- Complaints & Customer Feedback
- Distribution
- Field Service Records
- Document Control Issues
- Manufacturing
- Training
- Management Review
- Nonconformance
- Deviations
CAPA Streams

• Prerequisites for including all CAPA streams in the program:
  • All sites need feeder system programs in place.
  • All feeder systems need trending of data with review at site level and management review level.
  • All feeder systems need triggers determining escalation criteria.
  • Buy-in required from support groups.
CAPA Stream Considerations

• Regulatory vs. Non-regulatory
  – Site approach to triggers, trending and inclusion of certain CAPA streams may be dependent on the regulatory status.
Initiation
Initiation Enhancements

- Documented justification for not proceeding to CAPA from the feeder stream program.
- Procedural list of required information for the request for CAPA.
- Procedural problem statement minimum requirements and standard language.
Trending and Prioritization
Trending and Prioritization

- CAPA's will be prioritized by the QA CAPA coordinator (i.e. Critical, Major, Minor)
- CAPA plan due dates will be based on the issue prioritization.
Investigation
Investigation Enhancements

• Need effective technical writing training.
• Need effective root cause analysis training.
• Training on what CAPA is?
• What is a Correction, Corrective Action and Preventative Action
• Considerations of verification and validation
Investigation Assignment

• Approaches considered:
  – Process owner is assigned CAPA investigations.
  – Assign investigations to the most knowledgeable person.
  – Dedicated resource for root cause investigation.
  – Team process owners with a professional investigator to accomplish investigations.
  – Certified investigators.
  – QA leads investigation teams.
  – Team process owners with a certified investigator to accomplish investigations. (Chosen by the team)
Corrective Action Plans

- Is the CA a project or more simple.
- Actionable steps in the CA.
- Notifications on tasks due to owners.
- Impact on other systems.
- Expanding to other lots, systems.
- Justifications of elements that are not required...N/A is not enough.
Preventative Action/Effectiveness

- Effectiveness check failure results in a return to the RCA process in same CAPA.
- Clearly defined effectiveness criteria.
- Allowing just a preventative action feature in the system for process improvement.
- Complaint rates alone can not be used as effectiveness criteria unless justified.
- Effectiveness check period and assignment will be documented in the plan.
Approvals
Approvals

- CAPA Request - Initiator only
- CAPA Initiation - QA CAPA coordinator approve, functional owner notification
- Investigation - Business rep. and QA
- Implementation Verification - QA with objective evidence
- Effectiveness Check - QA with objective evidence