Knowledge Management
AGENDA

- Why Knowledge Management?
- Generating Knowledge
- Analyzing Knowledge
- Recording Knowledge
- Using Knowledge
- In Practice
WHY KNOWLEDGE MANAGEMENT?

This is the solution we've devised for dealing with the flooding caused by climate change.
ICH Q10

Pharmaceutical Development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

Investigational products

GMP

Management Responsibilities

Process Performance & Product Quality Monitoring System
Corrective Action & Preventive Action (CAPA) System
Change Management System
Management Review

PQS elements

Enablers

Knowledge Management
Quality Risk Management
Knowledge management is a systematic approach to gaining, analyzing, storing and processing information. This information can be related products, processes and their inherent components.

Product and process knowledge need to be managed from development up to the final market withdrawal of the product.

Knowledge should include, knowledge of guidelines and rationale behind it.

In fact no boundaries
• Possible sources of knowledge:
  – Knowledge that is already available (public domain / approved internally);
  – Development studies;
  – Technology transfer activities;
  – Process validation studies during entire product life-cycle;
  – Production experience
  – Innovation
  – Continuous improvement;
  – Change Management activities.
KNOWLEDGE MANAGEMENT DELIMITATIONS

• Knowledge is divided over:
  - Different staff members,
  - Over different departments,
  - With different disciplines,
  - Over several locations,
  - That use different languages

• “Knowledge is Power”
  - Political Climate
• But also consider the following:
  – Complexity of the Supply Chain(s)
  – Outsourcing
  – Virtual Manufacturing
  – Globalization
  – Cross-Location Teams
  – Mega-Companies
  – Re-organizations, Mergers, Take-Overs
• A complaint is received regarding a batch of capsules, after testing it is found that the capsules do not contain an API...
• The original analysis- and batch documentation show no irregularities...
• Later it is found that the color on the packaging is slightly different than the company’s own packaging...
• It is probably a falsification...
• A recall is initiated...

• What information (knowledge) do you need, as a producer, to perform this investigation including a root-cause analysis?

• And what information (knowledge) do you need when you have outsourced the production of your filling?
GENERATING, ANALYZING, STORING, REVEALING
• “Knowledge management is a systematic approach to gain, analyze, store and process information...”

• Generating
• Analyzing
• Storing
• Revealing
GENERATING KNOWLEDGE

• Creating entirely new knowledge:
  – Idea

• Applying existing knowledge:
  – Applying knowledge to a different field of expertise
  – Combining knowledge of different fields of expertise

• “Extracting existing knowledge:”
  – You don’t know everything you know!

• “For cause:”
  – You are uncertaining and seek knowledgee!
GENERATING KNOWLEDGE

• By:
  – Research:
    • Product Development
    • Technical Transfer
    • Daily Routine
    • Process Analysis (Annual Reviews, Trending, Data Analysis)
    • Process Improvements (Change Controls)
  – Fortunate Coincidences
  – Deviations
• Only “positive” knowledge is seen as knowledge (only the successes; not the failures)
  – Record everything, the research that solves/proves something, but also the research that does doesn’t prove anything

  discipline in research!
• Knowledge is missed

  - What seems to be common practice now, may be completely unacceptable in five years
  - Talk of the trade, abbreviations, etc.

  **discipline** in documenting/recording is crucial
ANALYZING KNOWLEDGE

• What knowledge is valuable?

• What knowledge is valuable to which person?
STORING KNOWLEDGE

• Storing / recording knowledge in documents:
  – Language
  – Use of Language
  – Validity
  – Confidentiality

• Not all knowledge is suitable for recording:
  – Visual / Audio recording
  – OTJ Training and Experience

Manage logically where to store information
KNOWLEDGE STORING

• Types of Documents:
  – Logs
  – Registration Documentation
  – Guidance Documents
  – SOP’s and Work Instructions
  – Reports
  – Reviews
  – Tech Transfers
  – Deviations, Changes
• **Availability:**
  – Making sure knowledge is stored
  – Making sure the stored knowledge is/remains available
  – Make sure knowledge is understandable

• **Accessibility:**
  – Automation

• **Retraceability:**
  – Knowing something is recorded
  – Retrieving recorded/stored information
  – A system which is logic
Problems:

- Not known that knowledge is available: people “forget” to search
- Not stored in the correct way
- Knowledge is “hidden” in a different document
- Reports are unreadable to a person with a different expertise
- Language barrier
KNOWLEDGE MANAGEMENT IN PRACTICE
IN PRACTICE

• How to start this up in an organization?:

  – Policy & Guidance documents
  – Define Product Knowledge
  – Infrastructure
• Stress the value of knowledge
• Reward the storage, sharing and using of knowledge

• Make it easy to see/find:
  – Where certain knowledge is generated
  – Where this knowledge will be applied

• Provide a sense of direction to the documentation process:
  – Prescribe standard attributes
  – Standard “language” based on the users
PRODUCT KNOWLEDGE

- Process development documentation
- Analyze development documentation
- Clinical Studies
- Registration Documentation
- Contracts (Technical Agreements)
- Technology Transfer Documentation
- Licences, Patents
- Site Master File (SMF)
PRODUCT KNOWLEDGE

- Changes, Deviations, Complaints, APR’s/PQR’s
- Risk Analysis
- Validation Documentation
- BOM
- SOPs, Batch Records, Analysis Procedures, Spec’s
- Reference Standards
- Stability Studies
- SHE data, licenses
• Product knowledge revolves around:
  
  – The huge amount of documents

  – The huge amount of detail

  – The incredible history
INFRASTRUCTURE

• Safe & Secure

• Available where needed

• Both:
  • Archive-data (scans),
  • “living documents” (SOPs) as
  • Electronic forms (Deviations, Change Controls)
EXAMPLE SME’S
(SUBJECT MATTER EXPERTS)
## Functional SME List Example

<table>
<thead>
<tr>
<th>Functional Areas</th>
<th>Sub Areas</th>
<th>Level -IV Beginner</th>
<th>Level -III Under Training and Grooming</th>
<th>Level -II Independent &amp; Functional</th>
<th>Level -I Independent &amp; Trainer</th>
<th>SME as in Jun’15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean Room Behavior &amp; Aseptic Processing</td>
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<tr>
<td>Sterilization by filtration</td>
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<tr>
<td>Disinfectant efficacy</td>
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<tr>
<td>Cleaning Validation</td>
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<tr>
<td>Complete EM program (including continuous particle monitoring)</td>
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<tr>
<td>Solution preparation VBI</td>
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<tr>
<td>Solution preparation VBIV</td>
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<tr>
<td>HVAC - AHU, fillers, DOP, Smoke Test, Zoning, Classification</td>
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<tr>
<td>Glassware Washing, sterilization</td>
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<tr>
<td>Autoclave Validation, DHS Validation</td>
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<tr>
<td>Gowning Policy &amp; Procedures</td>
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<tr>
<td>Cold Rooms, Refrigerators, Incubators, Freezers Mapping, Monitoring, Scada, BMS Systems, Temperature, RH, DP Monitoring</td>
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<td>Media Fill Validations</td>
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<tr>
<td>CIP/SIP</td>
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<tr>
<td>Reference/ Working Culture Storage Areas</td>
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</tbody>
</table>
A place holder for knowledge (and use for training)

- Process Description
- Block Flow Diagram (BFD)
- Process Flow Diagrams (PFDs), including input (materials), Process Parameters and Testing
- Description of buffers
- Bill of Testing
- Bill of Equipment
- Studies (FMEAs) and specifics
8.

• Relation between risk of incidents and our behavior

0
20
40
60
80
100
120

Risico Ratio

"good" behavior

slingeren
handen

loos

niet
desinfecteren

aan

kleding

trekken

leunen

tegen

muur

"good" behavior

Alle

2

Alle

3

• Effect of own behavior is easy to determine.

• Risk avoidance behavior (prevent suffering) must be central.

THANK YOU FOR YOUR ATTENTION

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