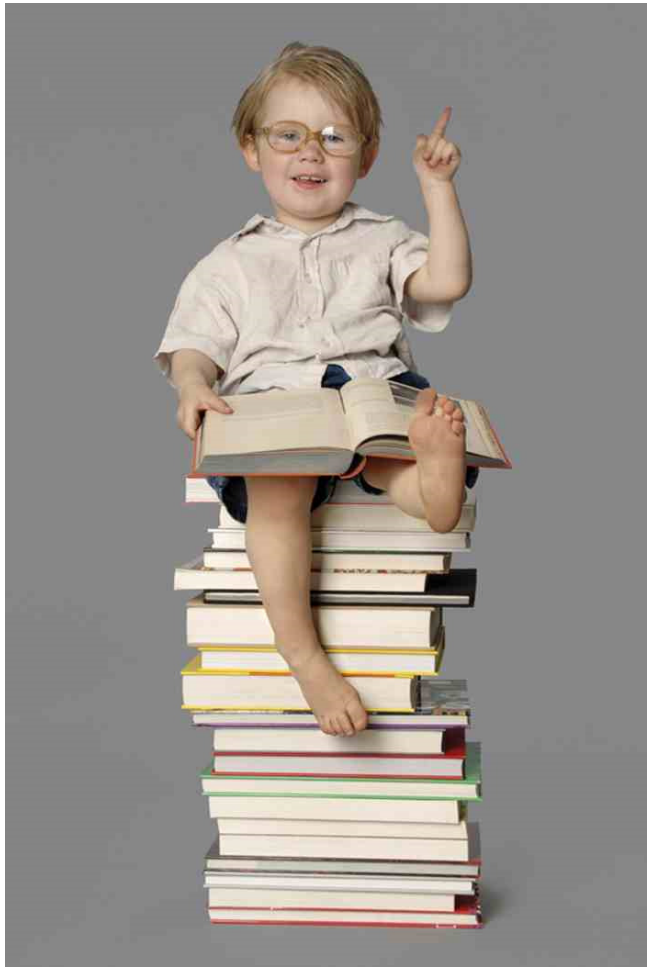

PHARMACEUTICAL
CONSULTANCY
SERVICES
Knowledge
Management

# AGENDA



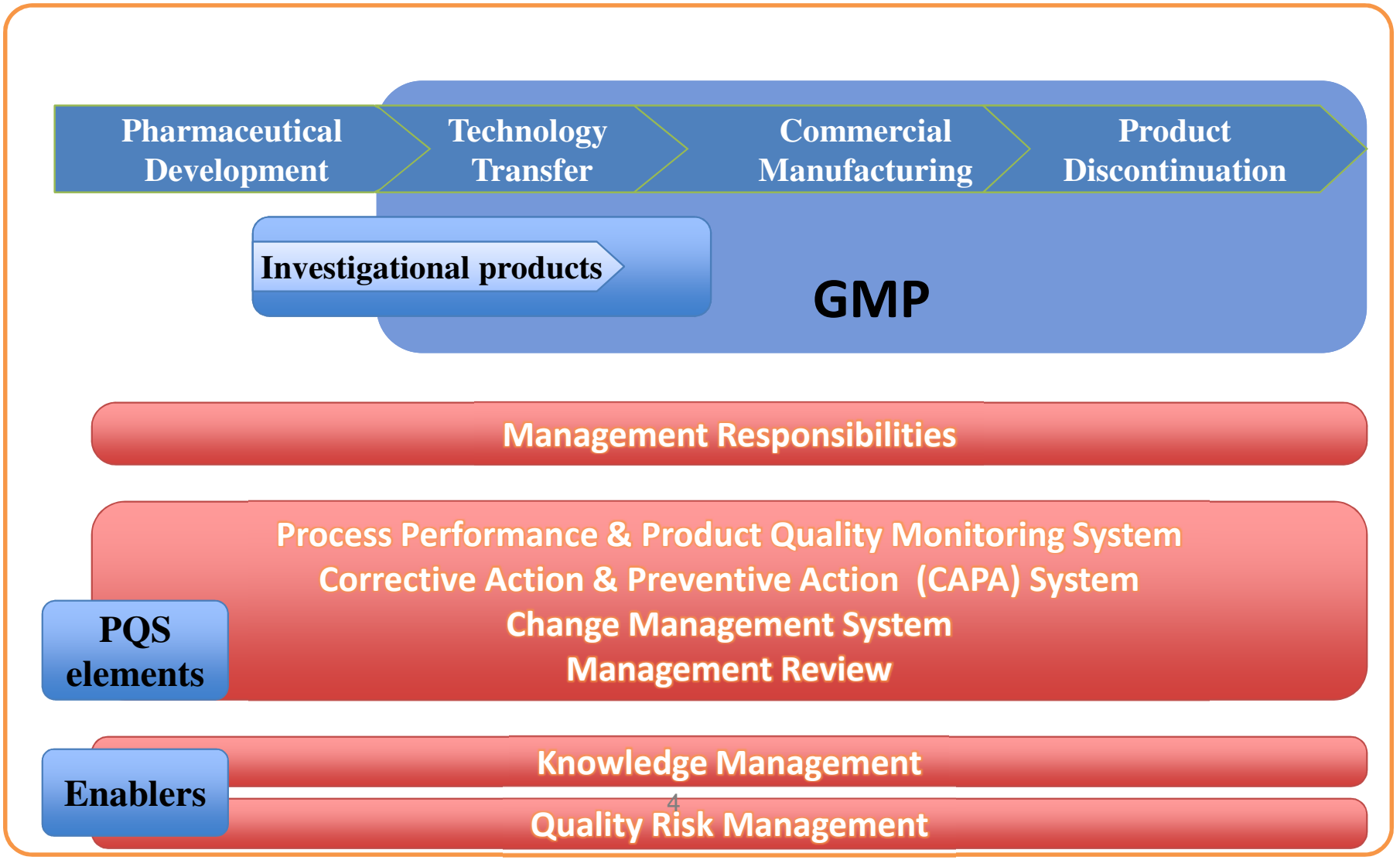
- Why Knowledge Management?

- Generating Knowledge
- Analyzing Knowledge
- Recording Knowledge
- Using Knowledge

- In Practice

# WHY KNOWLEDGE MANAGEMENT?

# ICH Q10

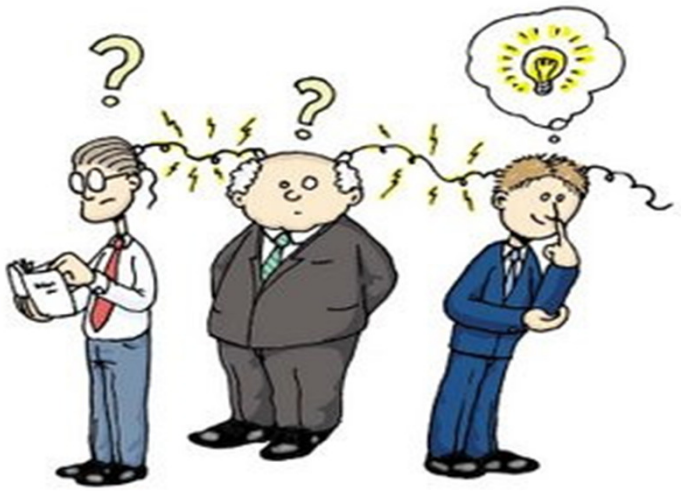

Pharmaceutical Development
Technology Transfer
Commercial Manufacturing
Product Discontinuation
Investigational products
GMP
Management Responsibilities
Process Performance & Product Quality Monitoring System
Corrective Action & Preventive Action (CAPA) System
Change Management System
Management Review
PQS elements
Knowledge Management
Quality Risk Management
Enablers

# KNOWLEDGE MANAGEMENT ICH Q10

- 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

# KNOWLEDGE MANAGEMENT ICH Q10

- **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.

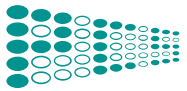


# KNOWLEDGE MANAGEMENT DELIMITATIONS

- 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

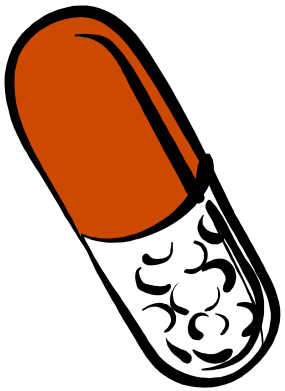


# KNOWLEDGE MANAGEMENT DELIMITATIONS

- **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

# IN PRACTICE (1)…

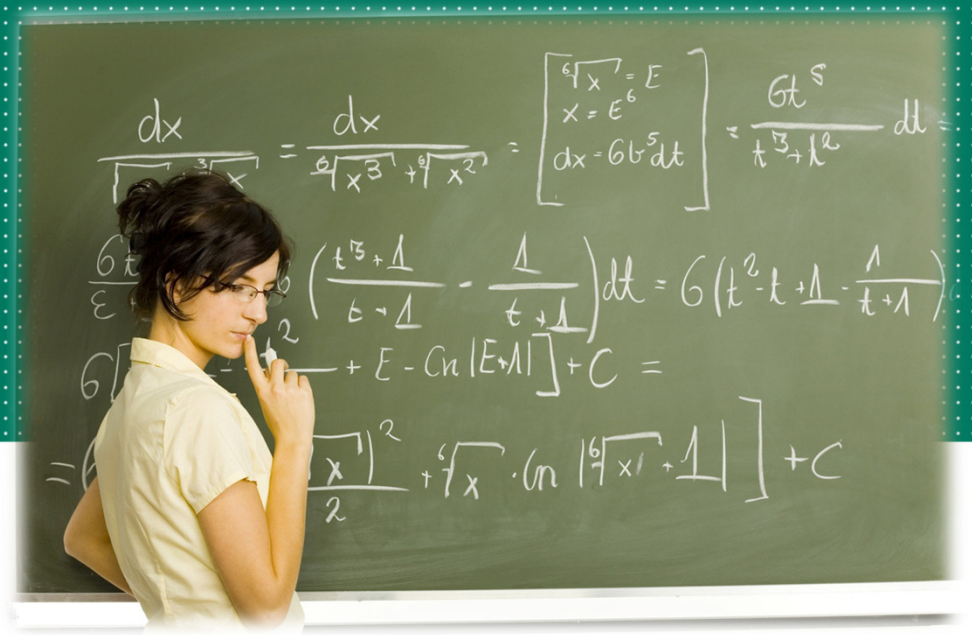


- A complaint is received regarding a batch of capsules, after testing it is found that the capsules do not contain an API…
- The original analysis- and batch documentation show no irregularities…
- Later it is found that the color on the packaging is slightly different than the company's own packaging…
- It is probably a falsification…

# IN PRACTICE (1)…

- 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

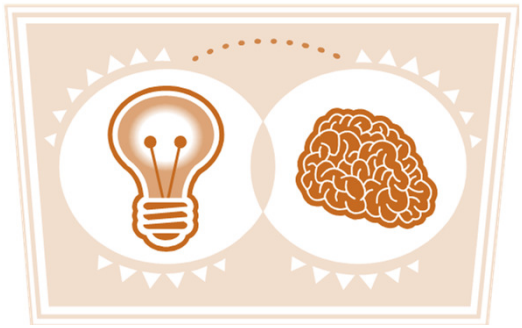


# KNOWLEDGE

- “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!

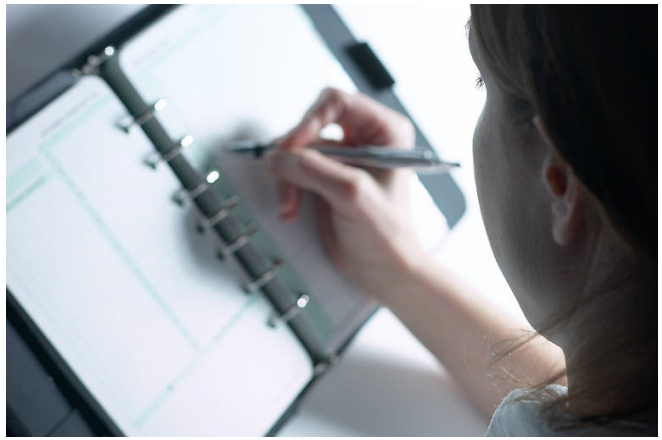
# GENERATING KNOWLEDGE

- **By:**
  - Research:
    - Product Development
    - Technical Transfer
    - Daily Routine
    - Process Analysis (Annual Reviews, Trending, Data Analysis)
    - Process Improvements (Change Controls)
  - Fortunate Coincidences
  - Deviations

# GENERATING KNOWLEDGE

- **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!**



# GENERATING KNOWLEDGE

- **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**

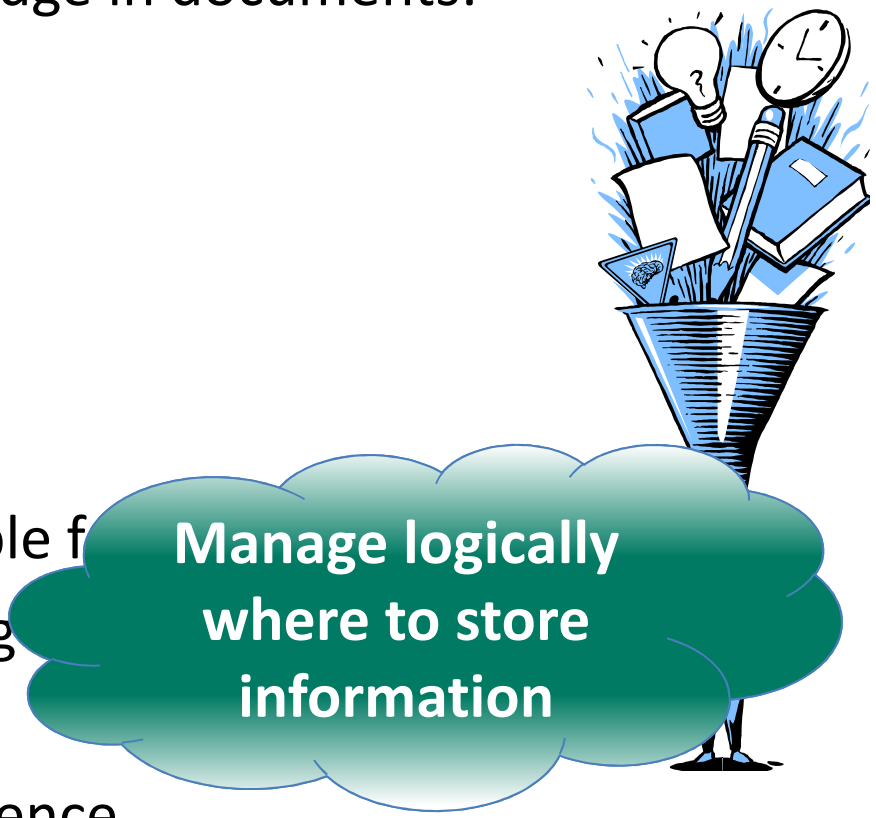
# ANALYZING KNOWLEDGE

- 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 f
  - Visual / Audio recording
  - OTJ Training and Experience



# KNOWLEDGE STORING

- **Types of Documents:**
  - Logs
  - Registration Documentation
  - Guidance Documents
  - SOP's and Work Instructions
  - Reports
  - Reviews
  - Tech Transfers
  - Deviations, Changes

# REVEALING KNOWLEDGE

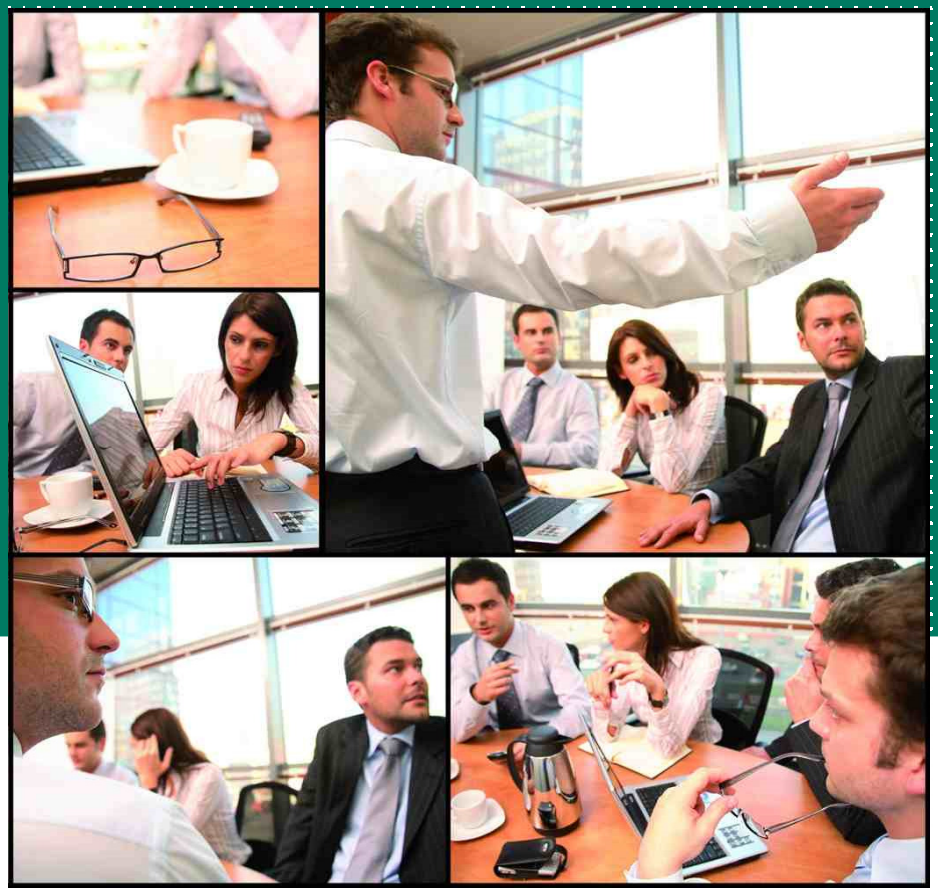
- **Availability:**
  - Making sure knowledge is stored
  - Making sure the stored knowledge is/remains available
  - Make sure knowledge is understandable
- **Accessibility:**
  - Automation
- **Retraceability:**
  - Knowing something is recorded
  - Retrieving recorded/stored information
  - A system which is logic

# REVEALING KNOWLEDGE

## 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

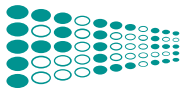
# POLICY & GUIDANCE DOCUMENTS

- **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



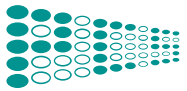
# PRODUCT KNOWLEDGE

- 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



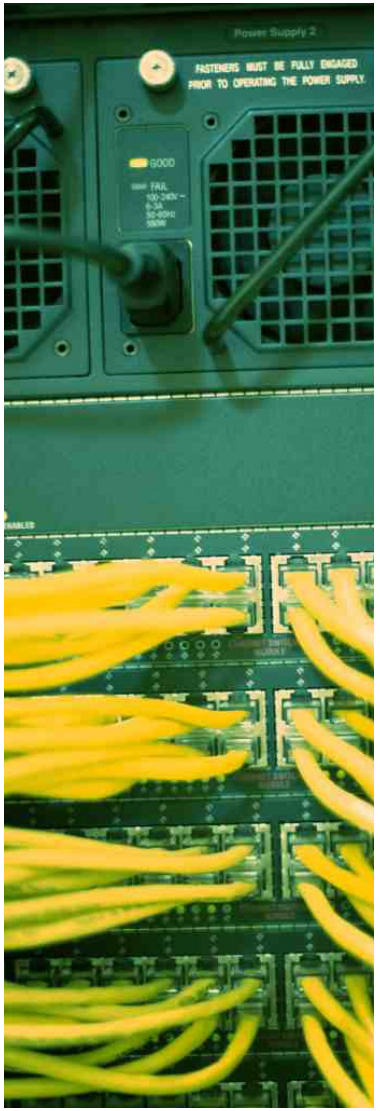



# PRODUCT KNOWLEDGE

- Product knowledge revolves around:
  - The huge amount of documents
  - The huge amount of detail
  - The incredible history

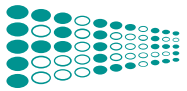
# INFRASTRUCTURE

- Safe & Secure
- Available where needed
- Both:
- Archive-data (scans),
- “living documents” (SOPs) as
- Electronic forms (Deviations, Change Controls)



# EXAMPLE SME'S (SUBJECT MATTER EXPERTS)



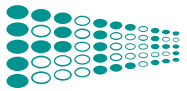



# FUNCTIONAL SME LIST EXAMPLE

| FUNCTIONAL AREAS | SUB AREAS | Level -IV Beginner | Level -III Under Training and Grooming | Level -II Independent & Functional | Level -I Independent & Trainer | SME as in Jun'15 |
|---|---|---|---|---|---|---|
| Clean Room Behavior & Aseptic Processing | | | | | | |
| Sterilization by filtration | | | | | | |
| Disinfectant efficacy | | | | | | |
| Cleaning Validation | | | | | | |
| Complete EM program (including continuous particle monitoring) | | | | | | |
| Solution preparation VBI | | | | | | |
| Solution preparation VBIV | | | | | | |
| HVAC - AHU, fillers, DOP, Smoke Test, Zoning, Classification | | | | | | |
| Glassware Washing, sterilization | | | | | | |
| | | | | | | |
| Autoclave Validation , DHS Validation | | | | | | |
| Gowning Policy & Procedures | | | | | | |
| Cold Rooms, Refrigerators, Incubators, Freezers Mapping, Monitoring, Scada, BMS Systems, Temperature, RH, DP Monitoring | | | | | | |
| Media Fiill Validations | | | | | | |
| CIP/SIP | | | | | | |
| Reference/ Working Culture Storage Areas | | | | | | |

# EXAMPLE PROCESS MANUAL



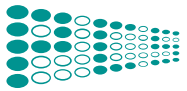



# PROCESS MANUAL

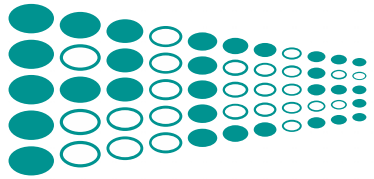
A place holder for knowledge (and use for training)

- 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



# THANK YOU FOR YOUR ATTENTION

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