Is Knowledge Management part of your Pharmaceutical Quality System?

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Todays Agenda:

- Background & the roots of KM
- What we mean by KM
- The Knowledge Cycle and Learning
- Business Strategy
- People and Content
- Impact on the Pharma Industry

What is Knowledge?

Facts, **information**, and **skills** acquired through **experience** or **education**; the theoretical or practical understanding of a subject

What is Wisdom?

The quality of having **experience, knowledge, and good judgement**

Introduction to KM

- No set formula
- Every company has own approach
- Means different things to different people
- It is about **Content Management** (CM)
- It is also about **people**

What is KM?

*Knowledge Management is a discipline that promotes an **integrated approach** to **identifying, capturing, evaluating, retrieving**, and **sharing** all of an enterprises information assets. These assets may include databases, documents, policies, procedures, and previously un-captured expertise and experience in individual workers*

(*Duhon, 1998*)

The roots of KM

- Knowledge transfer has been around a long time
- Aboriginal rock art:
    - **40,000 years old**

Aboriginal pictographs known as Wandjina in the Wunnumurra Gorge, Barnett River, Kimberley, Western Australia

- Business practice since the 1990s
- KM born from the use of computer-based tech, intranets, practitioners, data management etc

Shared knowledge = profit

What do we mean by KM?

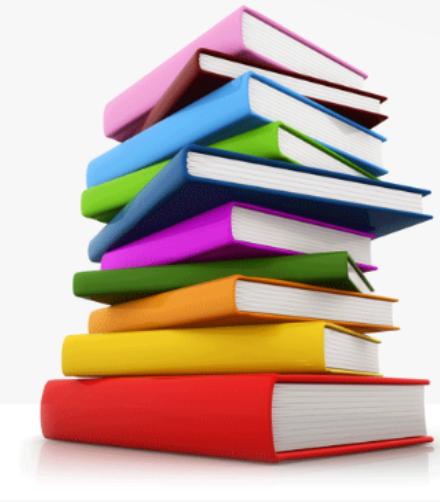
- Useful to describe **data**, **information** and **knowledge** as a hierarchy
- Some also add a further layer to include **wisdom**
- **Lets use an analogy:**
  - I am in the city and I want to get home...

"How do I get home?"

- **Data:** Departure times in the timetable
- **Information:** Additional content that enhances the data
- **Knowledge:**
  - **Explicit:** Announcement: "*Train is delayed by 20 minutes*"
  - **Tacit:** Passenger says "*This train is always late when the footy is on!*"

Two types of knowledge

Explicit Knowledge: written or recorded in documents, databases, websites etc. It is tangible-can be stored, accessed, transmitted and distributed.



Tacit knowledge: Know-how, experience, intuition, ideas etc. Difficult to define and access. Needs the right environment, culture and questioning techniques to unlock and share it

- Knowledge that is "*behind the eyes and between the ears*".

The flow between Tacit and Explicit knowledge

Articulated through images, symbols & language e.g. product concept, design, brand

Generated through common experiences e.g. conversation, skill, know-how, care, trust etc

Tacit

Explicit

Systematized & packaged e.g. documents, specifications, manuals, patents, licences

Lets start here!

Learning from written material, videos, presentations etc

Knowledge Transfer processes

The Knowledge Cycle

The "what" for KM

Explicit & Tacit knowledge

Use

Knowledge is truly shared and learned when it is applied to improve work, make decisions and create new opportunities

Create

New knowledge is generated through learning, experience, research & application

Capture

Knowledge is collected from individuals & groups, and stored in a way that can be shared with others

Organise & Manage

Systems & processes enable the structured organisation of knowledge so that it can be easily found when needed

Access

Knowledge needs to be easily accessible when needed

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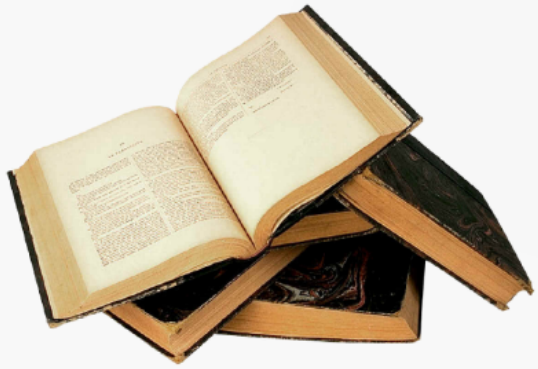

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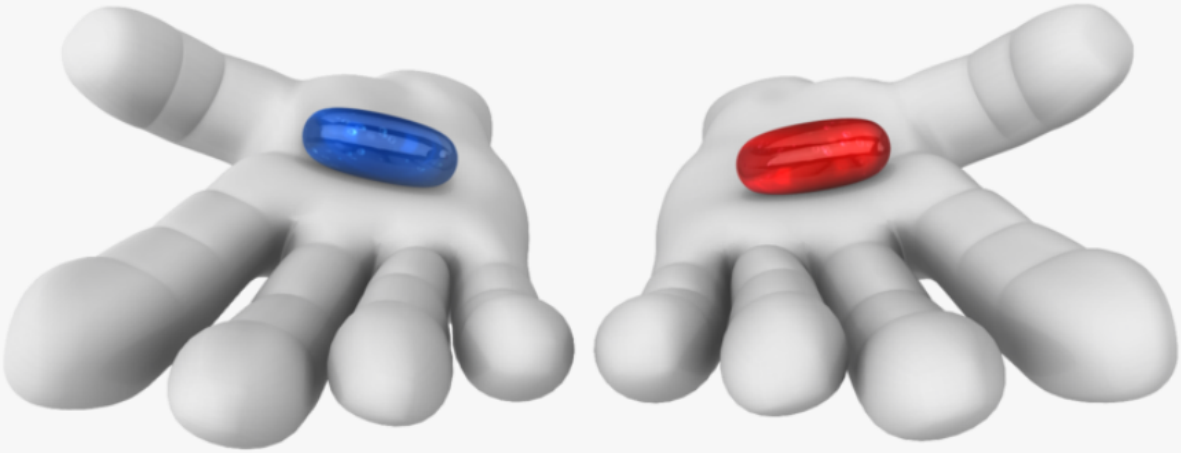

Learning

The "*when*" of KM

Learn Before:

"Before I start, what can I learn from others who have done something similar"?

"**Learn Before**" mirrors the left hand side of the Knowledge Cycle:

- **Access**
- **Use**

Learn During:

"What am I learning that I could usefully share with others?"

"**Learn During**" embodies the whole Knowledge Cycle:

- **Create**
- **Capture**
- **Organse & Manage**
- **Access**
- **Use**

Learn After:

"What did I learn that I could usefully share with others?"

"**Learn After**"echoes the right hand side of the Knowledge Cycle:

- **Create**
- **Capture**

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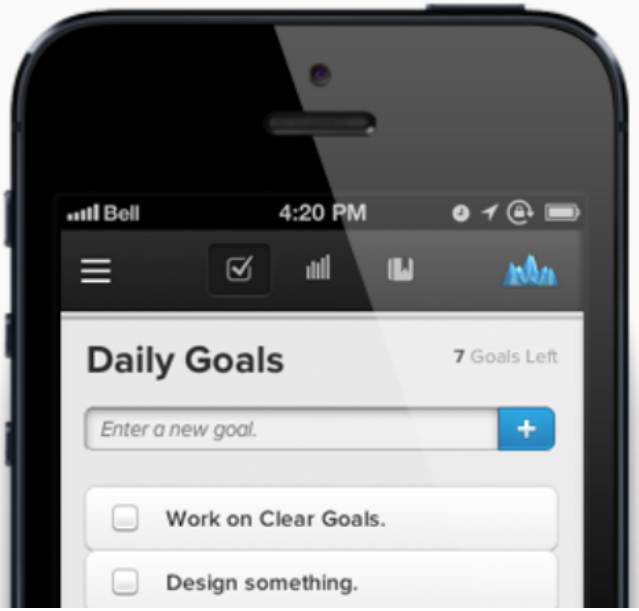
Linking KM to Business Strategy & Goals

- Requires resources, effort & commitment
- KM initiatives aligned with business strategy
- Plays a key role in delivering its goals & objectives



Why put effort into a Knowledge Management process?

Improve product quality and improved services

Building on lessons learned & shortening the learning curve

Increased profitability

Lower Operating Costs

Innovation

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Other drivers:

- **Many people soon to retire, or loss of key people to competitors.**
  - Knowledge Retention Program required.
- **Low or variable operational efficiencies.**
  - Facilitate Best Practice transfer.
- **Repeated failures in the business-learnings not being identified or are forgotten.**
  - Action Learning Reviews

KM KPIs

- **Difficult to connect KM activity to the bottom line**
- **How do you measure the the impact of sharing a Good Practice?**

Collecting the right kind of measures

- Tangible results of a KM program can take a while to come through, so some early measures or metrics are required
- The American Productivity & Quality Center (APQC) has carried out some work on this:

1. Use the organisations measure of success as the starting point

Instead of creating separate KM measures of outcomes, develop measures that relate to the business outcomes that the KM activities are supporting

i.e. transfer of knowledge that enables an existing process to startup at a new site versus another site

2. Define Specific Measures for Specific KM Interventions

For example, the cost and impact of a Community of Practice (CoP) will be measured differently from those of a Content Management System

3. Select metrics to reflect activity that relates to the business outcome

Many indicators of activity possible, especially during early stages of a KM program:

- # of documents added to a collaborative workspace
- # of times documents are accessed
- trend in the # of hits on a website/wiki etc

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Relating People and Content

- Some organisations focus on managing knowledge **as a resource** (coupled with IT, DM, IM etc)

- Others focus on **learning, sharing** knowledge, **stimulating new ideas** (linked with HR, L&D)

Together, they provide the sources of knowledge available to the organisation

Content Management (CM)

- Vast array of technology available to support CM
- **Must have:**
  - Version control, taxonomies, meta data
  - Ensure consistent function of system
  - Users can retrieve data easily
- At the centre of the **Knowledge Cycle**
  - Managed by an Admin, SME, Trainer, Mentor

Commitment from people

Such infrastructures **will only work if people adopt and use them consistently**:

- Part of their behaviour
- Part of the organisation's culture.
- **Needs to be incentives:** positive reinforcements or negative consequences.

KM Tools, Processes & Technology

Two mental models:

- The Knowledge Cycle
- Learn Before, During & After.

Break these down into four areas:

- Learning Interventions that are usually associated with LB, LD and LA
- Good/Best Practice and Knowledge Transfer
- CoPs
- Technology

Range of tools for LB, LD and LA:

- **Research & Benchmarking:** (LB)*"Spend a little time to save more time, reduce the risk of mistakes & produce a better result"*
- **Peer Assist:** (LB) workshop-based.
- **Visits:** (LB & LD).
- **After Action Reviews:** (LA)
- **Learning Reviews:** (LA)
- **Learning History**: (LA)
- **Lessons Learned:** (LA)
    - Who might benefit from it, useful for future, capturing lessons, supporting info, storage, strong LB culture to benefit

Good/Best Practice & Knowledge Transfer:

- **Good Practice Transfer**-needs to be shared
- Can provide ideas & inspiration for improvement
- Can prompt people to recognize that they cannot stand still

- **Knowledge Transfer**: "source" and "receiver"
  - **Tacit to tacit** - Peer Assist (LB)
  - **Tacit to explicit** - knowledge harvesting, knowledge retention
  - **Explicit to tacit** - e-learning, doc-based training
  - **Explicit to explicit** - CM component

Communities of Practice (CoPs)

*"A **dispersed** group of people with a **common interest** in a subject who have **decided to work together** to **share** what they know, **learn** from each other and **work collaboratively** to achieve **common goals**. Their involvement with each other is **voluntary**, although it may be driven by **cascaded objectives**, and they do not have the same management reporting line ."*

Richard McDermott and Etienne Wenger.

Technology

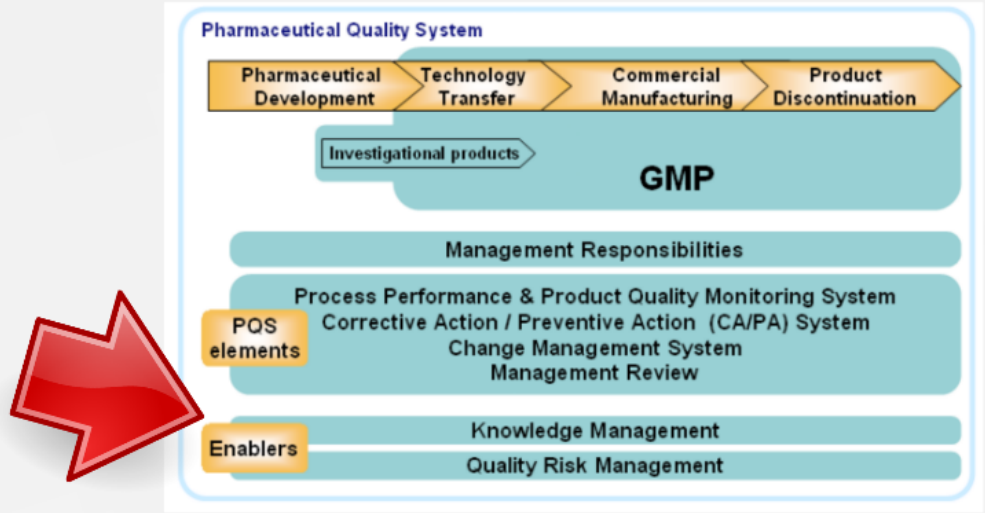
- Technology supports the CM element and facilitates people-to-people connections
- Blogs, collaborative workspaces, CM systems, DM systems, Forums, email, IM, intranets, podcasts, RSS, VoIP, social media, webinars, wikis.

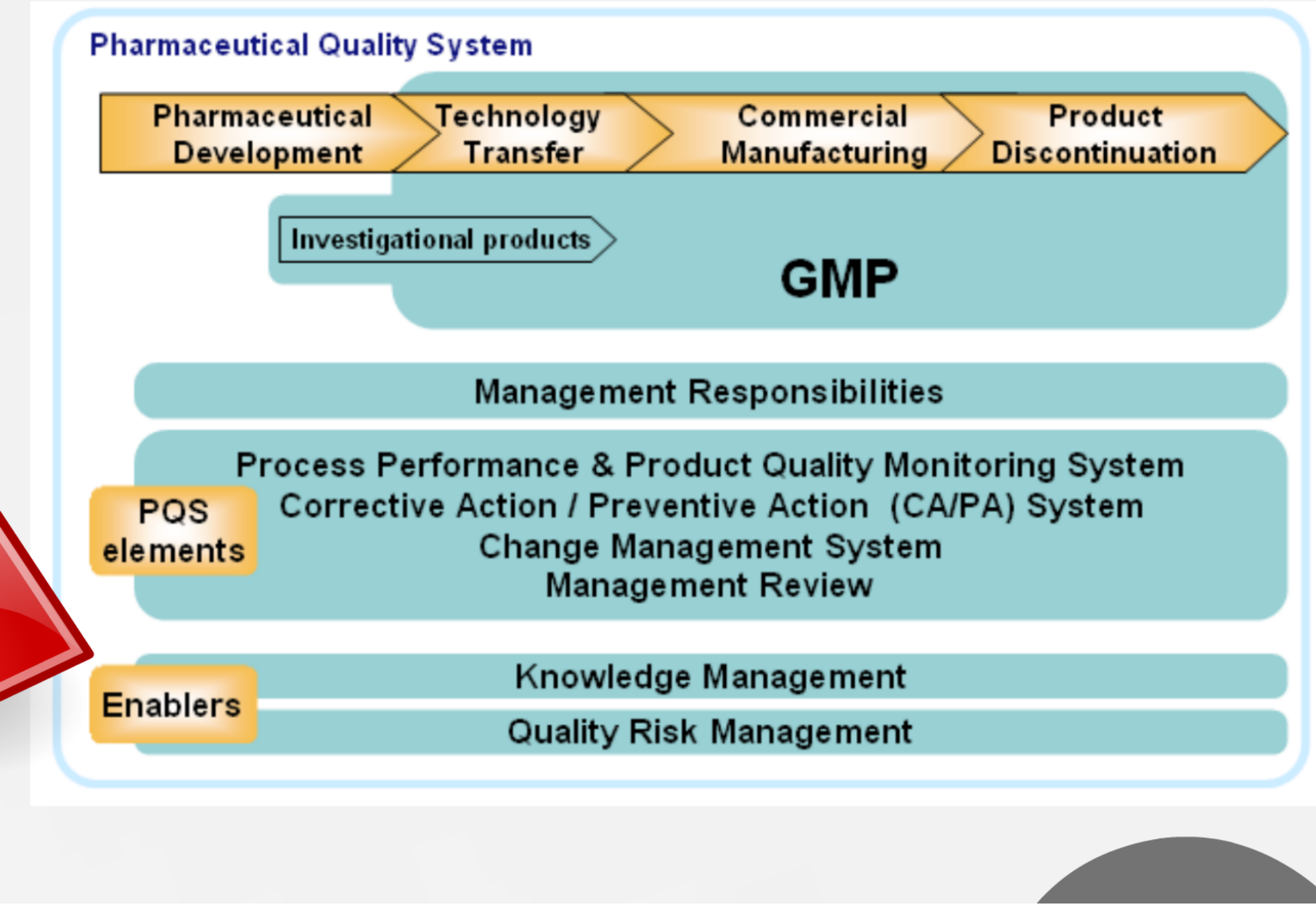
Todays reasons for KM?

- Evolution of the pharmaceutical value chain-discovery to market
- From medicinal chemistry to biopharma & biotech
- Single drug targets to stratified medicines
- Changes in the nature of manufacturing & in the supply chain

KM framework in the context of our industry

- Knowledge is generally considered as "**the other product**" from the industry
- **ICH Q12** being drafted to cover this




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

ICH Q10 PQS

1.6 Enablers: Knowledge Management and Quality Risk Management

Use of *knowledge management* and quality risk management will enable a company to implement ICH Q10 effectively and successfully. These enablers will facilitate achievement of the objectives described in Section 1.5 above by providing the means for science and risk based decisions related to product quality.

1.6.1 Knowledge Management

Product and process knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. For example, development activities using scientific approaches provide knowledge for product and process understanding. Knowledge management is a systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing processes and components. Sources of knowledge include, but are not limited to prior knowledge (public domain or internally documented); pharmaceutical development studies; technology transfer activities; process validation studies over the product lifecycle; manufacturing experience; innovation; continual improvement; and *change management* activities.

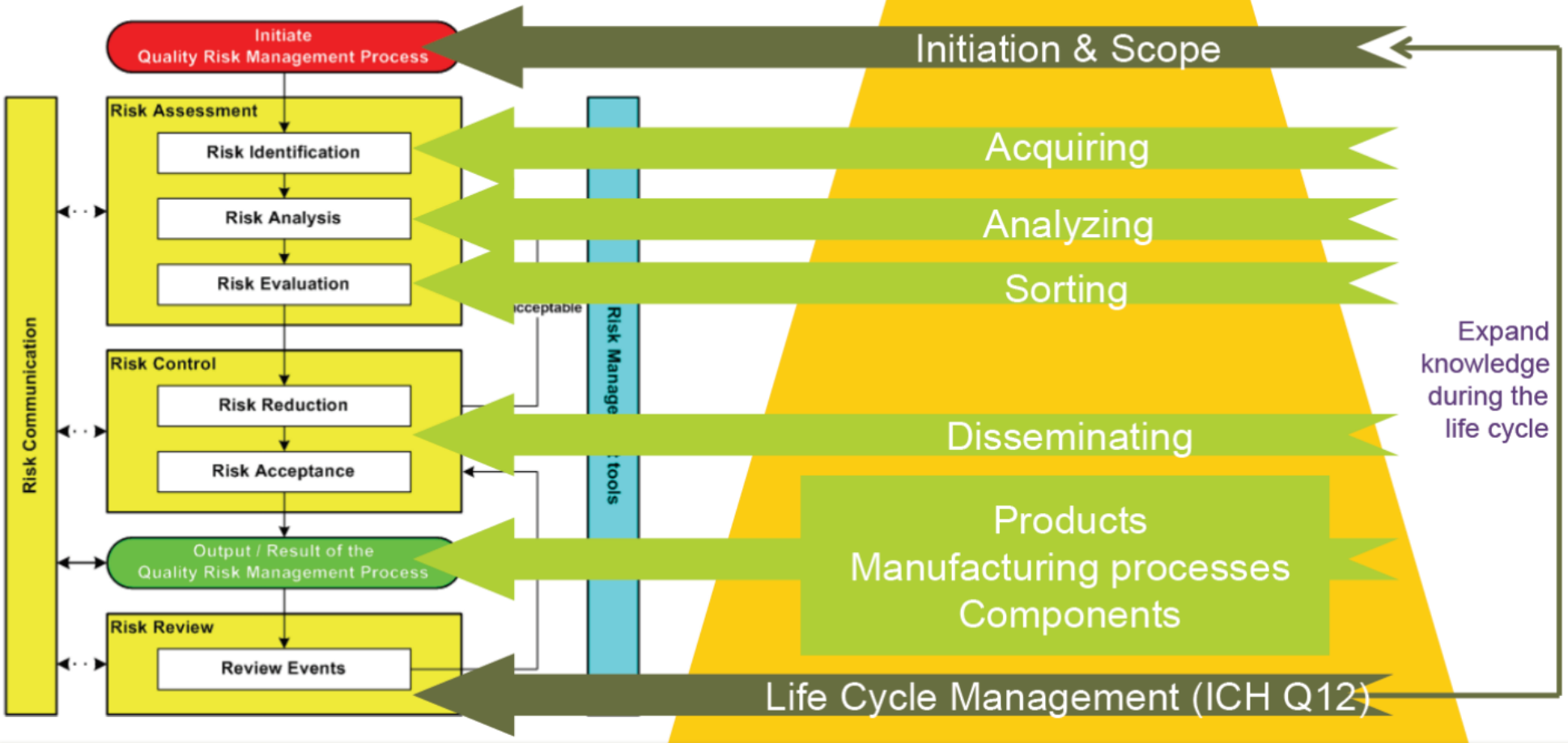
QRM and KM...together!

Q9 already covers Q12…

Quality Risk Management & Knowledge Management

A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle (ICH Q9)

A systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components (ICH Q10)



Use ICH Q9: No need to describe a 'KM process'

Final Quote:

"You must know all there is to know in your particular field and keep on the alert for new knowledge.
The least difference in knowledge between you and another man may spell his success and your failure."

Henry Ford

Pharm
Regulatory Knowledge, Practicall

Thank you for your time.
Questions?

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References:

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