Table 16: Knowledge Management - the Nuts and Bolts

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SCOPE:
The ICHQ10 definition of knowledge management is “... a systematic approach to acquiring, analyzing, storing and disseminating information related to products, manufacturing processes and components”. Development of therapeutics is an iterative process that is enabled by knowledge to understand larger picture impact and draw connections. This knowledge must be current, accurate, well organized, and easily accessible across a complex and matrixed organization. Sources of knowledge can be extensive and include prior knowledge, development experience, manufacturing experience, technology development, continual improvements, etc.

Effective knowledge management in the pharmaceutical industry is therefore essential for efficient development and product lifecycle management. This roundtable aims to discuss the process of knowledge management within an organization i.e. creating, sharing, using and managing knowledge and information with specific focus on the more logistical aspects of how to establish and ensure that knowledge will flow, grow and evolve over time.

QUESTIONS FOR DISCUSSION:
1. How is knowledge captured, developed, shared and used in your organization i.e. who, what, where, when, why and how of knowledge management?

2. How does one establish a knowledge flow i.e. logistical aspect (tools, strategy etc.)?

3. How to manage and retain implicit knowledge, that which is not explicit or formally captured, i.e. expertise of people/ knowledge in people’s heads?

4. What hurdles or opportunities are there to knowledge management?

5. Any restrictions to knowledge management i.e. best use and when to avoid?

6. What are the key variables for successful implementation of knowledge management?

DISCUSSION NOTES:
- Variety of tools have been tried. Big challenges are that:
  - often no one uses the tools
  - implementation
- Try to identify the points your need knowledge. A key point is before Process B/commercial molecule development
- Leverage database structure:
  - Need to apply knowledge into the risk assessment – used company (4tune engineering) – a company that put CQA assessment and process risk assessments
base on the CQA assessment and put them in the database. Takes the QTPP, risk
assessment, CQA assessment and output is the control strategy. Allows process
mapping. Clever and efficient solution.
  o Structures the information and the user uses it. The main users are the people in
    process and analytical development – accountable for the process until marketing.
  o Knowledge is present when the need it.
  o Built the process and then looked for an automation process. – take excel
    spreadsheet and upload into database.
• Big datasets how to continually keep tabs on all the data. Need to convert the data to
  knowledge and output needs to be in a usable format.
• Other examples of knowledge tools used or in development in some companies:
  o Protocol and report templates
  o IND/IMPD templates
  o Module 3 templates
  o Agency question and Company responses
• How to incorporate global requirements early? Need unstructured data from interactions
  with regulatory agency bodies to get out of excel spreadsheets into a useable format that
  is structured, extractable and available to cross functional team. This is very challenging
  – need to do this for efficient lifecycle management of a product. Agency
  requests/feedback is also key prior knowledge for a Company.
• Spots in the process to use prior knowledge – how to structure to use it properly.
  o When developing the commercial process
  o To help you understand variability in the process
  o Need knowledge structured and then take that and put into the authoring of
    initial file
• Delay in timelines due to not completing reports - need better templates so report writing
  is more automated. Data needs to be structured so can be lifted directly into the filings.
  Building the core content needed globally and then go from there – decrease the
  reinventing of the wheel and repeat discussions. Improves the speed of data verification.
• How to get people to implement –
  o Need people to buy into the benefit to them. Increase in efficiencies need
    to be clearly visible.
  o Time savings needs to be clear to both management and the team members
    and that work now is for future gain with efficiencies, consistencies and
    often improved quality/avoiding errors.
• For efficient knowledge management naming conventions must be held consistent. Value
  to create Company defined terms used consistently within all functions,
• Need a process to get the product specific knowledge back to the project team as well as
  to other product teams.
  o Without knowledge management you have no prior knowledge to lean on.
  o Learn from your failures. Lessons learned are largely unstructured and not
    accessible to the next team. Not enabling learning from your lessons.
• How to get a new person up to speed – Wiki’s are useful but can become too large.
  o Need document system as a source and draw from that.
  o Need a core set of content messages/slides that people can pull from.
    Needs to be multilayer. It is a small thing but would be a huge help in
time savings – repeat duplication in slide generation and ensures consistent messaging.

- Do not try to implement knowledge management in SOPs.
- Start small and build out.