



The Future State - Knowledge Management and Sharing to Reduce Regulatory Burden

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Breakfast II: Knowledge Management – Q12 Update

Knowledge is important



The **basic economic resource** –
the **means of production** –
is no longer **capital**, nor **natural resources**, nor **labor**.

It is and will be **knowledge**.”

– Peter Drucker

ICH Q8 (November 2005)	ICH Q9 (November 2005)	ICH Q10 (June 2008)	ICH Q11 (May 2012)	ICH Q12 (in progress)
30	12	20	35	?

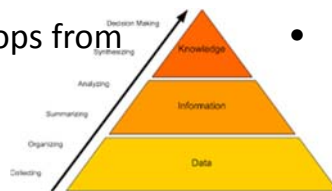
Number of times the term «knowledge» is mentioned in ICH guidelines



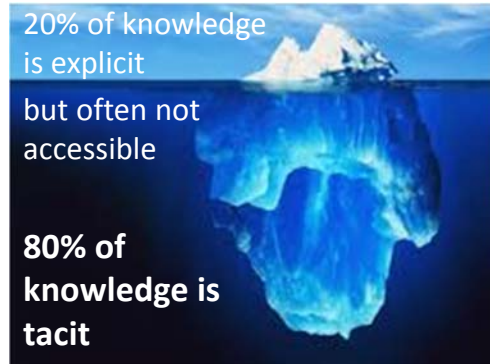
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Knowledge

- Knowledge develops from data, information
- Knowledge is information in action
 - Knowledge needs to flow



- Knowledge is sticky



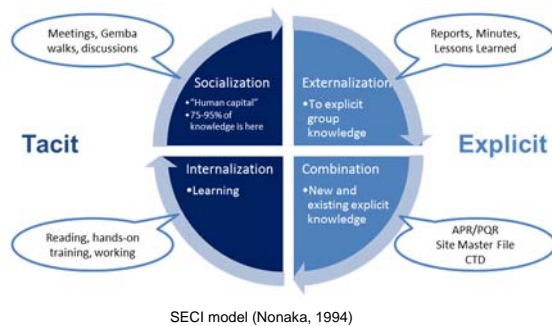
“Connectivity *above* hierarchies”



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How Knowledge creates Value

- **Dynamic knowledge flow** between tacit and explicit knowledge



- **Integrated use of knowledge** gained during the product lifecycle



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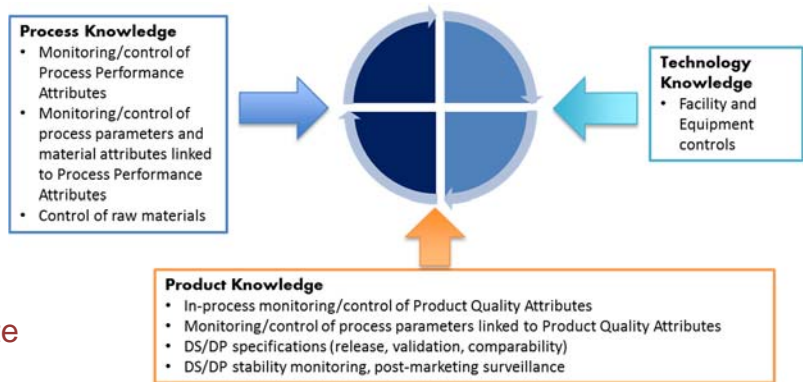
Knowledge Management

ICH Q10

"A systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components"

Systematic

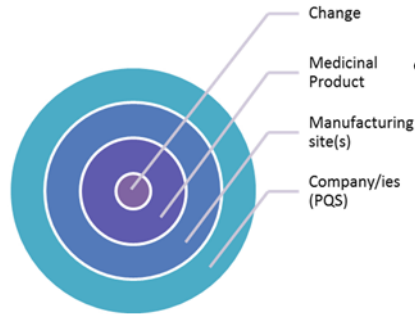
1. Acquire
2. Analyze
3. Store
4. Disseminate



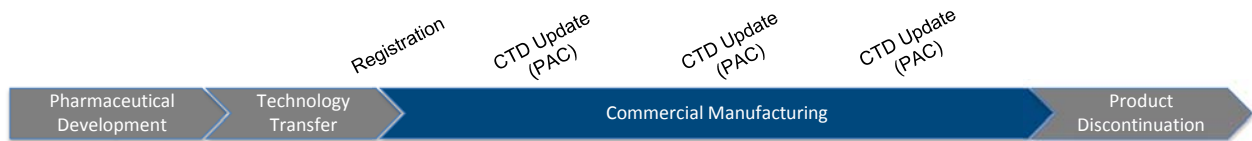
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Knowledge over the product lifecycle

- Knowledge grows over the product lifecycle
- Knowledge is used to support change management



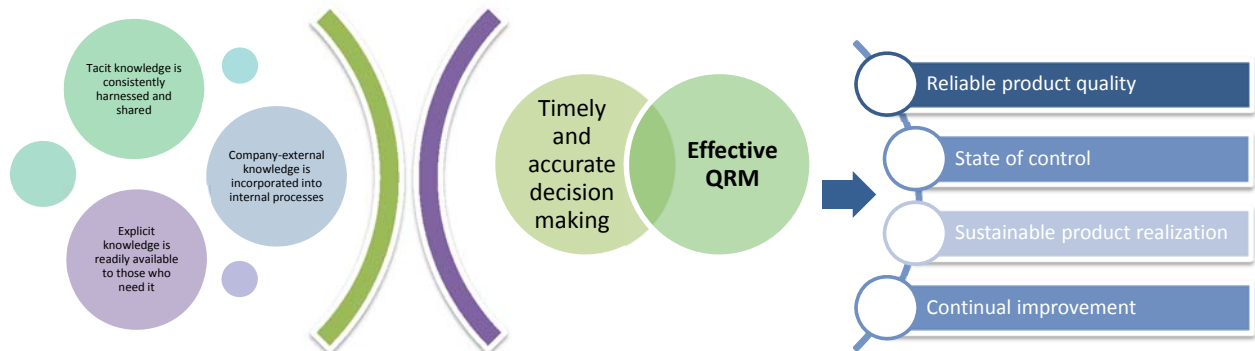
- Challenges
 - Many different changes
 - Supply chain complexity
 - Long timelines



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Effective Knowledge Management over the Product Lifecycle



Effective Knowledge Management
ACROSS THE ENTIRE SUPPLY CHAIN

Rapid and comprehensive access to product, process and technology knowledge



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Effective
QRM

Effective QRM supports PAC

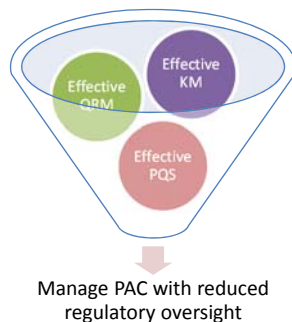
- Risk reduction
 - Identify changes that reduce risk of quality failures /manufacturing problems; improve process capability
- Change categorization
 - Distinguish changes of regulatory relevance from changes that can be managed solely in the PQS
- Effective change control
 - Assess risk level before and after PAC implementation to ensure no increase in risks to product quality or patient safety



Opportunities for regulatory flexibility



ICH Q10, Annex 1



Effectiveness Checks (Industry)

- PAC verification
 - Monitor deviations, process trends, analytical trends
 - Trend stability, deviations, OOS, technical / medical complaints, inspection/audit outcomes
- PQS effectiveness KPIs
- Internal audits
- Management review

Effectiveness Checks (Regulator)

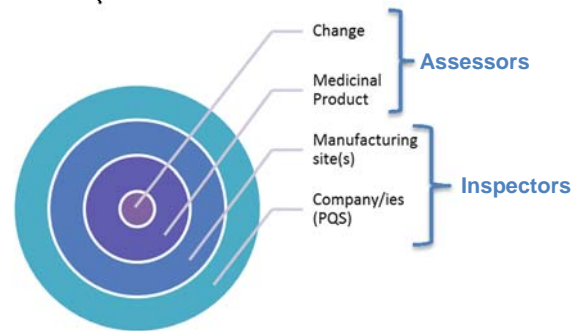
- Inspections
 - Verify that processes are in place and followed



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Established reporting channels result in fragmented access to company knowledge

- Knowledge shared with regulators is mostly explicit
- Assessors see part of it, inspectors other parts



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Enhanced knowledge sharing between industry and regulators



Convert tacit knowledge into explicit knowledge, make it available

- Post-Approval Change Management Protocols (PACMPs)
- Documented Lifecycle Management Strategy

Leverage opportunities for tacit knowledge exchange

- Meetings between MAH and Assessors
- During Inspections



Documented Lifecycle Management Strategy

- Facilitates communication between Company and Regulator; provides opportunity to discuss risks and plan proactively
- Elements of a product's LCM strategy
 - ❖ Product Established Conditions and Control Strategy Summary
 - ❖ Planned changes and regulatory approaches
 - ❖ Summary of product lifecycle management in the PQS

- Managing Product Knowledge During the Commercial Lifecycle
- Control System Management
- Managing Post-Approval Changes



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Knowledge sharing promotes better decision making

Industry - Regulators

Enhanced communication above established reporting channels

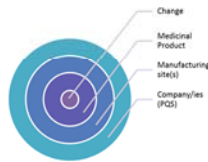
Access to tacit knowledge



PAC evaluation based on increased knowledge

Inspector - Assessor

Communication between inspectors and assessors



PAC evaluation in its context

Between Regulators

Communication between regulators

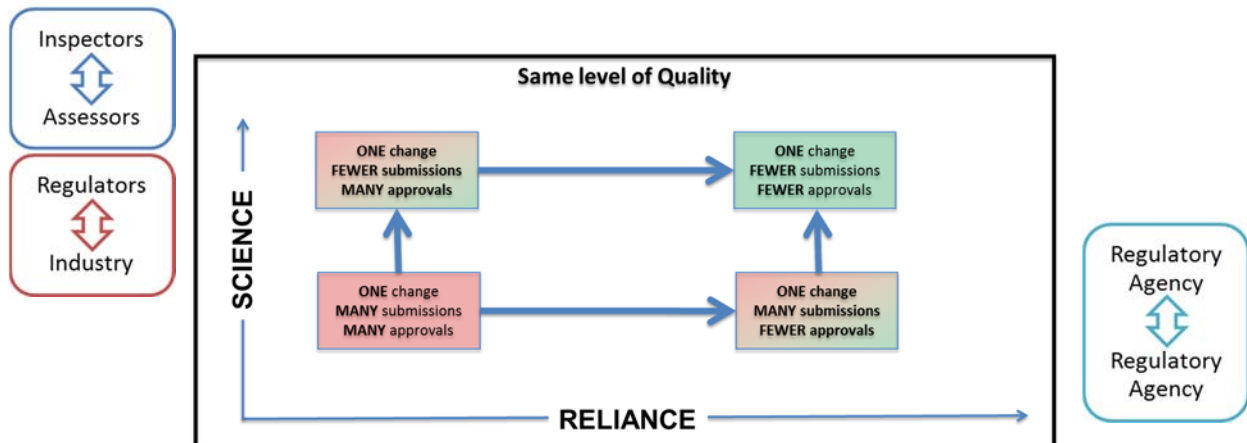


Mutual reliance / recognition

Enhanced regulatory decision making



Knowledge sharing reduces regulatory burden



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Regulatory flexibility means less control..

- Trust is a key success factor for regulatory flexibility
- Trust needs to be earned
- Knowledge sharing (transparency) with regulators increases trust

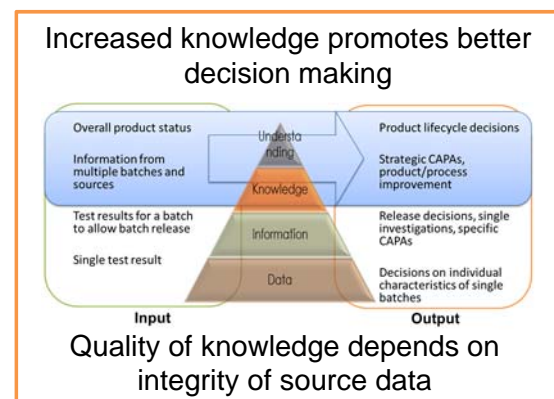


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Key take home messages

- Knowledge is needed to make **the right decision**
- Knowledge sharing enhances trust
- Trust promotes regulatory flexibility



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