A Practical Approach to Managing Knowledge

Making Knowledge Flow in Merck’s Manufacturing Division

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NASA Knowledge 2020
October 22, 2014
A Rich History of Scientific Achievement Impacting Society

1898 – Small Pox vaccine in US

1899 – Merck Manual Established (physician’s bible)

1933 – Vitamin B12 discovery

1936 – Vitamin B1 synthesis

1944 – Streptomycin discovery for TB, Cortisone synthesis for pain

1958 – First children's safety cap

1963-69 – First Vaccines for Measles, Mumps & Rubella *

1971 – MMR – first live vaccine trio*

1975 – SINE MET – Parkinson treatment

1985 – Imipenem (drug resistant infections)

1987 – Lovastatin - first statin for cardiovascular disease

1995 – World Bank Program to distribute MECTIZAN for River Blindness

1996 – CRIXIVAN – for HIV/AIDS

2006 – JANUVIA for type II diabetes

2006 – Gardasil – Human Papilloma Virus (99% efficacy)

2007 – Isentress – antiretroviral for HIV

2014 – Keytruda – FDA approval, breakthrough Anti-PD1 mAB for Melanoma

Today: Working on a cure for Hepatitis C, and much more

*Maurice Hilleman credited with saving more lives than any other medical scientist in the 20th century*
Today’s Merck

- **Merck** is a global healthcare leader working to help the world ‘Be Well’
  - In business since 1851, currently operating in 140 countries with approximately 73,000 employees
  - Pharmaceuticals, Vaccines, Biologics, Consumer Care, Animal Health
  - 2013 revenue: $44 billion

- **Merck Manufacturing Division (MMD)** manufactures a majority of Merck’s products through a global manufacturing network

- **Global Science, Technology & Commercialization (GSTC)** is an MMD function responsible for the late stage development, commercialization and life-cycle support of Merck products
  - GSTC is a large and diverse organization located at over 50 sites, in over 20 countries around the world
With Growing Pressures... the need for knowledge flow came in to focus...

**Insufficient knowledge capture**
- Explicit knowledge
- Tacit knowledge

**Past “KM” failures**
- KM = IT
- Lack of processes, culture, sponsorship

**Growing network, complexity**
- Globalization
- Externalization
- In- & Out-licensing
- Market pressures
- M&A

**Increased Expectations & Opportunity**
- Quality by Design
- Regulatory bodies
Taking the first step...

Build a **strategy** that would:

- Create alignment, set direction and concentrate resources
- Help us define and make choices such as tacit vs explicit
- Enable us to learn by doing
- Help us **think big, start small...but start**
It All Starts with ‘The Work’

*Using a knowledge map to identify needs*

<table>
<thead>
<tr>
<th>Department 1</th>
<th>Preparation phase</th>
<th>Execution phase</th>
<th>Final phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Department 2</th>
<th>Process 1</th>
<th>Decision 1</th>
<th>Process 2</th>
<th>Process 5</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>Department 3</th>
<th>Process 3</th>
<th>Decision 2</th>
<th>Process 4</th>
<th>Process 6</th>
<th>Finish</th>
</tr>
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</table>

*Process is illustrative only*
It All Starts with ‘The Work’

Using a knowledge map to identify needs

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Knowledge Needed</th>
<th>Created By</th>
<th>Used By</th>
<th>Explicit or Tacit</th>
<th>Where is it</th>
<th>Flow</th>
<th>Impact</th>
<th>Gap / Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Early Risk Assessment</td>
<td>API Engineering</td>
<td>Pharm Engineering</td>
<td>Explicit</td>
<td>Document Repository</td>
<td>Green</td>
<td>Red</td>
<td>None</td>
</tr>
<tr>
<td>B</td>
<td>Safe operating conditions</td>
<td>Safety Eng</td>
<td>API Engineering</td>
<td>Tacit</td>
<td>Partially captured on RA</td>
<td>Yellow</td>
<td>Red</td>
<td>Rationale not consistently captured</td>
</tr>
<tr>
<td>C</td>
<td>Summary of lab development</td>
<td>Analytical</td>
<td>Registration Team</td>
<td>Explicit</td>
<td>Local team workspace</td>
<td>Red</td>
<td>Red</td>
<td>No standard repository</td>
</tr>
<tr>
<td>D</td>
<td>Performance of similar product</td>
<td>Manufacturing</td>
<td>Development</td>
<td>Tacit</td>
<td>Local, at manufacturing sites</td>
<td>Yellow</td>
<td>Red</td>
<td>Limited access to SMEs and no standard expectations for reporting</td>
</tr>
<tr>
<td>E</td>
<td>Knowledge on powder processing</td>
<td>Pharm Engineering, Manufacturing</td>
<td>Manufacturing</td>
<td>Tacit</td>
<td>Unknown</td>
<td>Red</td>
<td>Yellow</td>
<td>No formal SME listing identified</td>
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It All Starts with ‘The Work’

Using a knowledge map to identify needs

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Guiding Principles

Explicit (20%)
- Easier to document and share
- Contributes to efficiency
- Easier to replicate
- Leads to competency

Tacit (80%)
- Skills and experience
- Hard to articulate
- Harder to transfer

Business Value Creation

Access - Create - Share - Review - Collect

People - Effective & Sustainable KM - Process - Content - Technology

credit: APQC
“Knowledge knows no organizational boundaries... it is boundaryless”

Merck Knowledge Ecosystem

Lessons Learned

Product Knowledge

Technology, Process & Business Knowledge

Connectivity & Expertise Location

Expertise Capture

Knowledge!

Explicit Knowledge

Tacit Knowledge

“The Work” Core business processes & practices powered by knowledge

Foundation: Knowledge-Enabled Culture (behaviors which capture, seek, share & leverage knowledge)
The VTN is...Connectivity!

Analytical Science & Technology
Applied Statistics & Experimental Design
Automation
Best Practices for Cleaning
Biologics & Sterile Processing
Data Standardization
Excipients

Packaging
Process Modeling
Powders Processing
Process & Environmental Safety

Lab Automation
Liquids, Elements & Crystals
Medical Devices
Moisturizers

Stability
Single Use Network
Solubilization & Biopharmaceuticals
Technical Challenges and Solutions in Emerging Markets
Technology Transfer Improvement
Women’s Health & Specialty Products

Women in Science and Engineering
VTN Enables the POWER of the NETWORK

“Have you seen...?”
“Does anyone know...?”
“What else should we try...?”
“How would you...?”

The NETWORK
- 27 Communities
- 4k members
- 1000 questions in 2013, 3100 responses
- 40% ex-US membership
- Countless new connections established

The IMPACT
- 50% hidden expertise
- 81% increased engagement
- No need to go “up and over”
- Tens of millions in business benefit from improved connectivity & collaboration
- 2014 winner: Workplace Leadership
$3MM and 20 weeks saved when our global network leveraged Tier Process, VTN and Compression Technology Platform to ensure reliable, cost-effective Supply of a Key Product.

What this looks like in action: Success Story

Our global network engaged rapidly to locate a spare turret in Singapore within 1 business day to replace a damaged turret used for a Key Product in the UK.

- Operational in 4 weeks versus 24 weeks for new turret from vendor
- Direct benefits plus great credibility building with partner, enhanced relationship for the future

“The VTN makes you feel like you’re part of something larger”
- Roger – GTO Ext Manf
MMD Lessons Learned System
*Generalized Life of a Lesson*

**Natural Flow of Work**

- Policies | Procedures | Work Processes
- Business Practices
- People

**Institutional Knowledge**
- Expertise
- Processes
- Connectivity
- Products

**Capture & Share**

**Lesson (s)** $1 \rightarrow n$

**AAR Selection**
**AAR of Work-Event**
Key Change Execution Concepts

blending social technologies for success*

Structured Methodology (CEM)

Key Change Execution Concepts

*blending social technologies for success*

Create an Energized Network

© Rob Cross

Key Change Execution Concepts

blending social technologies for success*

Behaviors are Critical

Ensuring people have the right:
• Direction
• Competence
• Opportunity
• Motivation

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<th>Which Enables...</th>
<th>Which Drives...</th>
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<tr>
<td>Products</td>
<td>Standard work powered by collaboration and knowledge</td>
<td>Right First Time ↑</td>
</tr>
<tr>
<td>Connectivity</td>
<td>Faster knowledge transfer and application</td>
<td>People Capability ↑</td>
</tr>
<tr>
<td>Processes</td>
<td>Employees more engaged, empowered &amp; connected</td>
<td>Employee Engagement ↑</td>
</tr>
<tr>
<td>Expertise</td>
<td>Reuse of captured knowledge across products &amp; platforms</td>
<td>Spend ↓</td>
</tr>
<tr>
<td>Connectivity</td>
<td>Connectivity &amp; platform knowledge avoid disruptions</td>
<td>Product Supply ↑</td>
</tr>
</tbody>
</table>
Key Lessons from our Journey

• Sponsorship, sponsorship, sponsorship
• **Alignment** with business priorities
• **Framework:** People, Process, Content, Technology
• Embed KM ‘**in the flow**’
• Stewardship, stewardship, stewardship
• Tell the new story
**Roadmap of our Journey**

- **Initial capabilities** – Create KM Program; Design & pilot 4 core capabilities for *product* knowledge, *people* knowledge, *connectivity* and *expertise* retention
- **2008-09: Getting Started** – Establishing case for change, benchmarking; Develop strategy
- **2010-11**
  - **Foundation & Installation**
  - **Realization**
  - **2012**
    - **Early realization & expansion** – Improve capabilities based on learning, Replicate & expand
  - **2013**
    - **Focused deployment** – Expand and embed capabilities ‘in the flow’, accelerate adoption via change management
  - **2014**
    - **Era of adoption** – Sustain, improve, accelerate; Enroll more users, more products, more technologies, more communities
  - **2015+**
    - **Sustain** – Managing knowledge as *how* we work; stewardship and continual improvement

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The Road Ahead

Challenges

• Getting everyone in the pool
• Creating and maintaining k-behaviors in a shrinking environment
• Many still see as an initiative
• Change capacity
• Articulating business value

Opportunities

• Operationalize in the flow of daily work
• Link to our organizational performance goals
• Opportunistically grow to deliver value to Merck
  • Build KM into new processes
  • Scope of knowledge and served population
  • New knowledge capabilities
With Special Thanks to...

- Dr. Michael Thien
- Dr. Jean Wyvratt
- Anando Chowdhury
- David Vossen
- GSTC Leadership Team
- MMD KM CoE Team
- APQC

and many fellow KM practitioners!
Martin J. Lipa
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For more details, see ISPE Pharmaceutical Engineering (Nov/Dec 2013, Vol 33 #6):
A Practical Approach to Managing Knowledge –
A Case Study of the Evolution of Knowledge Management (KM) at Merck
How to Reach Us

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Our Framework in Action

Dedicated Roles
- Knowledge Sharing and Seeking Behaviors
- Change Management/Adoption Plan
  (...)

People

KM Solution Framework

Process

Governance
- Capabilities "In the Flow"
- Measurement and Continuous Improvement
  (...)

Content

Critical Tacit and Explicit Knowledge
- Categorization: Taxonomy/Metadata
- Templates
  (...)

Technology

System Requirements and Architecture
- Web 2.0
- Search
  (...)

MERCK
Be well
**What is Design for Six Sigma?**

**“Did the strategy deliver?”**
- Control & monitoring plan
- Measure & sustain
- Improved business KPIs

**“What are the goals of improved knowledge flow?”**
- Charter effort, establish team
- Anecdotal evidence, baseline performance
- Link to business strategy

**“What is the desired future state & steps to achieve?”**
- **Strategic Plan**, including:
  - Principles, program, pilots
- **3 Year Roadmap**

**“What knowledge is most important to Merck’s mission?”**
- Voice of the Business
- Benchmarking
- Link to specific business KPIs

**“How does knowledge flow now?”**
- Knowledge maps
- Business case
What are the attributes of a transformational change?

Strategy Execution is applied when the change is transformational.

<table>
<thead>
<tr>
<th>INDICATORS OF TRANSFORMATIONAL CHANGE</th>
<th>INDICATORS OF NON-TRANSFORMATIONAL CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent driven; designed from the future (leap; innovate)</td>
<td>Designed from the current state (improvement)</td>
</tr>
<tr>
<td>Modifies behaviors, beliefs, and assumptions</td>
<td>Modifies methods, systems, and behaviors</td>
</tr>
<tr>
<td>No right answer; many right answers</td>
<td>Clear direction</td>
</tr>
<tr>
<td>Designed with a customer focus</td>
<td>Designed with a process focus</td>
</tr>
<tr>
<td>Different, unrecognizable, challenging</td>
<td>Familiar, improvement, better</td>
</tr>
<tr>
<td>A significant number of changes required across a large span of the organization</td>
<td>Fewer changes required and/or a smaller span of the organization affected</td>
</tr>
<tr>
<td>Major disruption of people’s expectations</td>
<td>Minor disruption of people’s expectations</td>
</tr>
<tr>
<td>Planned from an outcome perspective</td>
<td>Planned from a start point</td>
</tr>
<tr>
<td>Multiple interdependent components to integrate</td>
<td>More linear path</td>
</tr>
<tr>
<td>High shift to the politics of the organization</td>
<td>Minimal change to existing politics</td>
</tr>
<tr>
<td>A significant number of people will be unwilling or unable to complete the journey</td>
<td>A small number of people will be unwilling or unable to complete the journey</td>
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</table>

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