Creating a Technology Strategy & Roadmap for Manufacturing

Merck
Helping the World Be well
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WHO WE ARE  
Known as **Merck** in the United States and Canada, and ** MSD** elsewhere

RICH HISTORY  
Operating since 1851

BUSINESSES  
Pharmaceuticals, Vaccines, Biologics and Animal Health

2014 REVENUES  
$42.2 billion; 61% of sales come from outside the United States

2014 R&D EXPENSE  
$6.5 billion; 25 drug candidates in late-stage development; key areas: oncology, CV, diabetes, respiratory & immunology, neurology, infectious disease and vaccines

HEADQUARTERS  
Kenilworth, New Jersey, U.S.A.

EMPLOYEES  
Approximately 70,000 worldwide (as of 12/31/14)
Our Mission

To discover, develop and provide innovative products and services that save and improve lives around the world.
Business Areas of Focus

PRESCRIPTION PHARMACEUTICALS & VACCINES

Major Therapeutic Areas
- Cardiovascular
- Diabetes & Obesity
- Infectious Disease
- Neurosciences
- Oncology
- Respiratory & Immunology
- Vaccine-preventable diseases

ANIMAL HEALTH

- Livestock
- Companion Animal
- Aquaculture
Some Definitions...

**TECHNOLOGY:** In the context of this effort, technology is defined as a system comprised of scientific/technical knowledge, processes and equipment that is used to accomplish a specific goal.

**MANUFACTURING TECHNOLOGY:** Manufacturing technologies are combinations of knowledge, process and equipment that are directly or indirectly involved in the transformation of raw materials into products and their subsequent delivery in a useful form to our customers and final patients.

**PRODUCT CONFIGURATIONS:** These are actual changes in format to a product that a customer would see or perceive – for example formulation platforms or packaging configurations. For our purposes, they often help to classify various manufacturing technologies.

**COMMERCIAL INNOVATION:** New approaches, or new combination of existing approaches, to create or capture business opportunities. Includes marketing of products and services, production/distribution channels, partnerships, media, technologies, data management, etc. to improve patient access, adherence and outcomes.
Big Problem

• How do we effect transformations and coordinate actions at a sub-system level so that we have optimized results…
  - at physical sizes that span a global enterprise
  - at time scales that run decades
What do we need to do – Supply Chain Transformation

- Robust incoming materials
- Lower cost, environmentally sound products
- Customer-focused packaging
- Transport without human & environmental threats
- Access, adherence, ease

Diagram:
- Raw Materials
- Manufacturing
- Distribution and Logistics
- To Patient
Transformation requires integrated & aligned action

RANDOM MOB

SYNCHRONIZED MARCH

Citation: Public Domain Images
Create a systems-level overview for the technology platforms considered

- **Chemically-Synthesized Small Molecule API**
- **Biologically-Derived Small Molecule API**
- **Therapeutic Protein Bulk**
- **Vaccine Bulk**

- **Oral Dosage Form** (e.g. tablets, capsules, soft chews)
- **Non Oral Specialty Formulation** (e.g. ointments, creams, rods, rings)

- **Non-Sterile Devices** (If applicable) (e.g. applicators)
- **Sterile Devices** (if applicable) (e.g. pens)

- **Primary Packaging**
- **Secondary Packaging**

- **Distribution & Logistics**

**Info Tech**  
**Analyst Tech**
Define a framework for the external world

Patient

Providers

Health Care Provider
Family & Friends
Managed Health Care Providers
Hospitals

Payers

Govt Agencies
Drug Wholesalers /Retailers
Insurance Provider

Financial Stakeholders

Shareholders
Investment Analysts
Health Authority
Regulators
Neighbors
Public

Regulators

Manufacturer

Research & Development
Science & Technology
Procurement

Global Quality
Sales & Marketing
Supply Chain Franchise Mgmt
Planning & Scheduling

Active Ingredient Sites
Formulation Sites
Packaging Sites

Raw Materials Suppliers
Site Quality
Quality-Regulatory
Global Safety & Environmental

Raw Materials
Suppliers

Planning & Scheduling
## Convert the needs to measurable KPIs

<table>
<thead>
<tr>
<th>MAJOR PARAMETER</th>
<th>KEY PERFORMANCE PARAMETER</th>
<th>MEASURE DEFINITION</th>
<th>STAKEHOLDER WHO CARES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRODUCT</strong></td>
<td>A winning product fashioned with the customer value drivers in mind and continues to deliver this value consistently.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Safety &amp; Tolerability</td>
<td>The safety profile of the medicine.</td>
<td>Patient, Provider, Payer, Regulator</td>
</tr>
<tr>
<td></td>
<td>Efficacy</td>
<td>How effective is the medicine in effecting the disease target, generally measured by bioavailability over time.</td>
<td>Patient, Provider, Payer, Regulator</td>
</tr>
<tr>
<td><strong>PROCESS</strong></td>
<td>Sustainable and profitable business/manufacturing system to create and deliver the product robustly, wherever they are needed while building and leveraging institutional wisdom seamlessly.</td>
<td>Manufacturing Efficiency and Robustness Measures</td>
<td>Manufacturer, Regulator</td>
</tr>
</tbody>
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Solid Oral Dosage Forms – RM to Bulk Product Tech Road Map

(Note: Bulk Product to Customer would be covered on another map as we have structr


Products/Technologies in Use
Projects not funded
Projects Funded/In Progress
Technology in Commercialization


BGx Operating Models
External Development
Development Partner Network

BGx Operating Models

Products/Franchises of Focus & Their Plans i.e., Commercial Strategy

Sandwich in Business & Organization Models

Physical Technologies

Dotted Lines Indicate Connections Between Commercial & Technology Work

Color is Type of Activity Required Exploratory, Vs. Incremental Innovation

Market Segments

Premium/Existing Mkt
Emerging Mkt
Middle Class
Bottom of the Pyramid

Business & Organizational Models

RM Technologies
API Technologies
Formulation Tech

Major Tech Category
Institutionalize the process

Science & Technology Landscape

Technology Inventories (a subset of which are Proven Technology Toolkits)

Market Dynamics

Product Family Plans

Customer Needs/ Business Requirements

Customer Understanding

Technology Roadmaps

Informs

Technology Funnel

Horizon III

Horizon II

Horizon I

A

B

C

Proven Delivered Customer & Business Value

Proof of Science

Hint of Commercial Potential

Proof of Technology

System-level Concept

Proof of Regulatory, Operational & Commercial Use

Proof of Robustness

Feedback & Collaboration

Technologists

Marketeters

Voice of the Technology

Voice of the Customer
<table>
<thead>
<tr>
<th>PATHWAY AKOQR</th>
<th>PROCESSES</th>
<th>OPERANDS</th>
<th>TECHNOLOGY &amp; PSE INITIATIVES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHEM SYNTH</td>
<td>ORAL DOSAGE</td>
<td>NON-STERILE DEVICE</td>
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Diabetes example: All projects work in unison to transform supply chain

- Reduce API costing
- Green chemistry
- Biocatalysis

Near IR enabled, Chemometric Real time release testing

Packaging allows for adherence

Serialization & Trust

Raw Materials Suppliers → Raw Materials → Finished Product → Packaging → Distributor → Hospital Clinics/Pharmacies → Patients

- Raw Materials
- Manufacturing
- Distribution and Logistics
- To Patient
Technology Feasibility for Mfg Use

Technology Management Paths

Proven (H1)

Unproven (H3)

Install/Implement

Sunset of Tech/Prod

Proactive Investment

Clairvoyance Path

Reaction To Need

Creation of Need

No Immediate Need Exists for Use

Product(s)/System Need Exists For Use

Extent of Products Uses for Market Needs
• Enterprise level transformation to meet human health and sustainability challenges requires many efforts to work in unison

• This innovation, alignment and prioritization cannot be left to chance: Technology roadmapping provides an effective solution for managing wide-scale technical transformation.

• It enables the connection from activities directed at molecular size and immediate time scales to global size and multi-year time scales
BE WELL. A PROMISE MADE TO THE WORLD.