HOW TO STRUCTURE THE EXECUTION OF THE WORLD LARGEST BIOTECH PROJECT

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Novo Nordisk and Product Supply

- **Novo Nordisk** is a global healthcare company with more than 90 years of innovation and leadership in diabetes care.
- Novo Nordisk also help people defeat other serious chronic conditions as haemophilia, growth disorders and obesity.

**Product Supply** is responsible for the supply of all marketed and phase III development products within the treatments of:

- Diabetes
- Haemophilia
- Growth disorders
- Menopause
- Obesity
The Triple Bottom Line
Our business

Financially responsible

Patients

Socially responsible

Environmentally responsible
Community Impact

Giving Back to our Communities
Products made at Novo Nordisk Clayton

NovoLog®
Levemir®
NovoLog® Mix 70/30
Victoza®
Saxenda®
Tresiba®
Diabetes API US
Clayton, NC
DAPI, US Project Groundbreaking
Business rationale: Diabetes API expansion in US

Expanding API production capacity in the US will enhance robustness of Novo Nordisk supply chain.

- **Satisfy demand for existing and new products**
  - Satisfy growing demand for existing and future products primarily Victoza® and new innovative oral treatment of diabetes (currently in phase 3).

- **Supplement current API footprint in Denmark**
  - Ensure dual source API supply to enhance robustness of Novo Nordisk supply chain.

- **US providing access to talent**
  - Expand with local presence in largest diabetes market and get access to large pool of skilled pharma talents.
Key facts

The facility will deliver API to primarily **Victoza®** and new innovative **oral treatment** of diabetes currently in phase 3

The facility is expected to grow to ~**700 FTEs** when entering into **operation in 2020**

Total Project Cost (TPC) estimated to ~**USD 2 billion** of which EPCM (TDC) makes up ~**USD 1,181 million**

Roughly **80,000 sq. meters** and covering app. **85 acres of land**
Site Selection
Clayton, NC
Strategic Partners (Fluor/ToC/JoCo/DOT/DEQ/NCRR/DEP)
Talent Acquisition
Craft and Equipment Strategies
Manufacturing and Business Process Mapping
Total Project Staffing

Preliminary

Equivalent People

Peak: 2,759
Site development and infrastructure

Comprehensive site infrastructure setup included in Basic Design deliverables from Fluor

Comprehensive site infrastructure has been developed incl.:
- Safety planning
- Site utilities (temporary and permanent)
- Parking
- Toilets
- Canteens
- Office trailers
- Road pattern
Diabetes API US

Work Packages
• Mech.Eng (Denmark)
• Large Scale projects in Denmark, USA, Ireland, Indonesia, Brazil, China
• NNE – Novo Nordisk Subsidiary
  • 1996
  • Many Large Novo Nordisk Projects
  • Many Large XXX Projects
• NNE US
  • 2007
    • West Coast Office
  • 2010
    • Various Director Roles in US HQ RTP
200 New Project Staff

Largest Novo Nordisk Capital Investment Ever

Different Large Project Execution Methods

On New Turf

Internal Handbook for World Largest Project

Cultural Differences
Structuring projects around work-packages - Introduction

Structuring around work packages makes it easier to manage large scale projects

**What is it?**
- A way to divide a large project into manageable pieces
- A way to delegate responsibility into the project
- Work packages containing responsibility for scope, schedule, cost and risk
- On-going reporting and risk management

**What are the benefits?**
- Create ownership at operational level
- Secure transparency around responsibilities and risk
- Empower people to take on more responsibility and create development opportunities
- Make it clear for external stakeholder where in project organisation to tap in

**How is it set up?**
1. Define overall project structure (project tracks)
2. Assess distribution of PMD’s based on synergy and capability fit
3. Define WP’s and identify interfaces
4. Prepare work package descriptions and interface matrices
Work Package Overview

Work Breakdown Structure

6.0 Purification
6.1 Management
6.2 HCP Filtration
6.3 HPLC & MPLC
6.4 Acylation, Ligations & UF/DF
6.5 Precipitation
6.6 Sterile Packaging

7.0 Site support
7.1 Management
7.2 EHS
7.3 Clean Utilities
7.4 Utilities & Water
7.5 Sterile Utilities

8.0 Project Management
8.1 Project Management
8.2 Project Management

7.3.1 Purified Water
7.3.2 Clean Steam
7.3.3 Process Air & Vacuum

(101) Softened water Production
(102) Softened water Distribution
(103) PW Production 1
(104) PW Distribution 1
(105) PW Production 2
(106) PW Distribution 2
(107) Fermentation air Production 1
(108) Fermentation air Distribution 1
(109) Process Air Distribution 1

(103) Nitrogen Cryo Storage
(104) Nitrogen Site Distrib.
Structuring projects around work-packages - Operation

Structuring around work packages creates a direct link from operational project level to highest corporate level

**Project governance structure (illustrative)**

- **Corporate level**
- **Project lead**
- **Project track**
- **Work package**

**Dynamics**

- Guidance
- Coaching
- Feedback
- Review

- Reporting
- Risk mgmt.
- Decisions
- Problem solving

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**Operation**

- Operation
- Structuring around work packages creates a direct link from operational project level to highest corporate level
Project Organisation: Overview

Project organisation divided into three overall groups; Project Delivery, Project Operations and Project Support
Work Package Owners are key to our success!

Source: See Project Execution Plan for elaboration
Interface Agreements
## Interface Overview Example Recovery

<table>
<thead>
<tr>
<th>Step ID</th>
<th>Work Package</th>
<th>Interface</th>
<th>Management (5.1)</th>
<th>Clarification (5.2)</th>
<th>Capture (5.3)</th>
<th>Crystallization (5.4)</th>
<th>CIP (5.5)</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>Supply Chain &amp; Sourcing</td>
<td>Material supply chain</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Overall Recovery agreement:</strong> Ordering, sizes, and packaging of materials</td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td><strong>Individual Work Packages:</strong> Communication of new needs, requesting to start sourcing procedure</td>
</tr>
<tr>
<td>3.4</td>
<td>Warehouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Overall Recovery agreement:</strong> Ordering, type, number of consumables, number of spares, and how/when consumables are transferred to local Recovery warehouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Raw Materials</td>
<td>13</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td><strong>Individual Work Package:</strong> Ordering, type, number of consumables, transferred to local warehouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Consumables</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td></td>
<td></td>
<td><strong>Individual Work Package:</strong></td>
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<td></td>
<td></td>
<td>Consumables for CIP</td>
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<td></td>
<td></td>
<td></td>
<td><strong>Individual Work Package:</strong></td>
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<tr>
<td></td>
<td></td>
<td>Intermediate Product Storage</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td><strong>Individual Work Package:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Samples</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Overall Recovery agreement:</strong> Communication of new needs, requesting to start sourcing procedure</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Individual Work Packages:</strong> Types of tests, sample size, number of samples, scheduling of samples and results</td>
</tr>
</tbody>
</table>
Diabetes API US Engineering Project

Project Plan for Engineering Project

Project Procedures for Engineering Project

- Management
- Planning
- Cost Estimation
- Scope Mng.
- Change Control
- Procurement
- Cost Control
- Organization
- Training
- Doc.-Mng.
- Quality Revie
- Risk Mngt.
- Project Standards
- Stakeholder Mng.
- Communication
## Interactive PM Handbook (User Interface)

### DAPI US

**1. Project Governance**

<table>
<thead>
<tr>
<th>Project Management and Governance Excellence (PMGE)</th>
<th>Workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Management</td>
<td>Project Management</td>
</tr>
<tr>
<td>Scope Management</td>
<td>Scope Management</td>
</tr>
<tr>
<td>Process &amp; Technology Alignment</td>
<td>Process &amp; Technology Alignment</td>
</tr>
<tr>
<td>Schedule &amp; Resource Management</td>
<td>Schedule &amp; Resource Management</td>
</tr>
<tr>
<td>Stakeholder Management</td>
<td>Stakeholder Management</td>
</tr>
<tr>
<td>Project Interface Management</td>
<td>Project Interface Management</td>
</tr>
</tbody>
</table>

### Input

- **Organize decision tree**
- **Define roles and responsibilities**
- **Assign people with required competencies**
- **Manage project meetings**
- **Manage issues and decisions**
- **Report project progress/performance**
- **Control project progress/performance**

### Activity

- **Organize decision tree**
- **Define roles and responsibilities**
- **Assign people with required competencies**
- **Manage project meetings**
- **Manage issues and decisions**
- **Report project progress/performance**
- **Control project progress/performance**

### Output

- **Description**
- **Roles**
- **Procedures**
- **Tools**

### Description

- **Organize decision tree**
  - This process of organizing boards, committees, teams, and providing members respectively.

- **Define roles and responsibilities**
  - The process of identifying competencies needed, assigning authority, and escalating risk.

- **Assign people with required competencies**
  - The process of identifying the right people to manage tasks and assigning them to the appropriate decision-making role.

- **Manage project meetings**
  - The process of preparing, executing, and following up on project meetings from the project's planning.

- **Manage issues and decisions**
  - The process of taking action when an issue occurs, escalating or resolving it as necessary.

- **Report project progress/performance**
  - The process of reporting information about project status and forward-looking forecasts.

- **Control project progress/performance**
  - The process of controlling project status, which includes decision making, direction setting, and clear hurdles for execution teams.

### Key Benefits

- **Organize decision tree**
  - The key benefit is ensuring correct and efficient decision making/resolution.

- **Define roles and responsibilities**
  - The key benefit is ensuring transparent organization and responsibilities.

- **Assign people with required competencies**
  - The key benefit is having people with the required competencies in appropriate positions.

- **Manage project meetings**
  - The key benefit is identifying management of project status, which enables decision-making, direction setting, and clear hurdles for execution teams.

- **Manage issues and decisions**
  - The key benefit is handling, monitoring time, cost, and risk.

- **Report project progress/performance**
  - The key benefit is that it informs management of project status, which enables decision making, direction setting, and clear hurdles for execution teams.

- **Control project progress/performance**
  - The key benefit is ensuring project progress is on track and aligned with business time.
DAPI US PM Training

PM F2F training for DAPI US Work Package Owners
4 x 4 hours

Module 1: Half Day
Framework and PMI

Module 2: Half Day
Specific Topics

Module 3: Half Day
Specific Topics

Module 4: Half Day
Specific Topics

Foundation
- DAPI US Project
- PMI Knowledge Areas
- Stakeholder Management
- Communication
- WPO Roles and Responsibilities

Specific Topics
- Scope Management
- Baseline, NN and Fluor
- Document Management
- Collaboration

Specific Topics
- Schedule
- Project Controls including cost and risk management
- Change Management
- Procurement

Specific Topics
- Quality
- Conflict Management
- Impact and Influence
- EXAM

Work will be assigned in between modules.