



HOW TO STRUCTURE THE EXECUTION OF THE WORLD LARGEST BIOTECH PROJECT

Gary Lohr, Project Director – Site Support and
Deputy Site Head, Novo Nordisk

Carsten Nicolai Petersen, Director, NNE
Pharmaplan

ISPE CASA Technology Conference
14 March 2017

ENGINEERING

3:00 PM - 3:45 PM

PRODUCTS MARKETED IN
180 COUNTRIES

AFFILIATES IN COUNTRIES 75



R&D CENTRES
IN CHINA, DENMARK,
INDIA AND US

OBESITY



EMPLOYS APPROXIMATELY
42,300 PEOPLE

DKK 107.9
BILLION
IN TOTAL REVENUE



230,000
SHAREHOLDERS

STRATEGIC
PRODUCTION SITES
IN BRAZIL, CHINA, DENMARK,
FRANCE AND US



GROWTH
DISORDERS

SUPPLIER OF MORE THAN
HALF OF THE
WORLD'S INSULIN

26,800,000
PEOPLE USE OUR PRODUCTS

HAEMOPHILIA



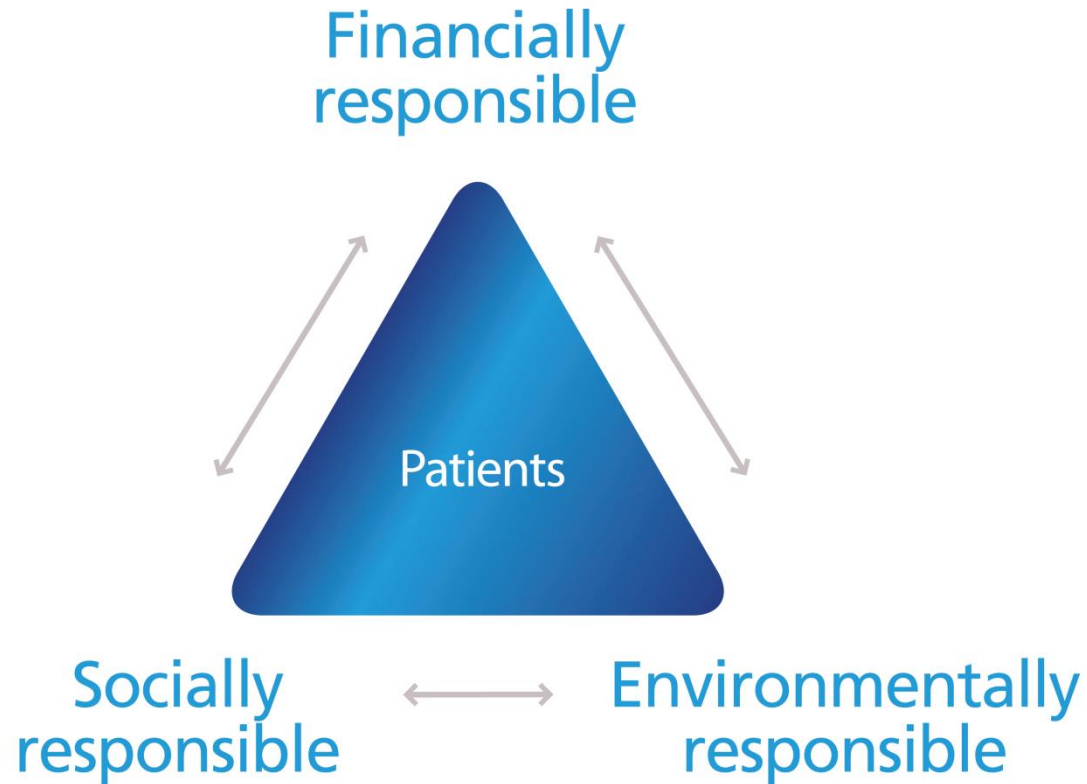
Novo Nordisk and Product Supply

- **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



Community Impact



Giving Back to our Communities





Products made at Novo Nordisk Clayton





Diabetes API US

Clayton, NC

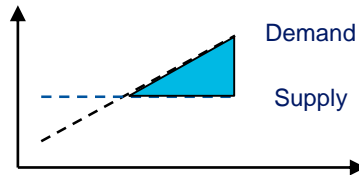
DAPI, US Project Groundbreaking



Business rationale: Diabetes API expansion in US

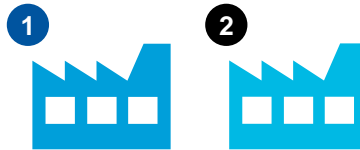
Expanding API production capacity in the US will enhance robustness of Novo Nordisk supply chain

Satisfy demand for existing and new products



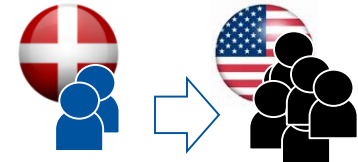
Satisfy growing demand for existing and future products primarily Victoza® and new innovative oral treatment of diabetes (currently in phase 3)

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



Infrastructure
Talent Acquisition
Strategic Partnering
Known Performance

Horn
1 - DUNHAM, INC. 02708
PUB. NO. 1-1000





Strategic Partners
(Fluor/ToC/JoCo/DOT/DEQ/NCRR/DEP)

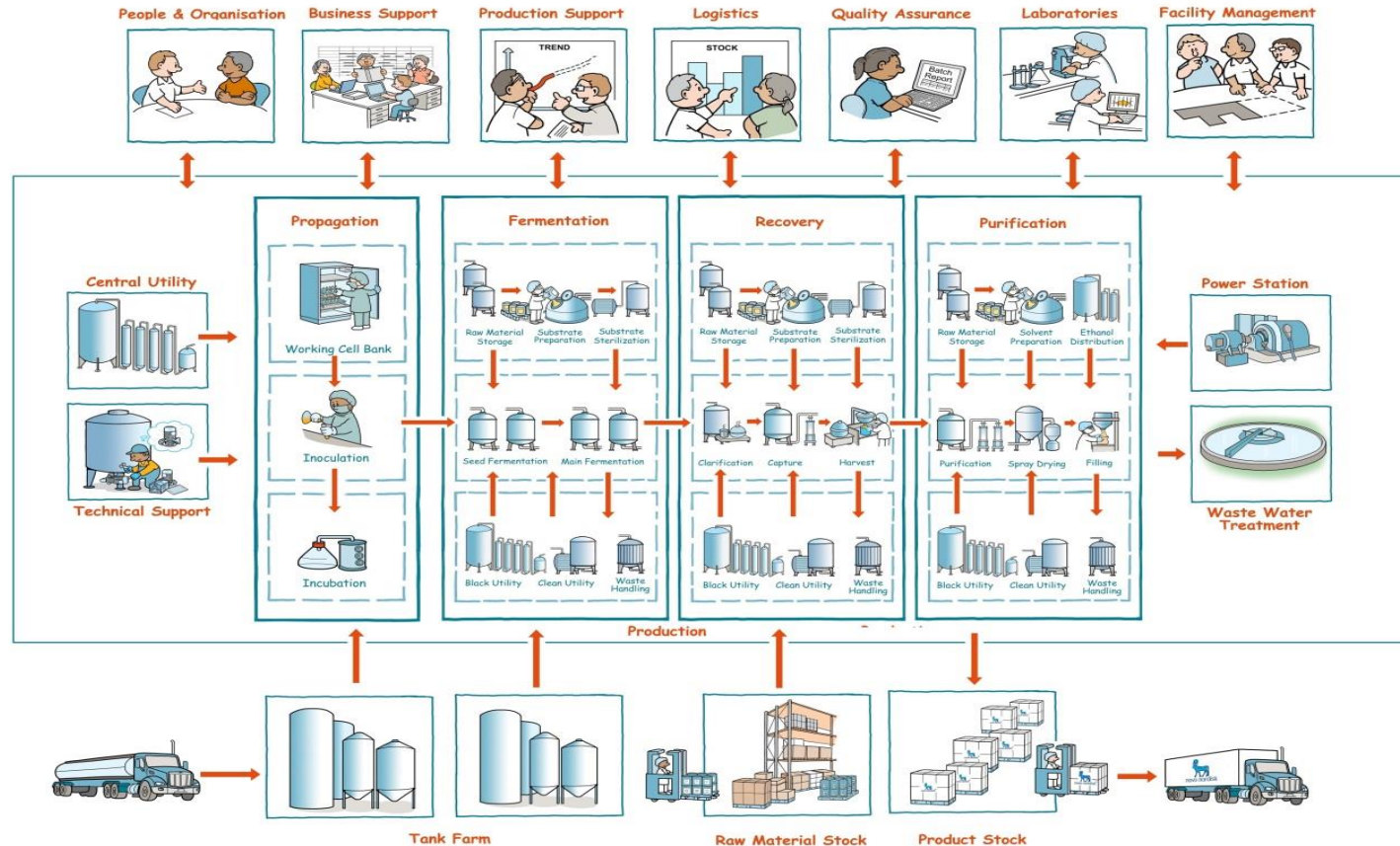
Talent Acquisition

Craft and Equipment Strategies

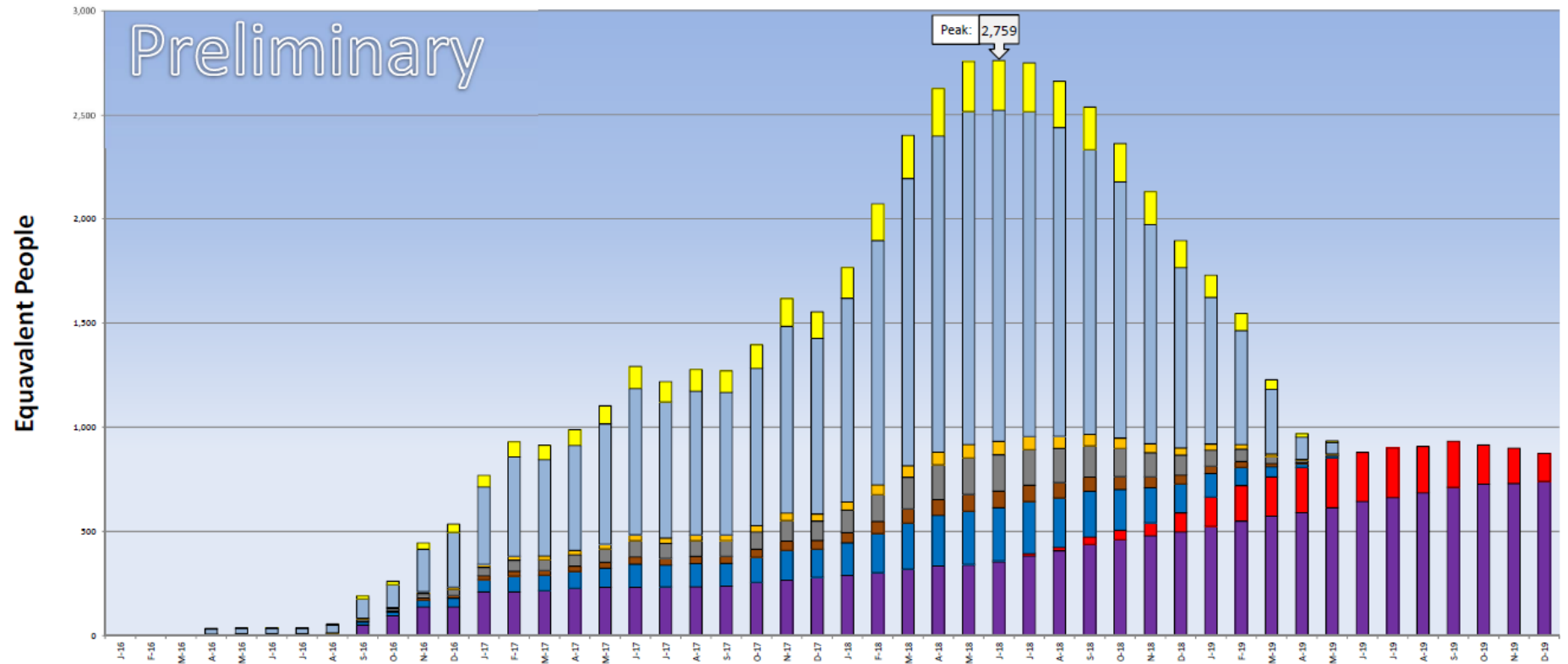


Manufacturing and Business Process Mapping

17

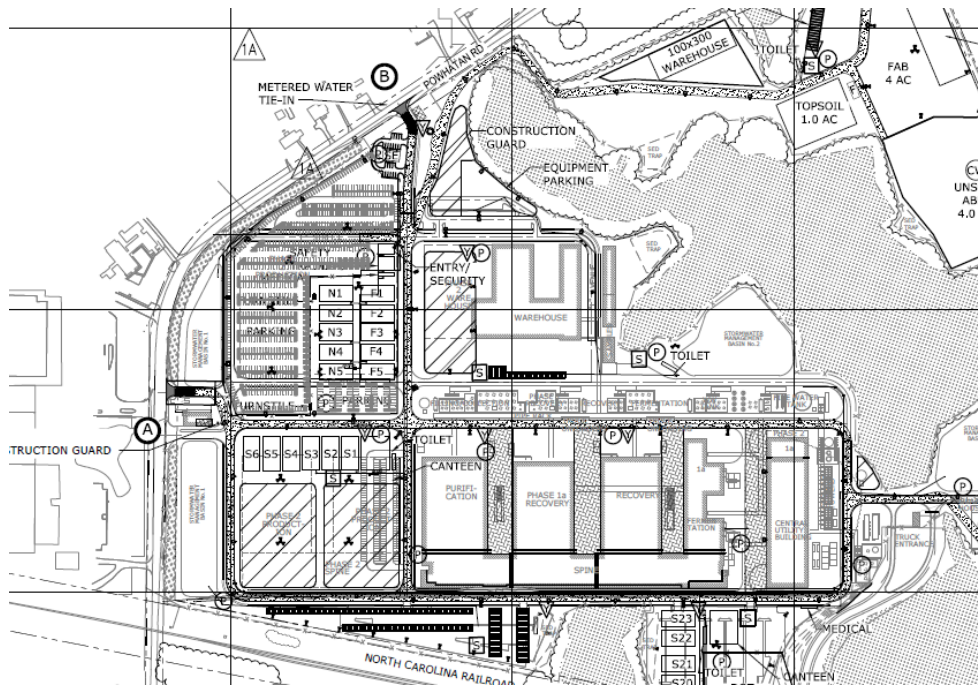


Total Project Staffing



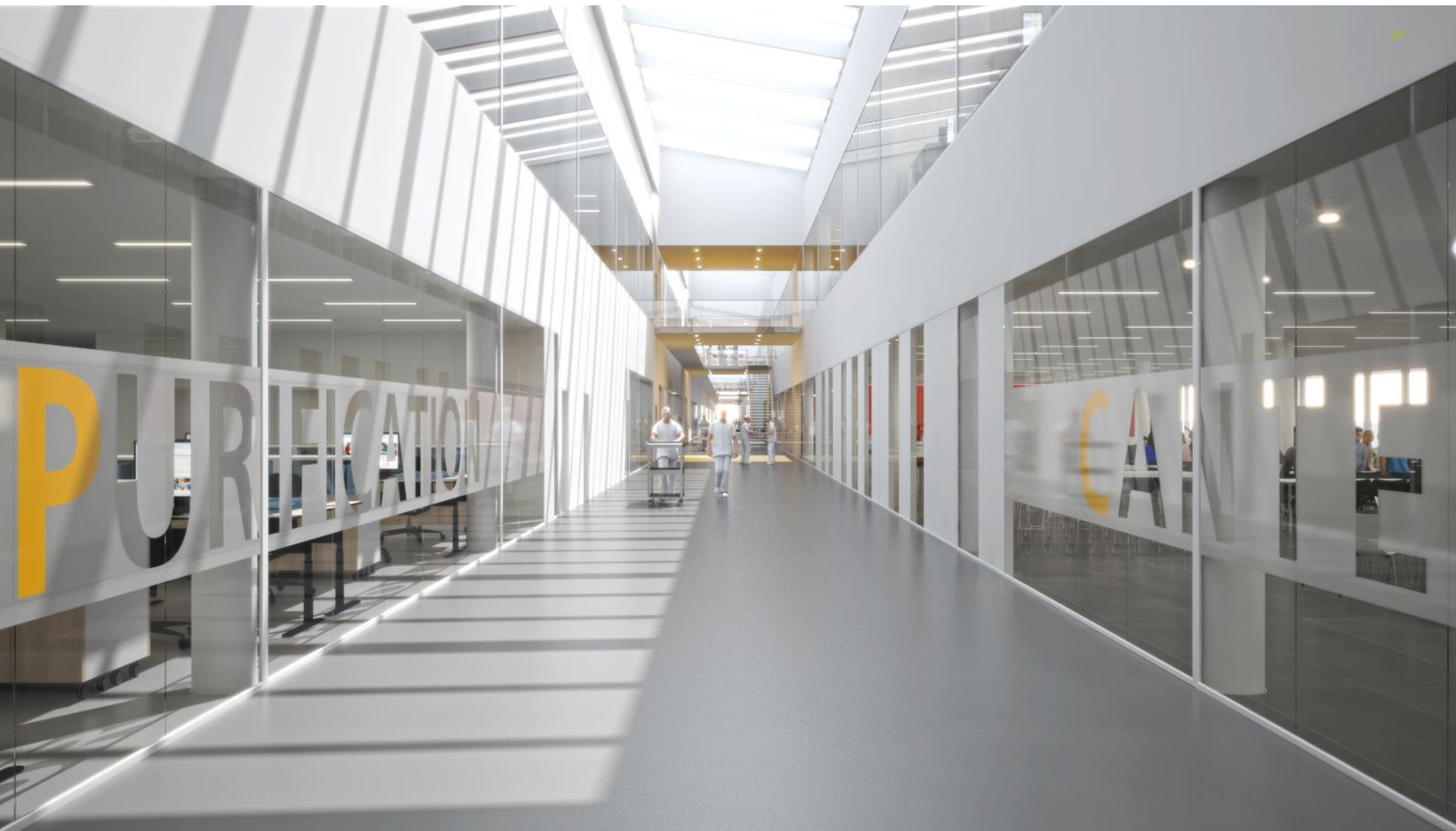
Site development and infrastructure

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













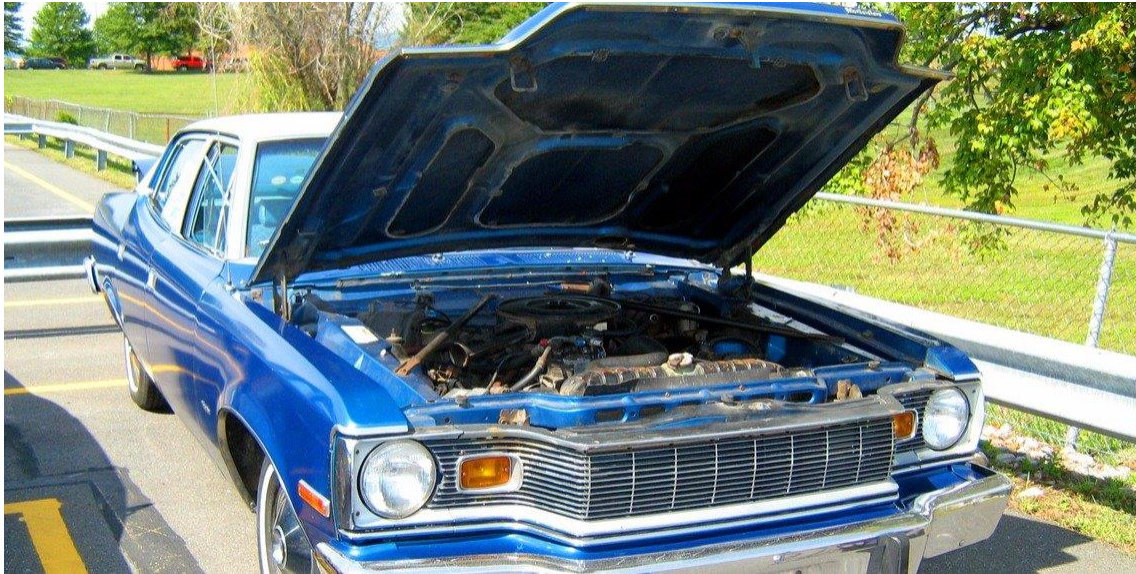


Diabetes API US

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

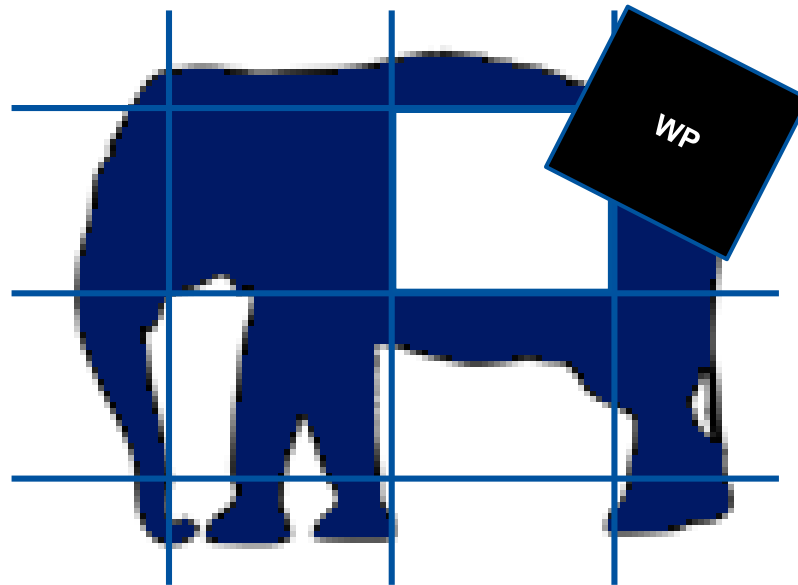
Different Large Project Execution Methods

Strategic Partners setup

On New Turf

Cultural Differences

Internal Handbook for World Largest Project



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

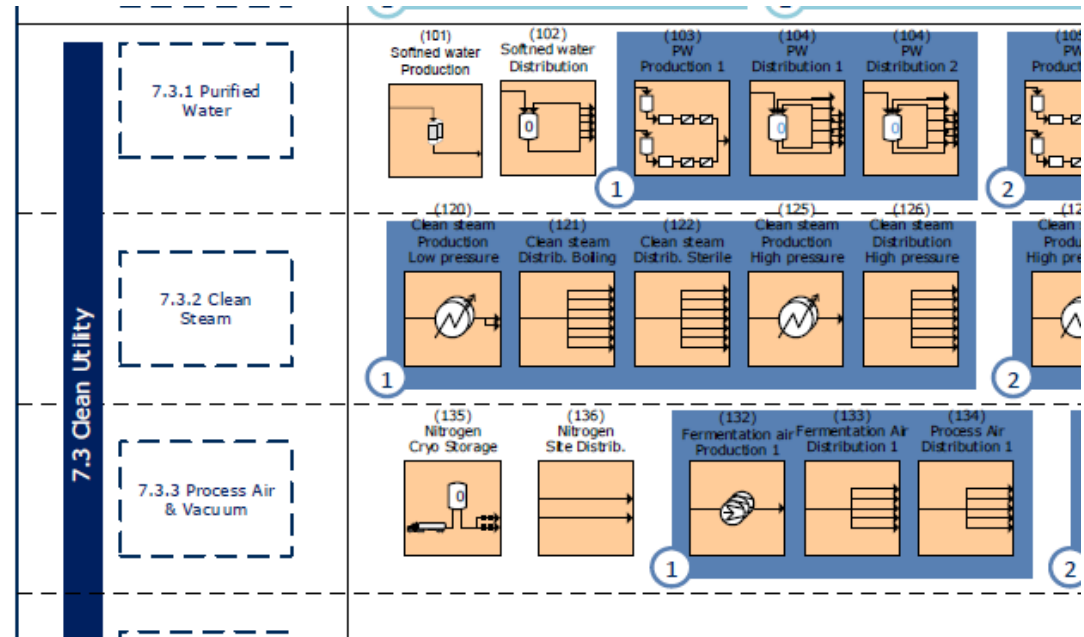
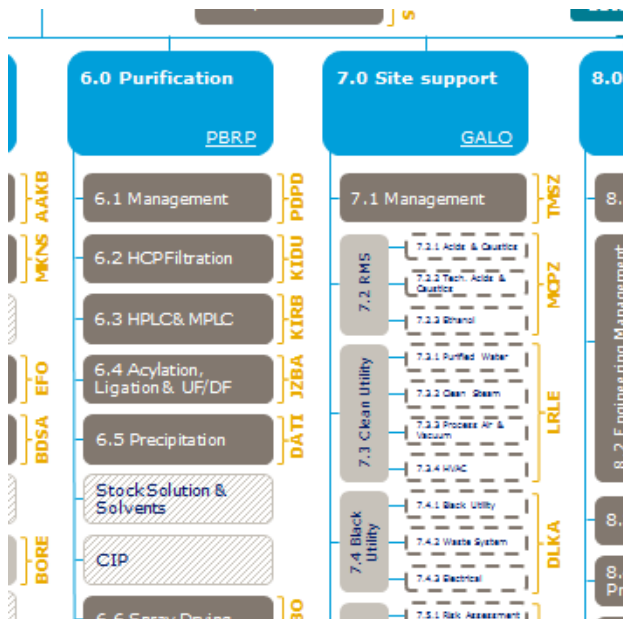
How is it set up?



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

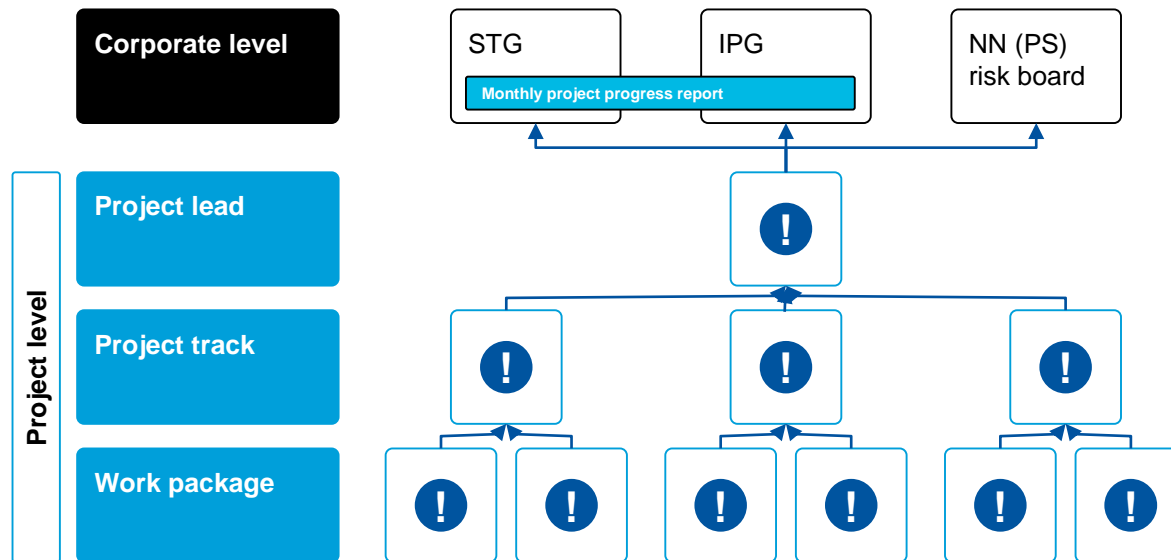
Work Breakdown Structure



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)

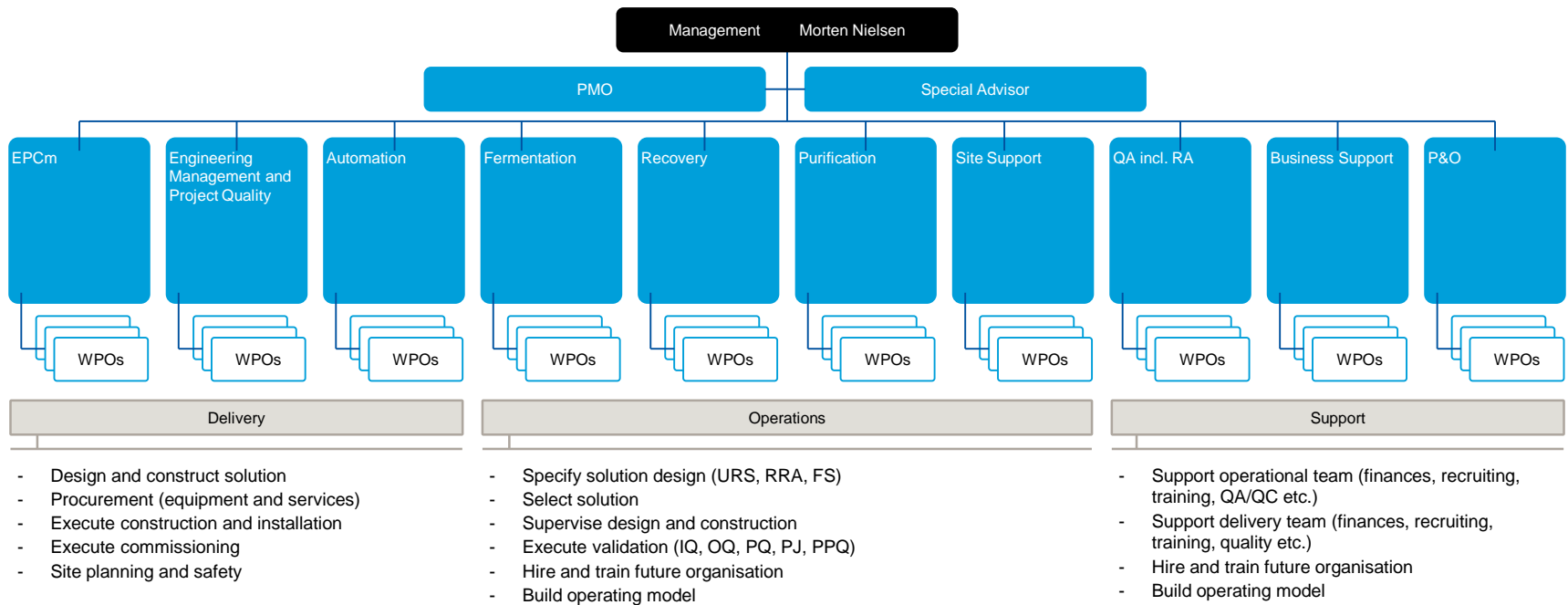


Dynamics



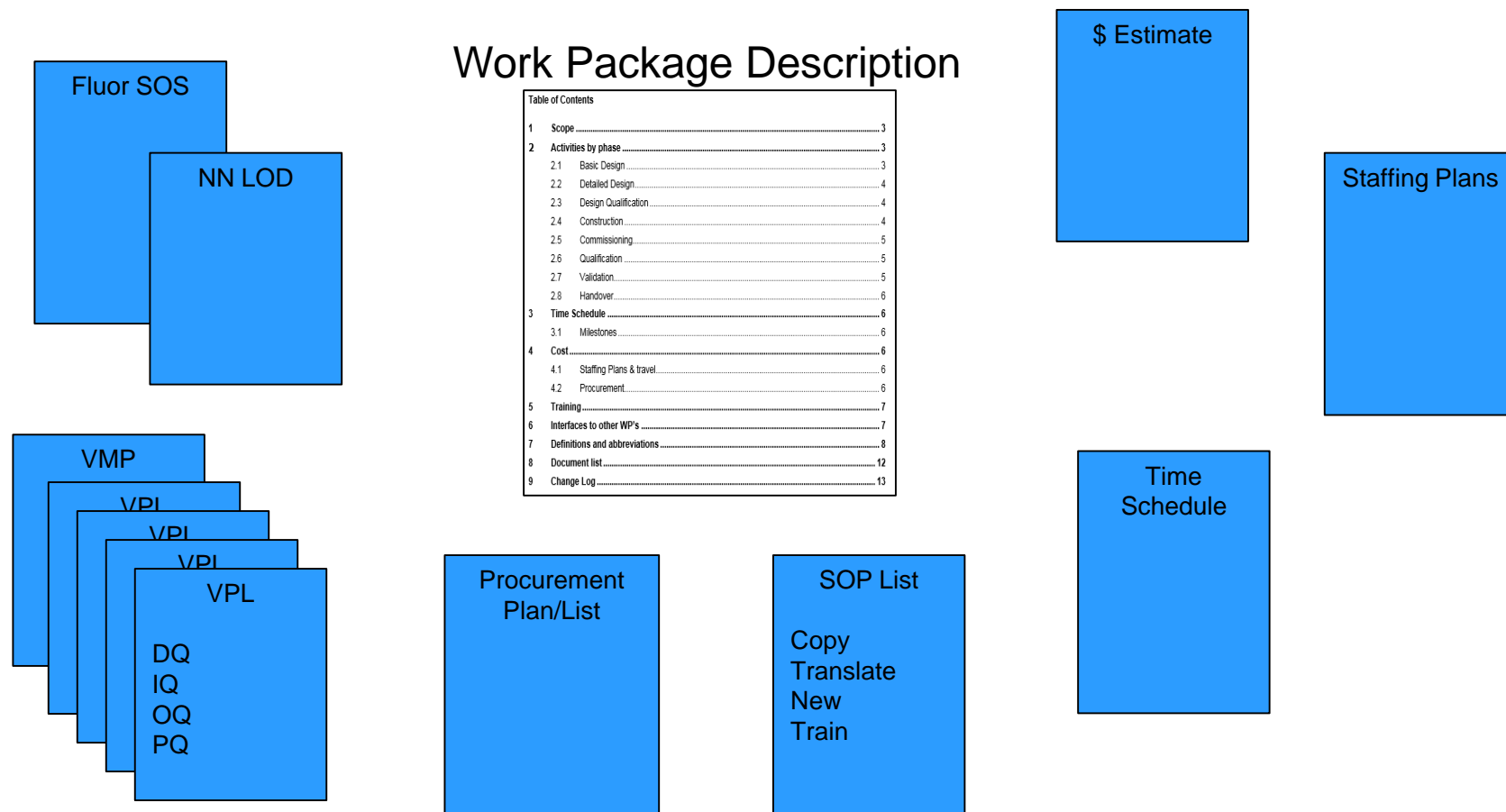
Project Organisation: Overview

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

WPD input Landscape

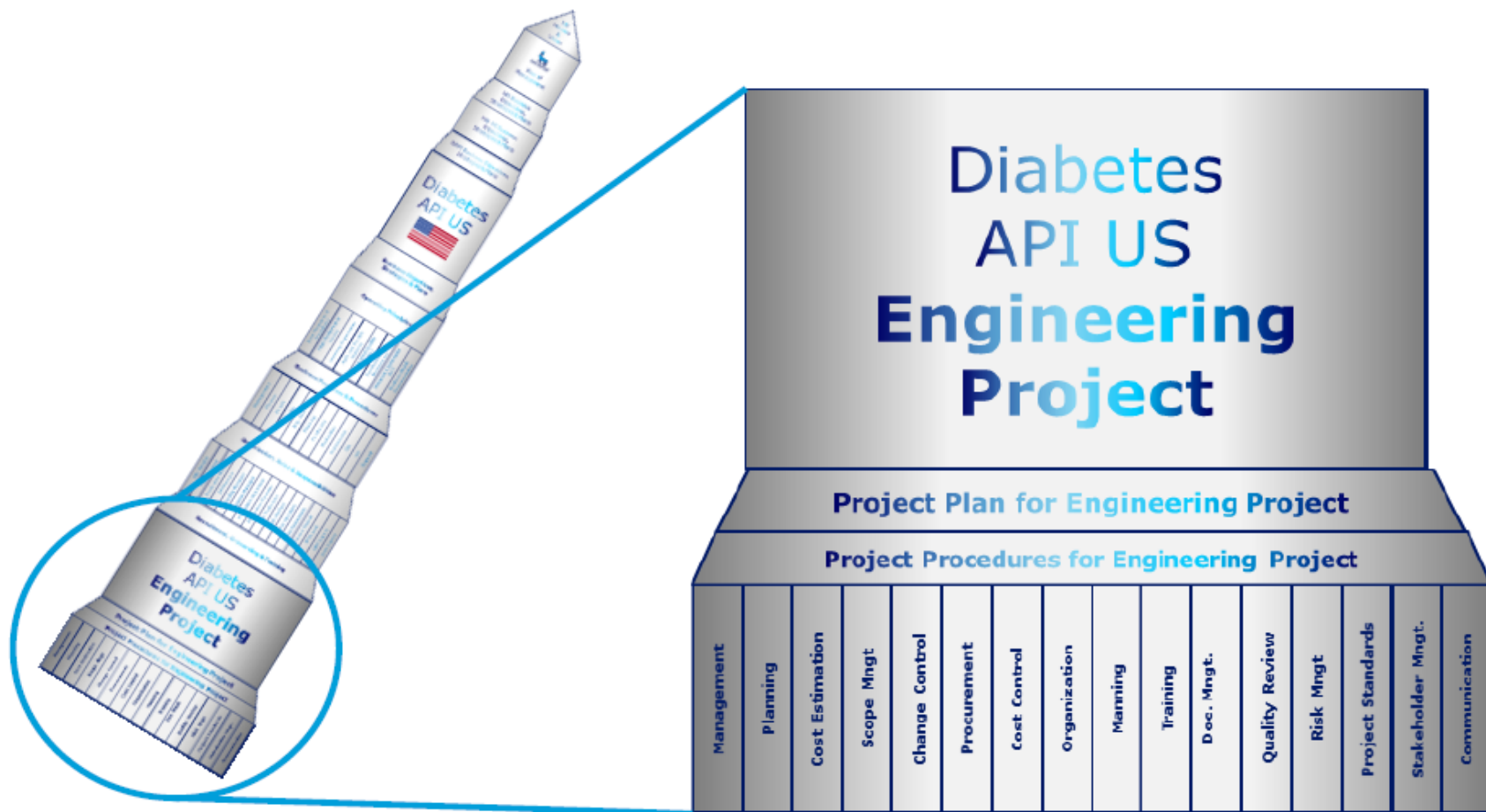


Interface Agreements

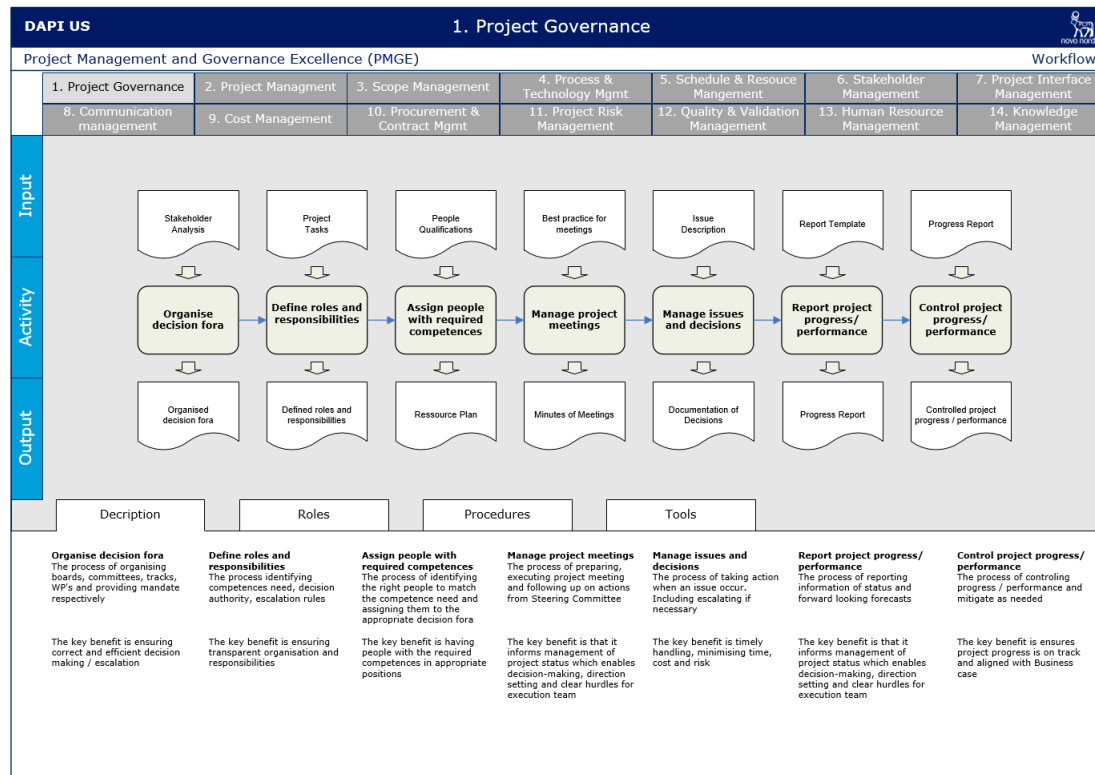


Interface Overview Example Recovery

DAPI US Recovery 1 Interface Overview			Recovery Track (5.0)					Overview
Step ID	Work Package	Interface	Management (5.1)	Clarification (5.2)	Capture (5.3)	Crystallization (5.4)	CIP (5.5)	Content
3.3	Supply Chain & Sourcing	Material supply chain	12					Overall Recovery agreement: Ordering, sizes, and packaging of materials
				12	12	12	12	Individual Work Packages: Communication of new needs, requesting to start sourcing procedure
3.4	Warehouse	Raw Materials	13	13				Overall Recovery agreement: Delivery, scheduling, size, and packaging of raw materials to local Recovery warehouse
		Consumables	13	13	13	13	13	Overall Recovery agreement: Ordering, typenumber of consumables, number of spares, and how/when consumables are transferred to local Recovery warehouse
		Consumables for CIP					13	Individual Work Package: Ordering, typenumber of consumables, transferred to local warehouse
		Intermediate Product Storage				13		Individual Work Package: Transferring scheduling
		Samples	14					Overall Recovery agreement: Communication of new needs, requesting to start sourcing procedure
				14	14	14	14	Individual Work Packages: Types of tests, sample size, number of samples, scheduling of samples and results,



Interactive PM Handbook (User Interface)

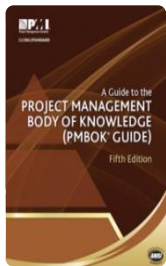


DAPI US PM Training

PM F2F training for DAPI US Work Package Owners

4 x 4 hours

Module 1: Half Day Framework and PMI

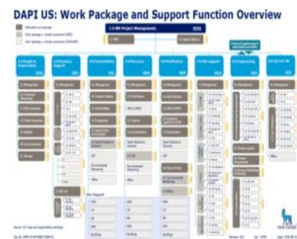


Foundation

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



Module 2: Half Day Specific Topics

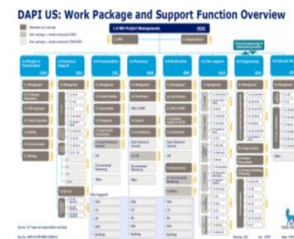


Specific Topics

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



Module 3: Half Day Specific Topics

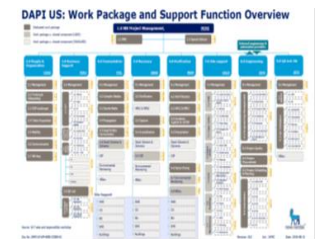


Specific Topics

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



Module 4: Half Day Specific Topics



Specific Topics

- Quality
- Conflict Management
- Impact and Influence
- EXAM

Work will be assigned in between modules.

