Diabetes API US
Agenda

1. Introduction to Novo Nordisk and Diabetes API US
2. “Site tour”
4. Organisational build up
5. Structuring around work packages
**Novo Nordisk at a glance**

**Global leader in diabetes care**
- A **focused** pharmaceutical company with **leading positions** in diabetes, haemophilia and growth hormone
- **Double digit top line growth** driven by diabetes pandemic
- Significant **growth opportunities** fuelled by global presence and strong R&D pipeline
- **High barriers to entry** in biologics
- **Operating margin** targeting **40%**
- **Operating profit growth** targeting **15%**
- Earnings **conversion to cash** targeting **90%**
- **Cash generated returned to shareholders**

**The core equity story**
- Global insulin market share: **47%**
  - Europe: Market share **47%**
  - North America: Market share **37%**
  - Japan & Korea: Market share **49%**
  - China: Market share **57%**
  - International Operations: Market share **55%**

Source: IMS MAT Feb 2015 volume figures, Roadshow 2015 Q2 presentation
**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 estimated to ~USD 2 billion.

Roughly 80,000 sq. meters and covering app. 85 acres of land.
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Ensure dual source API supply to enhance robustness of Novo Nordisk supply chain

Expand with local presence in largest diabetes market and get access to large pool of skilled pharma talents
## Example ramp up plan: Fermentation

### Milestones:
- **BD**
- **DD**
- **Construction part I**
- **Construction Part II**
- **Commissioning & testing (IQ / OQ)**
- **PQ & PJ**
- **PPQ**

### Activities:
- **URS**
- **TS / FS**
- **P&ID**
- **Data sheet equipment**
- **Design review**
- **Change request**
- **3D models**
- **Vendor supervision / audits**
- **FAT / SAT protocols**
- **Accept. test protocols**
- **IQ / OQ protocols**
- **Engineering changes**
- **Construction testing**
- **Preparation for testing**
- **SOPs (equipment)**
- **SOPs (site)**
- **SOPs (facility)**
- **SOPs (facility)**
- **FAT / SAT protocols**
- **Accept. test protocols**
- **IQ / OQ protocols**
- **Validation non-conformities**
- **Change management GMP**
- **Calibrations**
- **Finalisation of SOPs**
- **Equipment testing**
- **PQ/PJ/PPQ protocols**
- **Production tools**
- **PQ / PI reports**
- **PQ / PJ reports**
- **Job instructions**
- **PPQ reports**

### Manning:
- **Director**
- **Team leads**
- **Professionals**
- **Staff**

### Temporary support:
- **Engineering mgmt. partner**
- **Engineering mgmt. partner**
- **Engineering mgmt. partner**
- **Engineering mgmt. partner**
- **Engineering mgmt. partner**

### Note:
Staff includes 1 Admin, 2 GMP partner, 1 GMP coordinator, 1 cLEAN coordinator, 1 training coordinator
Ramp up plans prepared for each organisational unit

Ramp up plans subject to ongoing update and revision based on revised manning need
Project organisation – ramp up, baseline

The organisation will be gradually ramped up to 677 FTE’s in full operation

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**Project phases:**

- BD
- DD
- Construction
- IQ / OQ
- PQ / PJ
- PPQ

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1) Includes Business Support, Supply Chain, People & Organisation, Site Management and Manufacturing Development
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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

**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

**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. Prepare work package descriptions and interface matrices
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**
  - STG
  - IPG
  - NN (PS) risk board
  - Monthly project progress report

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

**Dynamics**

- Guidance
- Coaching
- Feedback
- Review
- Reporting
- Risk mgmt.
- Decisions
- Problem solving
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