Concept designs for vaccine facilities: Conciliation of local and global expectations

DCVMN conference

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27-30 October 2014, New Delhi
Outline

- Why Conceptual Design?
- What are the objectives of a Conceptual Design?
- Vaccine facility design.
- Local/Global expectations.
- Case study: From Conceptual Design to Build
About NNE Pharmaplan

- With 80 years of experience we are passionate about our services to the pharma and biotech industries
- Consulting and engineering for Pharma and Biotech
- > 200 with hands-on development or production experience
- 30 office locations
- 17 countries
- 2,929 projects in 2013 (all activities)
- Center of Competence (COC) in Bangalore, India for Global vaccine projects
Closer to our customers

NNE Pharmaplan employs close to 1,700 people at more than 30 locations in 16 countries around the world.

97% of our revenues come from the pharma and biotech industries.
Our work split

The main part of our employees have a background in pharmaceutical production companies.
NNE Pharmaplan; 75 COI’s, global network –

- COI Biocontainment
- COI Vaccines
- COI Biotech Production
- COI Aseptic Processing
- COI Building Architecture
- ISPE
- PDA
- EMEA
- FDA

Next: Session outline
Centre of Competence (COC) for Vaccine Projects (Bangalore)
What we do – when we do Conceptual Design

DEVELOP
- Process & Product development
- Project development

ESTABLISH
- Investment project
- CD / BD / DD / CON / C&Q

IMPROVE
- Optimisation, training, revamps,
- GAP analysis, operational support

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Conceptual design of vaccine facilities: 3 principal facets

**Technology:**
1. Vaccine mfg. platform & technology
2. Process/ Equipment

**Design:**
1. GMP Compliance
2. Biosafety & Containment Compliance

**Operations:**
1. Manufacturing scheduling
2. Operations strategy
Biosafety versus GMP – an illustration

**Biosafety**
- Protect the employees
- Prevent escape of materials
- Production flow: Clean to dirty!

**GMP**
- Protect the product
- Minimize cross contamination
- Production flow: Dirty to clean!
Biosafety Level – ‘Steps’ in Engineering & Operational complexity
(related to risk groups of biological agents)
Why Conceptual design for vaccine facilities?
Why Conceptual Design?

The most important investment, because it ensures:

- **Fit for purpose**
  - Technology fit for purpose, manufacturing fit for purpose <broad level of uncertainties>
  - Understanding of biological agent translated to design measures

- **Risk reduction**
  - Limitations and possibilities are identified from the start, facilitating choice awareness
  - The project is ensured minimum sensitivity to changes during the planning phase
  - A CD maps possibilities now and going forward, ensuring a firm and time robust solution

- **Economy control**

- **Holistic project approach**
  - A CD provides a cross-disciplinary design which take into account all relevant areas
  - An overall overview of all project elements is created from the outset

- **Sustainability**
  - Environmental considerations are integrated in the project
  - The sustainability issue might have high impact on image development

- **Alignment with business strategy**
Conceptual design:
Basis for **Decision** v/s Basis for **Design**

START

Decision for manufacturing capability

CapEx approved?

NO

Conceptual Design Type A

Pre-design

Decision support

NO

GAP

Conceptual Design Type B

Pre-design

Decision support

YES

Basic Design
Note: Production program is "key" to Process level feasibility & Configuration level feasibility.
What concept makes the best business case?

$ - $$$
$/ dose
Conceptual Design end-points

Typical pre-design content:
- Capacity analyses
- Process, utility & building specification
- Technology & equipments
- Organisation & staffing
- Facility area needs
- Flow
- Layout
- Health Safety & Environment
- Project execution plan

- Cost
- Timeline

Basic Design

Pre-design
Investment & Commitment Timeline

Early decisions have most impact on the Investment

The graph illustrates that the major part of investment committed to a project will be determined very early in the project phases, i.e. the very early decisions will have the strongest impact on investment level.

Maximum room for manoeuvre for lowest possible cost
Conceptual design philosophy

**Picasso “A guitar Player”**
- Possibilities/Inspiration
- Open ends
- A selection of scopes
- Without specific requirements to functions, etc.

**Vermeer “A guitar Player”**
- Fixed cost +/- 10%
- Without open ends
- Well defined scope
- Buildable
Standardised vaccine facilities
Standardised vaccine facility:
Flexibility, compliance & construction modularity
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Purification chromatography + purification UF/DF rooms = product specific
Standardised vaccine facility:
Flexibility, compliance & construction modularity
Site/integration level feasibility
Medigen vaccine facility, Taiwan

- Medigen vaccine facility
- Designed for viral vaccines: EV71 and Flu
- Option for other Viral products
- Designed for Formulation and Filling
- State of art facility
- Project start: 2012
- Expected completion: 2015
Design strategy, design drivers

- **Vaccine manufacturing units:**
  - Designed as Multi-product facility
  - Designed for flexibility and high level segregation
  - cGMP
  - BSL2+ for bulk 1
  - BSL2 for bulk 2
  - Single use technology where appropriate
  - Common support functions
  - Closed system approach in order to lower room classification
Containment strategy for vaccine pilot units

- **Maximal segregation by:**
  - Dedicated HVAC units for each unit
  - 100% fresh air for BSL areas
  - Advanced pressure regime with lowest pressure in the return corridor
  - Uni-directional flow of people for all BSL area
  - Access control for all airlocks
  - Dedicated operators for each pilot unit
  - Decon-area for solid waste in connection to return corridor
  - Two step de-gowning area before leaving the BSL area
  - Kill system in basement for decon of liquid waste
  - Risk based approach
Site Plan
Slides withheld

- Customer confidential
Slides withheld

- Customer confidential
Slides withheld

• Customer confidential
Work in progress: Today
“Rigorous conceptual designs are the foundations strategic vaccine manufacturing capabilities”

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