Construction in a GMP qualified environment

Joost van Raaij Sr. Project Manager DPS Group



Agenda

- Introduction
- Preparation
- Enabling work
- Shutdown & CQV
- Summary



Introduction | relevance



Over 200 pharma companies in Benelux

Facility investment levels <u>hundreds of millions euros</u> annually

Majority of projects related to upgrade or refurbishment of facility



Relevant project experience (recent years):

>> 270M€ of capital investments
>> 1,000,000 construction hours



Introduction | framing

Projects involving construction work in an operating production facility





Introduction | framing

Key Success Factors - parallel production & construction





Introduction | framing













28-6-2018







WE SHARE THE KNOWLEDGE

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28-6-2018































Preparation	Enabling Work	Shutdown Work CQV	Operation
 Engineering 	• Field works	 Safe shutdown 	Qualified State
 Investigations 	 Temporary routes & 	 Dismantle, demolish, decontaminate 	Minimum Interruption
PEP Qualit		TH THE END IN MIND	• Safe
planning	Prepare stock	Commissioning (IC & OC)	• In control
Prepare stock	 End point samples, 	 Qualification (IQ & OQ) 	 High performance team & stakeholder
 Prefabrication 	calibration	 PQ (sampling / monitoring) 	success





Measure progress and remedy issues





Document Management System

- Approval of documents and drawings electronically.
- Full visibility of internal comments and number of versions and history.
- Approvers of documents are restricted to appropriate qualified personnel.
- All documents are approved on a cloud based platform to facilitate inter- office execution of projects.
- Documents can be approved with mobile devices.
- Vendor document management.







"If it is not documented, it didn't happen"

"C&Q engineers should not have an opinion"

As Built Data is to be fully trusted

"Post hoc ergo propter hoc"





Any Questions?



BACK-UP SLIDES

Key Delivery Strategies

- Suite Teams
- Pre-engineered solutions
- Off Site Prefabrication

- Scheduling Tools
- Bidding/Tender Management
- Materials Tracking
- Contract
 Administration
- Integration of Project Controls and Resource Management
- NODULAR DESIGN CONTR ROJE 700LS STRATEG PROJECT COLLABORATIO **Document Management** ٠ Project Communications
- Design Delivery Road Map
- Pull Planning / Last Planner in Design
 - Target Value Design

- Facility / Process Modelling
- Software Tools
- BIM / LOD



3D Software Tools

Autodesk Revit

Specifically built for Building Information Modeling (BIM), including features for architectural design, MEP and structural engineering, and construction.

CADWorx Plant

Provides intelligent spec-driven piping design, equipment, ISOGEN isometrics, live database connectivity, model - P&ID synchronization and links to Stress Analysis.

CADWorx Intelligent P&ID

Provides quick and intuitive P&ID creation, large usermodifiable symbol library, spec-driven P&ID's and bidirectional project database.

Autodesk Navisworks Manage

Aggregate models from multiple design packages, model review, clash and interference management, 5D scheduling and quantification.

Autodesk® 3ds Max® Design

Visualisation tools that provides cinema-like image quality to help communicate design intent to clients and win new business.



CADWorx Intelligent P&ID's

- List Capability (Equip, Line, Valve, Instrument etc.)
- Instrument Datasheets
- Instrument Loop Drawings
- Process Equipment Datasheets



BIM

General

- BIM Level of development (LOD)
- Project BIM Execution Plan
- Model review guidelines
- ▶ Model Sharing Tools
- Clash management Guideline

BIM 3D, 4D, 5D

- 3D as standard
- 4D Linking components to schedule (Project Specific)
- 5D Bills of Material's/Schedules to support cost management. As standard





Document Management System - Asite

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Project Communications - Asite

Intelligent Forms to track key project communications

- ► RFI's.
- ► Site Query.
- ▶ Field Change Notice (FCN).
- ► Technical Design Query Internal use.
- Emails.
- Minutes of Meeting and associated Action Register



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Last Planner System In Design



Measure progress and remedy issues

WE SHARE THE KNOWLEDGE

- <u>Weekly Work Planning</u> Project schedule lookahead is published to Design Leads to plan works.
- Weekly Planning Co-Ordination Activities are broken down into daily commitments per Design and any conflicts are identified and resolved. A WWP schedule is agreed.
- 3. <u>Weekly Constraint Identification –</u> Roadblocks to achieving these Activities are identified (P&ID, Specs, Clashes etc) and an owner identified to resolve.
- Daily Huddle Activities and Variances are tracked. Designs performance is measured.
- <u>Weekly Review.</u> Constraints, Performance and impacts from previous week reviewed. Improvements identified and implemented.