Innovating the Capital Appropriation Process

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Innovating the Capital Appropriation Process

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  • Project Executive

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  • Principal Consultant

• Brent Pilgrim, Beck Technology
  • Director of Services
Presentation Outline

• Innovation in Process/Facility Design & Planning
• Business Drivers for Process/Facility Design & Planning
• Regulatory Changes/Drive Toward “Design Space”
• Relevant Technology Improvements
• Innovative Solution – DESTINI Profiler
• DESTINI Profiler Introduction & Video
• Benefits of this Solution
“Virtualizing the Planning of Manufacturing Processes within Facility Design, using Parametric Tools”
Clinical Timelines & Facility Requirements

“Valley of Death”
(Discovery to Phase I: 5 Yrs)

Phase II Trials
(Phase IIA  Phase IIB: 4 Yrs)

“Valley of Financial Pain”
(EOPII & Phase III Plan: 18 Mos)

Phase III Trials & Launch

Traditional Design/Bid/Build
(Approximately 3-4 Yrs)

Manufacturing Trials

*Early Facility Design and Process Integration Decreases Time to Market!
Business Drivers: A Changing Paradigm

- **Big Pharma**
  - Reduced engineering staffs
  - Facility management outsourcing
- **Mid-Stage Pharma**
  - Dependent upon external expertise
- **Early-Stage Pharma**
  - No investment in early facilities planning
Business Drivers: Facilities Design

- Broader Product Portfolios
- Patient Specific Medicine
- Smaller Targeted Patient Populations
- Global Competition
- New Manufacturing Platform
- Multiple Product Facilities
- New Technologies
Process/Architecture/Engineering Challenges

- Planning & Design Process is Slow & Imprecise
- Prolonged Decisions Making
- Costly Initial Work & Costlier Rework
- Delayed Product Delivery
Regulatory Paradigm & “Quality by Design”

ICH – Q9
ICH – Q8
ICH – Q10
ICH – Q11
QbD Should Initiate a Design Continuum

Facility Design/Information Management/Automation

QbD

Assess → QTPP → Risk Analysis → Process Development → Validation

Rework loops occur at each step, but the continuum starts at the benchtop!
Relevant Technology Improvements

- Process Modeling
- Building Information Modeling (BIM)
- Intelligent Objects
- Rapid Prototyping
- Virtual Analysis
Simulation & Modeling Systems

Current Software for Process Modeling:

- Intelligen – SuperPro Designer
- INOSIM – Process Edition
- AspenTech – AspenOne
- BioPharm – Biosolve Process

No current simulation system offer parametric process modeling and facility design simultaneously!
Simulation & Modeling Systems

DESTINI Profiler

- Planning stage conceptual modeling
- Equipment based space planning
- Real-time costing
- What-if scenario analysis testing
“Virtualizing the Planning of Manufacturing Processes within Facility Design, using Parametric Tools”
3D Cost Modeling with Process Integration

**Block Diagram**

- Preparation of Inoculum: BSL 2
- Scale Up Inoculum: BSL 2
- Add Inoculum to Bioreactor: BSL 2+
- Monitor During Fermentation: BSL 2
- Quality Control: BSL 2

**Downstream Process**

- Removal of Insoluble: BSL 2
- Product Isolation: BSL 2
- Product Purification: BSL 2

**Process Flow Diagram**
3D Cost Modeling with Process Integration

Process Flow Diagram

Equipment Specifier

Equipment Specifications

<table>
<thead>
<tr>
<th>Equipment Name &amp; ID</th>
<th>Equipment Name:</th>
<th>Equipment ID:</th>
<th>Equipment Description:</th>
<th>Unit Cost Override:</th>
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<tbody>
<tr>
<td></td>
<td>Flask Incubator</td>
<td>SI01</td>
<td>170 IR CO2 Incubator - IR sensor, no O2 control, stand, CO2 in line pressure regulator</td>
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<table>
<thead>
<tr>
<th>Equipment Attributes (User-Defined)</th>
<th>Catalogue Cost:</th>
<th>Quantity:</th>
<th>Extended Price:</th>
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<tr>
<td></td>
<td>$32,579.00</td>
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<tr>
<th>Vendor:</th>
<th>Model #:</th>
<th>Capacity:</th>
<th>Containment Classification:</th>
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<tr>
<td>New Brunswick Galaxy</td>
<td></td>
<td>2.5 cu.Ft.</td>
<td>ISO7</td>
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<table>
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<tr>
<th>Equipment Properties (Read-Only)</th>
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<tbody>
<tr>
<td>Size</td>
</tr>
<tr>
<td>Nominal Physical Dimensions (in)</td>
</tr>
<tr>
<td>W x L x H</td>
</tr>
<tr>
<td>30 x 48 x 36</td>
</tr>
<tr>
<td>Front Clearance Requirements (in)</td>
</tr>
<tr>
<td>36</td>
</tr>
<tr>
<td>Left Clearance Requirements (in)</td>
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<tr>
<td>16.5</td>
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<tr>
<td>Right Clearance Requirements (in)</td>
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<tr>
<td>16.5</td>
</tr>
<tr>
<td>Back Clearance Requirements (in)</td>
</tr>
<tr>
<td>12</td>
</tr>
<tr>
<td>Overhead Clearance Requirements (in)</td>
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<tr>
<td>Normal (B’ or Less)</td>
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<th>Utility Requirements</th>
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<tbody>
<tr>
<td>Electrical</td>
</tr>
<tr>
<td>Electrical (Amps)</td>
</tr>
<tr>
<td>30</td>
</tr>
<tr>
<td>Electrical (Volts)</td>
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<tr>
<td>120</td>
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<tr>
<td>Domestic Cold Water</td>
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<tr>
<td>0</td>
</tr>
<tr>
<td>Domestic Hot Water</td>
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<tr>
<td>0</td>
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<tr>
<td>Reverse Domestic Water (RDI)</td>
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</tr>
<tr>
<td>Water For Injection (WFI)</td>
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<td>0</td>
</tr>
<tr>
<td>Plant Steam</td>
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<tr>
<td>0</td>
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<tr>
<td>Pure Steam</td>
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<tr>
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<tr>
<td>HVAC Load Sensible Heat (BTU’s)</td>
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<td>1200</td>
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<table>
<thead>
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<th>Gases</th>
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<tr>
<td>CO2</td>
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<td>Yes</td>
</tr>
<tr>
<td>O2</td>
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</tr>
<tr>
<td>N2</td>
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Input/Output Points
3D Cost Modeling with Process Integration

Equipment Specifier → Equipment Placement
3D Cost Modeling with Process Integration

Equipment Placement

Convert to Model Object
(Space or Program Requirement)

Intelligent object with:
- Physical dimensions
- Utility requirements
- Room Finishes, etc.
- Detailed Cost
3D Cost Modeling with Process Integration

Convert Space

Populate Room Card

Inoculum Space

Room Card Editor

Room Name: Inoculum Prep
Department Name: Manufacturing
Area Classification: Controlled Not Classified
Containment Classification: Biosafety Level 2

MoA Required: 1
RFI Required: 1
Occupancy: 2

Wall Construction Type: Gypsum Board
Wall Finish Type: Epoxy Paint
Wall Protection: Crash Rails & Corner Guards

Ceiling Type: Cleanroom Tile
Door Type: Hollow-Metal
Door Qty: 2

Flooring Type: 3/16" Trowled Epoxy
Base Type: 4" Rubber Cover Base
Coved Corners: Yes

Utilities

HVAC Requirements
- Target Operating Temperature (°F)
- Temperature Tolerance (± F)
- Total CFM
- Relative Humidity
- Relative Humidity Tolerance (± %)
- Required Air Changes per Hour
- Filtration Type
- Supply
- Return
- Relative Pressure
- Environmental Monitoring
- Vacuum
- Internal Lighting Loads (W/’F’)
- Internal Equipment Loads (W/’F’)

Electrical Requirements
- Lighting (Foot Candles)
- Lighting Fixture Type
- Power for Equipment
- Power for General Purpose
- UPS
- Communications (Phone/Data)
- Special Grounding Requirements
- Fire Alarm
- Security

Fire Protection Requirements
- Type of System
- Head Type
- Portable Fire Extinguisher (lbs)
- Reverse Osmosis Deionization Water (RO)
- Water for Injection (WFI)
- Domestic Water (DW)
- Gas (CO2)
- Gas (N2)
- Compressed Dry Air (CDA)
- Compressed Air Instrument (CAI)
- Plant Steam

Annual Meeting 2015
3D Cost Modeling with Process Integration

Layout Spaces in Model → Convert to Functional Plan
3D Cost Modeling with Process Integration

Floor Plan
(Product, Material, Waste, & People Flow)

Convert to Baseline Building Model
3D Cost Modeling with Process Integration

Begin Detailed Analysis & Scope Refinement
3D Cost Modeling with Process Integration

Reports & Other Deliverables

- Process Flow Diagram
- Equipment List
- Floor Plan
- Design Criteria
- Detailed Construction Cost
- Schedule
3D Cost Modeling with Process Integration

Capital Appropriation Package

- Design Costs (A/E, Process)
- Automation Costs
- Capital Costs (Construction Cost)
- Commissioning/Startup (2%-4%)
- Validation (4%)
- Owner Management Cost (5%)
- Land/City/State/Fed Costs
- Permits
Technology Implementation Timeline

“Valley of Death”
(Discovery to Phase I: 5 Yrs)

Phase II Trials
(Phase IIA Phase IIB: 4 Yrs)

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(EOPII & Phase III Plan: 18 Mos)

Phase III Trials & Launch

Manufacturing Trials

Integrated EPCV
(18 months – 2 years)

Traditional Design/Bid/Build
(Approximately 3-4 Yrs)

CAPEX Gate #1

CAPEX Gate #2

CAPEX Gate #3

Manufacturing Trials

Opportunity

CAPEX Gate #4

1 Early Evaluation Bench/Pilot

2 Mid-Stage Eval Process Optimization

3 Design & Budget for Design/Build
The Future of This Innovation – “Optioneering”

Inspiration: Boeing’s RCD Process

(TOGW -38%)

Feasible Range

(Vandenbrande 2006)
The Future of This Innovation

Today’s Design Practice

• Allows for 5-9 Design Options
• Focuses on 3-4 Major Issues
• Takes 6-8 Months
• Spends Money
• Wastes Time
The Future of This Innovation

If there are Thousands of Potential Solutions in the Overall Design Space...

...Is the Current Design Effort Good Enough?
The Future of This Innovation

Tomorrow:

• Thousands of options
• Multiple parameters
• Two weeks
• SAVES money
• SAVES time
• ADD value
The Future of This Innovation
Optioneering at 50,000 ft

KEY

Baseline

Lowest Cost

Lowest Carbon Footprint

Infeasible Solution

3 Buildings, 5 Stories

3 Buildings, 6 Stories

3 Buildings, 7 Stories

3 Buildings, 8 Stories

4 Buildings, 5 Stories

4 Buildings, 6 Stories

4 Buildings, 7 Stories

4 Buildings, 8 Stories

Annual Meeting 2015
Questions

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