LEARNING THROUGH DOING: THE INTERPLAY OF PILOT PLANT, PRODUCT, AND PROCESS

ISPE Boston Area Chapter Meeting
March 24, 2016

Meeting Managers:
Stacy Price, Shire
Eric Felz, Shire

Moderator:
Brad Ebel, Shire

Panelists:
Bill Brazier, Amgen
Shaun Grier, Shire
Christof Schulz, Abbvie
David Sullivan, Pfizer
Kelly Wiltberger, Biogen

Product Development Life Cycle

Discovery Research → Process Development → Pilot Plant → Manufacturing

The Role of the Pilot Plant can be Development & Commercial Support:

- Material Production
- Technology Development
- Process Characterization

- Operations Design
- Scalability Assessment
- Training
Introducing our Panel:

Moderator: Brad Ebel

Panelists:

Christof Schulz
Bill Brazier
Kelly Wiltberger
David Sullivan
Shaun Grier
Specialty Medicines
- Multiple Sclerosis
- Inflammatory Bowel Disease (IBD)

Neurodegeneration
- Alzheimer's Disease
- Parkinson's
- ALS

Rare Diseases
- Hemophilia
- Spinal Muscular Atrophy (SMA)
- Neuropathic Pain

Cambridge, MA
- Process Sciences
- Manufacturing (MFG)

RTP, NC
- Process Sciences
- Large & Small Scale MFG

Switzerland
- Zug: International Headquarters
- Solothurn: Future Large Scale MFG

Denmark
- Pack & Label
- Large Scale MFG

Pfizer Today

$54 BILLION in revenue in 2014*

64 MANUFACTURING sites worldwide

175 MARKETS in which Pfizer sells products

10 PRODUCTS with sales greater than $1 billion in 2014

MORE THAN 200 NEW R&D COLLABORATIONS in 2014

MORE THAN 97,000 COLLEAGUES around the world

*As of February 2, 2016
Our purpose is to enable people with life-altering conditions to lead better lives.

We market our products in 88 countries around the world. We have offices in nearly 40 countries and employ more than 5,000 talented people.

**4 Business units**

- Rare diseases
- Neuroscience
- Gastrointestinal and Internal Medicine
- Ophthalmics

**Benchmarking Focus**

- **What is the current scope of your pilot plant?**
  - What platforms do you support?
  - What unit operations do you have?
  - What is your resource profile?
  - What is your organization structure?

- **What are the current capabilities?**
  - What is your group’s major contribution? (Toxicology, Team supply, demonstration)
  - Does your group have cGMP capabilities?
  - What level of technology and process development is provided?

- **What is the future vision?**
  - Do you plan to do technology development?
  - Do you plan to support Manufacturing training and cross training?
  - Do you plan to design/scale-up of equipment, operations, process controls?
  - Do you plan to support process characterization?
## Benchmarking Results

### Points of Parity

<table>
<thead>
<tr>
<th>Focus on Team Supply and Demonstration Runs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involved with Procurement, Design and Scalability</td>
</tr>
<tr>
<td>Disposable Systems in Use</td>
</tr>
<tr>
<td>Involved in Technology Development</td>
</tr>
<tr>
<td>No GMP Quality Systems</td>
</tr>
<tr>
<td>No cGMP Capabilities</td>
</tr>
</tbody>
</table>

### Points of Difference

<table>
<thead>
<tr>
<th>Points of Difference</th>
<th>80% - Primarily on Mabs</th>
<th>60% - Recombinants</th>
<th>20% - Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Contributions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material Generation</td>
<td>80% - Provide toxicology material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technology Development</td>
<td>100% - Support technology development and scalability</td>
<td>80% - Support equipment design</td>
<td></td>
</tr>
<tr>
<td>Central Services/Solution Preparation</td>
<td>60% - Solution preparation services to some degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cross Training</td>
<td>80% - Encourage cross training but requirements are not fully defined for some</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing Training</td>
<td>60% - Provide some level of manufacturing training</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operations Design, Range Finding</td>
<td>80% - Process operations design</td>
<td>40% - Process range finding</td>
<td></td>
</tr>
</tbody>
</table>
Pilot Plant of the Future
Mission Statement

We are a cutting edge, variable scale Pilot Plant Facility with capabilities ranging across multiple technology and modality platforms. We aim to stay ahead of our customers growing diverse needs by continually seeking out and implementing the newest technologies and advances in industry to enable readiness for manufacturing whenever needed.

Considerations:
- Technology/Product Modality
- Equipment
- Facility
- Resources

What does Agility mean for the Pilot Plant of the Future?

- Technology/Modality
- Equipment
- Facility
- Resources
How does Future Pilot Plant Agility Affect a GMP Pilot Plant?

To be (GMP) or not to be (GMP)?

That is the question...

- Benefits?
- Feasibility?
- Considerations?

- Technology/Modality
- Equipment
- Facility
- Resources