



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

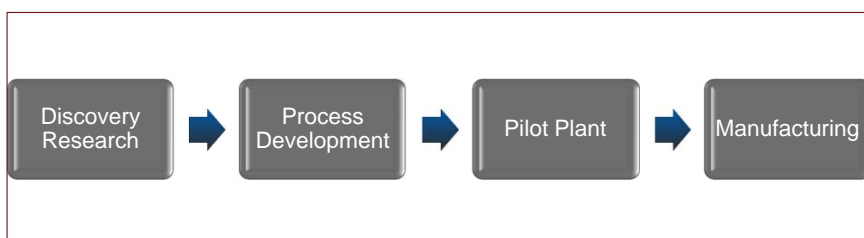
ISPE Boston Area Chapter Meeting  
March 24, 2016

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



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

Material Production  
Technology Development  
Process Characterization

Operations Design  
Scalability Assessment  
Training

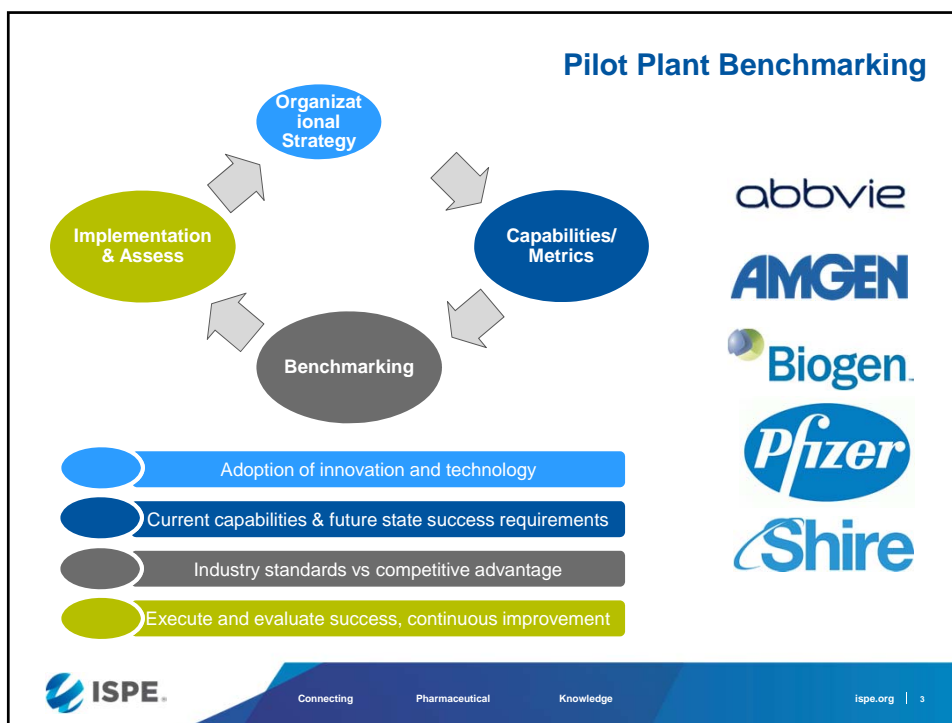


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### Introducing our Panel:


**Moderator:** Brad Ebel 


**Panelists:**

Christof Schulz 

Bill Brazier 

Kelly Wiltberger 

David Sullivan 

Shaun Grier 

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abbvie



**Corporate Headquarters: North Chicago, Illinois, USA**

**Approximately 25,000 Employees worldwide**

**170+ Countries**

**12 Manufacturing Sites | 6 R&D Sites**

Corporate Overview | September 2014 | Company Confidential © 2014 AbbVie

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**AMGEN**

**EPOGEN<sup>®</sup>**  
(EPOETIN ALFA)  
RECOMBINANT

**NEUPOGEN<sup>®</sup>**  
(FILGRASTIM)

**Aranesp<sup>®</sup>**  
(darbepoetin alfa)

**Neulasta<sup>®</sup>**  
(pegfilgrastim)

**Enbrel<sup>®</sup>**  
etanercept

**Sensipar<sup>®</sup>**  
(cinacalcet) Tablets  
30mg, 60mg, 90mg

**Mimpara<sup>®</sup>**  
FIRST-IN-CLASS  
cinacalcet

**Vectibix<sup>®</sup>**  
(panitumumab)  
Injection for IV infusion

**Nplate<sup>®</sup>**  
romiplostim

**prolia<sup>®</sup>**  
(denosumab) injection

**XGEVA<sup>®</sup>**  
(denosumab)

**Nexavar<sup>®</sup>**  
(sorafenib) tablets

**Kyprolis<sup>®</sup>**  
(carfilzomib) Injection

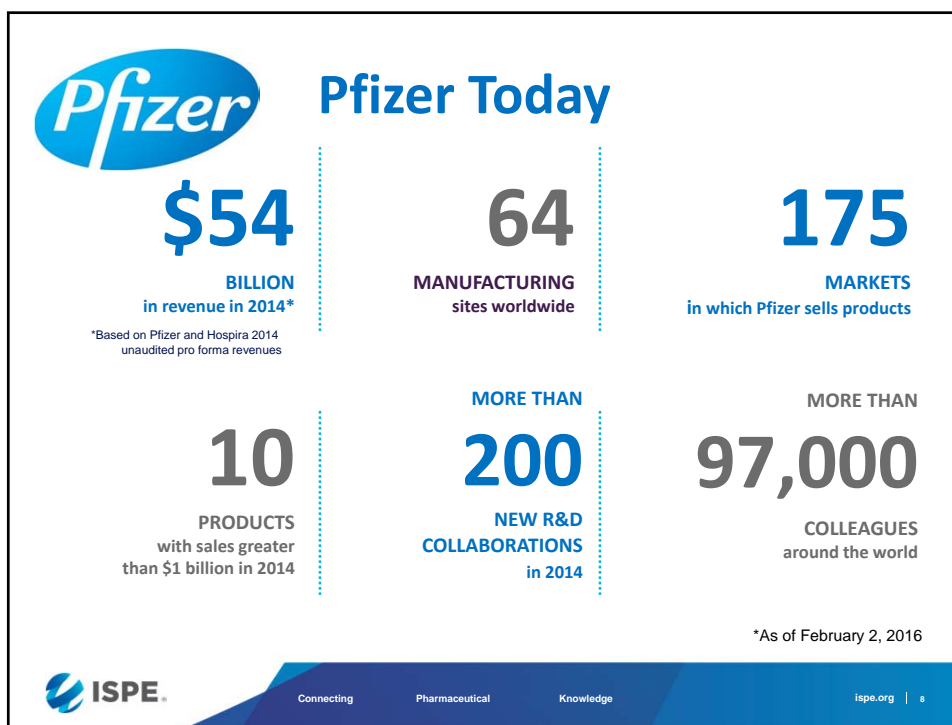
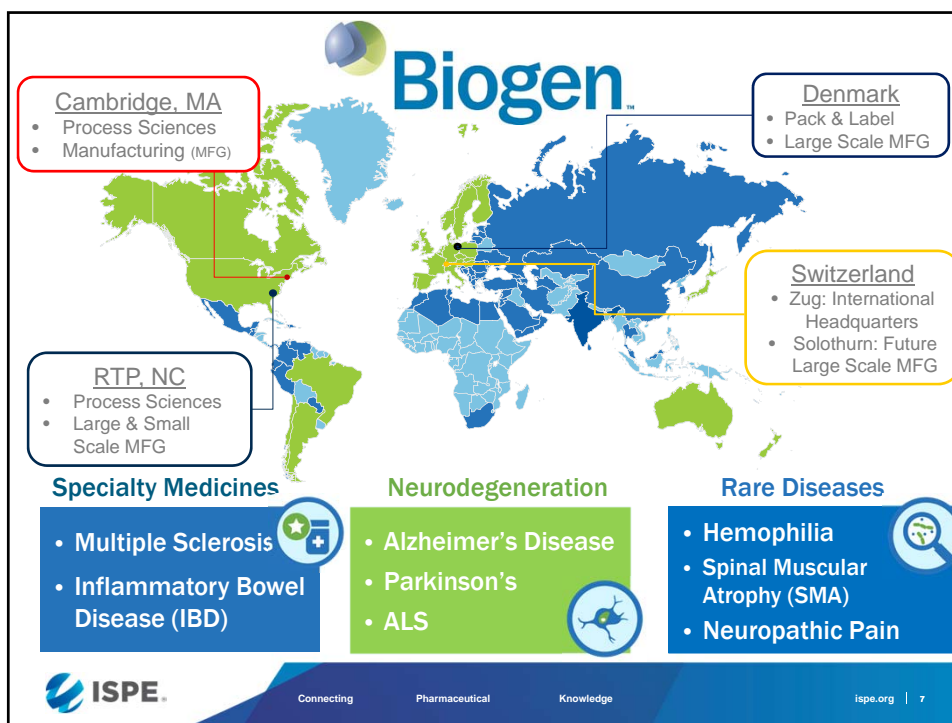
**BLINCYTO<sup>®</sup>**  
(blinatumomab) Injection  
35 mcg single-use vial

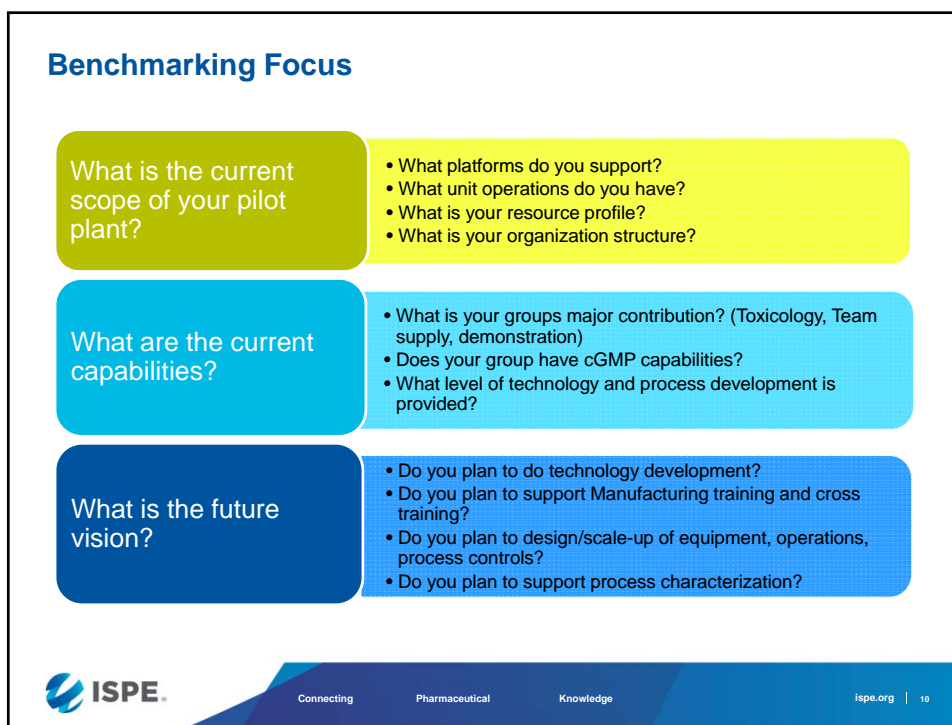
**Corlanor<sup>®</sup>**  
(ivabradine) 5 mg tablets

**Repatha<sup>®</sup>**  
(evolocumab) 140 mg/mL

For additional information about Amgen products, including important safety information, please visit [amgen.com](http://amgen.com); NEXAVAR<sup>®</sup> (sorafenib) is developed and marketed under collaboration and co-promotion agreements with Bayer HealthCare

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## Benchmarking Results

### Points of Parity

*Focus on Team Supply and Demonstration Runs*

*Involved with Procurement, Design and Scalability*

*Disposable Systems in Use*

*Involved in Technology Development*

*No GMP Quality Systems*

*No cGMP Capabilities*



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## Benchmarking Results

### Points of Difference

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



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## 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
- ✓ Facility
- ✓ Equipment
- ✓ Resources

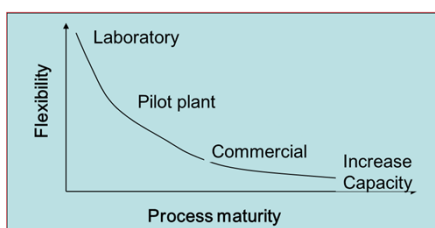


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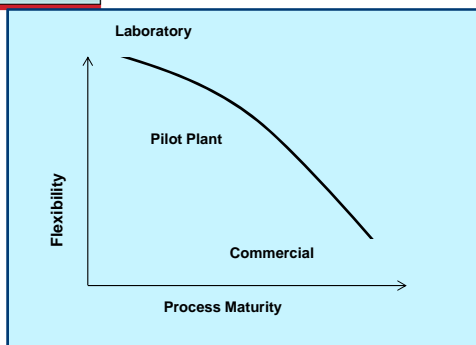
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What does Agility  
mean for the Pilot  
Plant of the  
Future?

- Technology/  
Modality
- Equipment
- Facility
- Resources

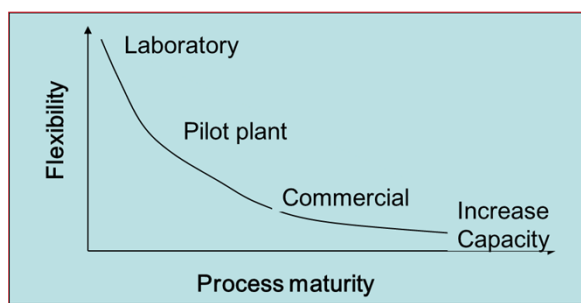


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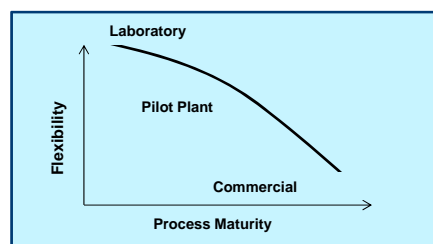
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How does  
Future Pilot  
Plant Agility  
Affect a  
GMP Pilot  
Plant?



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

That is the question...



- *Benefits?*
- *Feasibility?*
- *Considerations?*

- *Technology/  
Modality*
- *Equipment*
- *Facility*
- *Resources*



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