The industry's perfect storm - declining revenue, patent cliffs, low R&D…
  - Lead industry to reduce cost and improve supply chain efficiency

The Past …
- Did we get the balance right?
  - Quality versus cost tradeoffs
  - Supply versus cost tradeoffs
  - Consolidation to reduce costs (essential to industry valuation), but it increased supply risks

Today…
- Pipelines are robust and accelerating
- The supply network - facilities, sites, and suppliers are lean and strained

How Do We Know That We Have a Robust Supply Chain and Understand its Risks?
The Perfect Storm

Increased reliance on CMOs
Increased utilization to lower cost/unit
Reduced Inventories
Reduced investments in internal networks

Higher Incidences of Supply Shortages and Quality Issues

...resulted in pressure to streamline operations and reduce costs

Increased reliance on CMOs
Increased utilization to lower cost/unit
Reduced Inventories
Reduced investments in internal networks

How did the perfect storm impact the supply chain?
Response from Industry (Great Performance by Supply Chain)... Reduce COGM to Preserve Earnings

Industry Trend: Suddenly R&D Hits Growth Spurt
New BLAs Submitted at an Historic Rate
2013 - Good Year for Drug Approvals
Nine of the top ten forecast to reach >1$B sales in US five-years post launch

![FDA Approval Count vs. Total USA Product Sales 5 Years After Launch](chart1.png)

Source: Evaluate Pharma, June 2014

>$1 Trillion Dollars of Worldwide Rx Sales by 2020

Return to growth after 2012 contraction

![Worldwide Total Prescription Drug Sales 2006-20](chart2.png)

Source: Evaluate Pharma, June 2014
Clear Growth Within the Large Molecule/ Biologics Space

% Bio sales within top 100 products expected to increase to 52%

![Graph showing the growth of biologics sales](image)

**Biologics Sales**
- 14% in 2006 to 27% in 2020

Oncology Has Largest and Fastest Growth …11% Growth Annually

Driven by new class of anti-cancer products targeting the PD-1/ PD-L1 pathway

![Graph showing top 10 therapy areas in 2020](image)
Biosimilar Market of $25B by 2020 Will Absorb Significant Capacity Too

Emerging Markets Grow From 30% in 2012 to 40% of Global Rx Sales by 2017
US Market for Predictive Personalized Drugs is Expected to Double from 2013 to 2019

Oncology represents largest % of drugs with predictive CDx device or assay

Yet...
We Are Now At Our Lowest Point of Capacity Agility and Resilience

Pinched!
Limited capacity to support new growth

17 bio facilities being added now…
On-line in time?

Source: 2013 DR/ Decision Resources LLC

Source: Adapted from Gartner Hype Cycle
What is Needed: Tying Together Information Across Diverse Groups to Create Functional Interoperability

- Stochastic Modeling
- Real Options Analysis
- Investment decisions

ENTERPRISE JUDGEMENT
Strategic Implications

- Close Collaboration with R&D
- Focus PI on critical demand drivers
- Launch Capacity meets Greatest Flexibility
- External partnerships for Exceptions
- Process Fit > Lead Time Benefit
- Ruthless Prioritization
- Delay investments through strategic CMO use

To What Level of Demand Would You Build? And By When?

- Risk Adjusted Demand
- Upside demand
- Base demand
- Low demand

Demand in 15K L batches

Start Date
Licensure Date
What Does All This Mean?

- Depends on whether you are in Small Molecule versus Bio!
- Small Molecule
  - Growth focused upon emerging market
  - Pipelines showing promise for some but others still 4 to 5 years away
  - New pipeline may drive some re-investment in API
- Bio/Large Molecule
  - Very strong pipelines nearing fruition
    - 20+ large scale plants under construction
  - Bulk DS capacity very constrained 2016-2021
    - CMO’s sold out
  - DP CMO capacity can be at risk: Quality
- Resources
- Both Small and Bio/Large Molecule
  - Primary Care → Specialty Care
  - High Value / Low Volume
  - Further Small Molecule footprint consolidations in Western markets

Our Vision for ISPE

- Our history, our founding, our growth has always been tied to deliver of value to our Firms and Members in the Manufacturing Space
  - Engineering: Support of new facilities
  - Future technical needs
  - Manufacturing: Especially the development and start-up of new facilities
  - Regulatory Affairs: New facility licenses or license to operate
- It is important to understand that our focus on Regulatory Affairs is not tied to detailed technical content where that content is not directly related to our primary mission
- If our firms do not see value in ISPE membership, current economics will restrict membership
- Equally, if our members do not see personal or career value in membership, time constraints will restrict membership
Our Vision for ISPE

- Collectively across the full spectrum of our industry, we are now facing a growth stage
  - But not in our traditional areas of expectation
- In our traditional products space Emerging Markets (China, Southern Hemisphere) are large growth segment
  - Some companies looking at double digit growth in China
  - Southern Hemisphere
  - Japan
- Pipelines in both small and large molecules maturing for many firms
  - With a vengeance!
  - Fast track, Break-through Therapies are driving huge accelerations in timeline

Questions??