

07

BAYBIO

# BAYBIO2007

Innovators and Innovations

## Commercial Development



### Track Sponsors:



ALEXANDRIA®

**DATA SAFE**

RECORDS STORAGE AND INFORMATION MANAGEMENT



*Aiming Higher*

LASH GROUP  
HEALTHCARE CONSULTANTS



*Redevelopment Agency*

07

BAYBIO

**BAYBIO**2007

Innovators and Innovations

**Gearing up for Manufacturing**



# Biotechnology Manufacturing: *Strategic Considerations in 2007*

## **Overview**

Glenn Snyder

Lifesciences Principal, Deloitte Consulting LLP

April 2007

# Gearing up for Manufacturing



The shifting landscape of biotech operations – the only certainty is uncertainty

### Operational Issues

Company and product proliferation

Pricing and cost pressures leading to reduced margins

Operational strategies and capacity management

Inefficient and risky processes

Proliferation of data - lack of information

Scarcity of operational expertise

### Implications

- Rising number of biotechnology products in late stage trials
- Increased competition among companies
- Need to reduce high development costs - \$500m - \$1b per product
- Shift from production of blockbusters to smaller volume products
- Address threat of biogenerics
- Clearing increased regulatory hurdles
- Response to global manufacturing cost pressures and opportunities
- Demand for new business models/virtual global companies
- Shift from big batch vs. small batch
- Requirements for new plants
- Fragmentation of CMOs: a few big (5), many small (50)
- Adoption of new production technologies
- Proprietary expression systems
- Innovative statistical techniques to drive down lot deviation
- Establishing a GxP mindset in development and operations
- Increasing challenges to meet regulatory requirements
- Increased need for business intelligence
- Still coming up the learning curve
- Increased need for, alliances, out-sourcing, & global operations

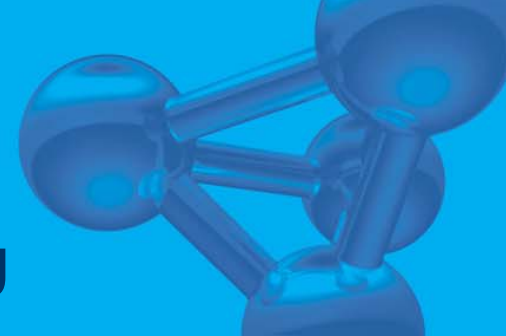
07

BAYBIO

# BAYBIO2007

Innovators and Innovations

## Gearing up for Manufacturing



**Operational missteps adversely affect value (i.e., 10% average share price reduction)**

Company	Operational Misstep	Event Date	% Change in Share Price*	\$ Change in Market Cap (\$Bn)
Schering-Plough	Failure to meet government manufacturing standards	3/29/2000	-8%	\$4.5
Johnson & Johnson	Manufacturing problem causing pure red cell aplasia	11/29/2001	-3%	\$5.3
Biogen Idec	Manufacturing problems w/pre-filled syringe of MS drug	5/6/2004	-4%	\$0.7
Chiron	Manufacturing problem with vaccine; failed to meet regulations	10/26/2004	-19%	NA
Decode Genetics	Manufacturing problem with most advanced drug candidate	10/6/2006	-10%	\$0.3

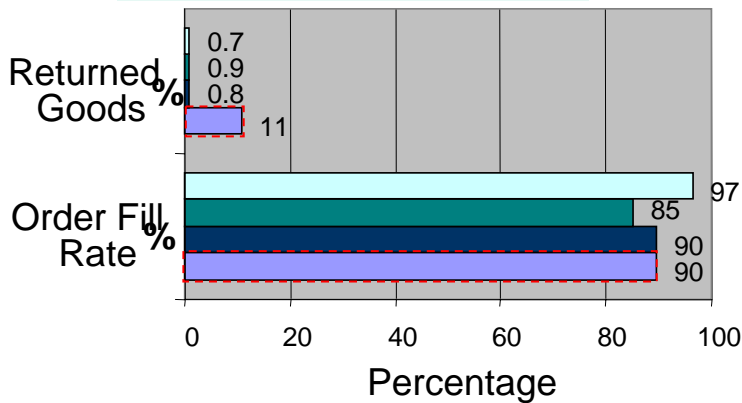
Source: Yahoo Finance/Factiva

## Gearing up for Manufacturing

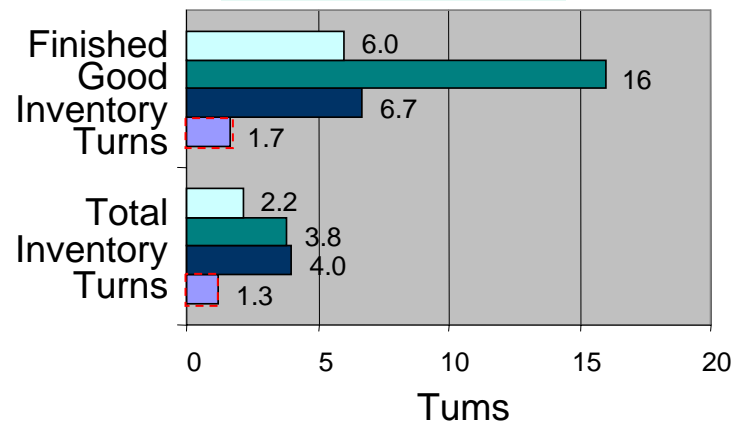


### Biotech operations under-perform relative to other life science operations

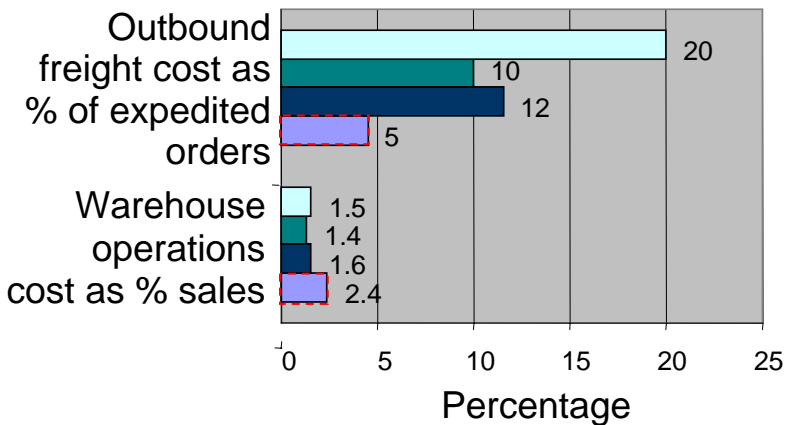
Customer Service Benchmarks



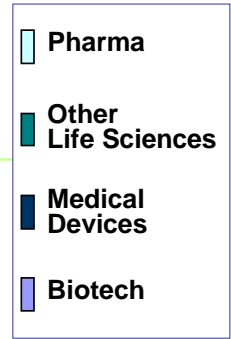
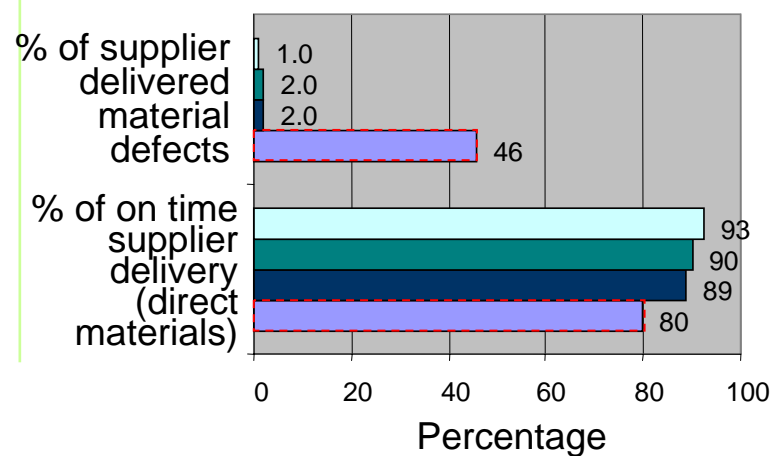
Inventory Benchmarks



Distribution Benchmarks



Sourcing Benchmarks

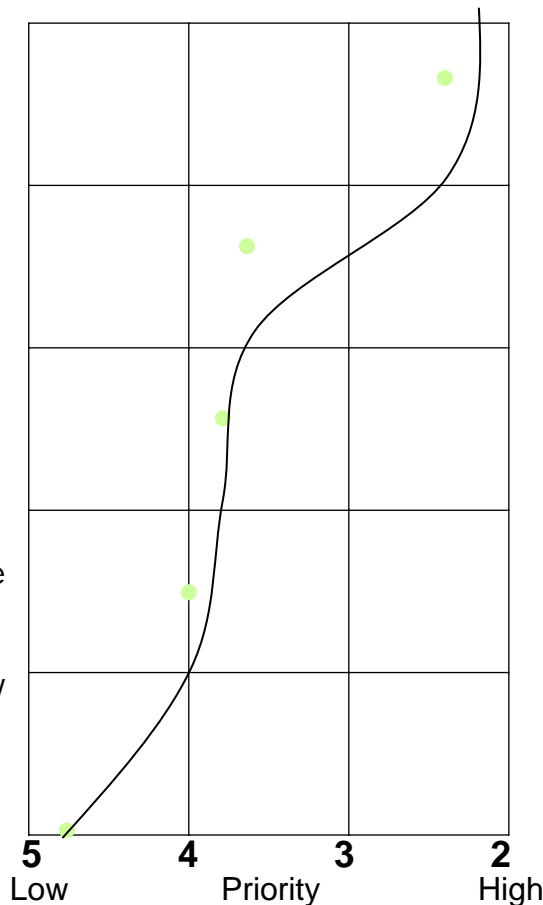


### Gearing up for Manufacturing



Biotechnology industry executives understand there is no shortcut to improving operations; several strategies stand out

- Best practice biotechnology development skills
- High yield manufacturing process practices and technologies
- Outsourcing development and/or manufacturing to US/Eastern Europe
- Reducing regulatory requirements for orphan drugs/personalized medicine
- Outsourcing development and/or manufacturing to low cost countries (China/India)
- Manufacturing innovation



07

BAYBIO

# BAYBIO2007

Innovators and Innovations

## Gearing up for Manufacturing



### Today's Panel

- **Robert Baffi, SVP Technical Operations, BioMarin**
- **Gustavo Mahler, Bayer HealthCare, Vice President of Technical Operations, Pharmaceuticals**
- **Tom McClung, Director of Materials Management, Nektar**
- **Glenn Snyder, Principal, Deloitte Consulting LLP (moderator)**

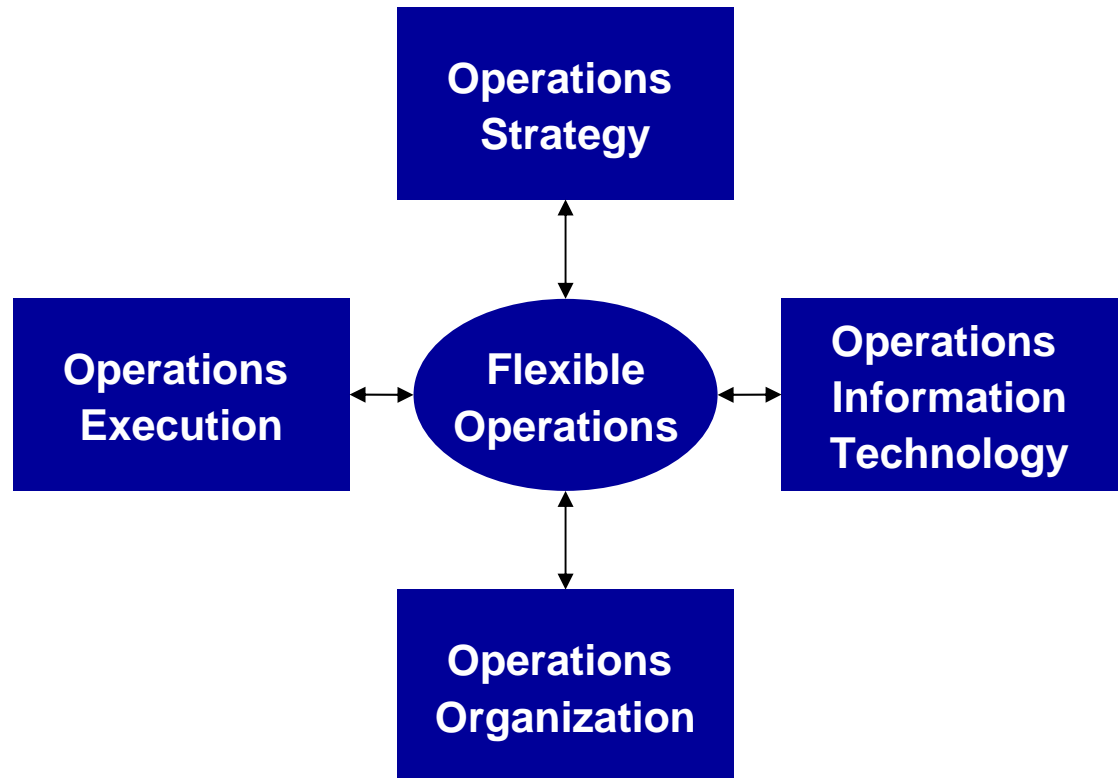


Operational flexibility is required to meet the challenges of the future

### Key Capabilities

- Flexible network with responsive capacity
- Rapid, lean and controllable processes
- Interoperable systems providing information (not just data)
- Operations capabilities and teams that deliver competitive advantage

### Biotechnology Flexible Operations Framework



07

BAYBIO

# BAYBIO2007

Innovators and Innovations

## Commercial Development



### Track Sponsors:



ALEXANDRIA®

**DATA SAFE**

RECORDS STORAGE AND INFORMATION MANAGEMENT



*Aiming Higher*

**LASH GROUP**  
HEALTHCARE CONSULTANTS



CITY OF  
**SAN JOSE**  
CAPITAL OF SILICON VALLEY

*Redevelopment Agency*