



Changing Biopharmaceutical Manufacturing Environment: Trends and Opportunities

Eric S. Langer,
President & Managing Partner
BioPlan Associates, Inc

BioNJ
Manufacturing
Summit
March 10, 2011



Changing BioManufacturing Environment

China #1 Outsourcing Destination in 2011

\$ Global Biomanufacturing
Budgets Up Across the
Board

**Single Use
Devices entering
GMP Production**

Biosimilars are
coming--to cost
25% less than
reference
product

**340 approved
biologics
60 applications
pending!!**

Outsourcing
Declining

SELECTIVE
HIRING
RETURNS

**mAb
revenues
\$40 billion,
up >10%**

Budgets for New Downstream Technologies up 6.4%



2011 8th Annual Report

- 352 Biopharmaceutical developers, CMOs
- 180 Industry Vendors
- 31 Countries
- Web-based methodology
- Comparisons:
 - US/Europe/ROW
 - Biomfgs/CMOs
- Confidential

8th Annual Survey Partners

BIO

Organization Partners:



Smart Business Decisions
since 1989



Knowledge Transfer Network



The European Association for Bioindustries



Massachusetts Biotechnology Council



Strategic Manufacturing Worldwide, Inc.



**BioMelbourne
Network**
Progressing BioIndustry



All India Biotech
Association



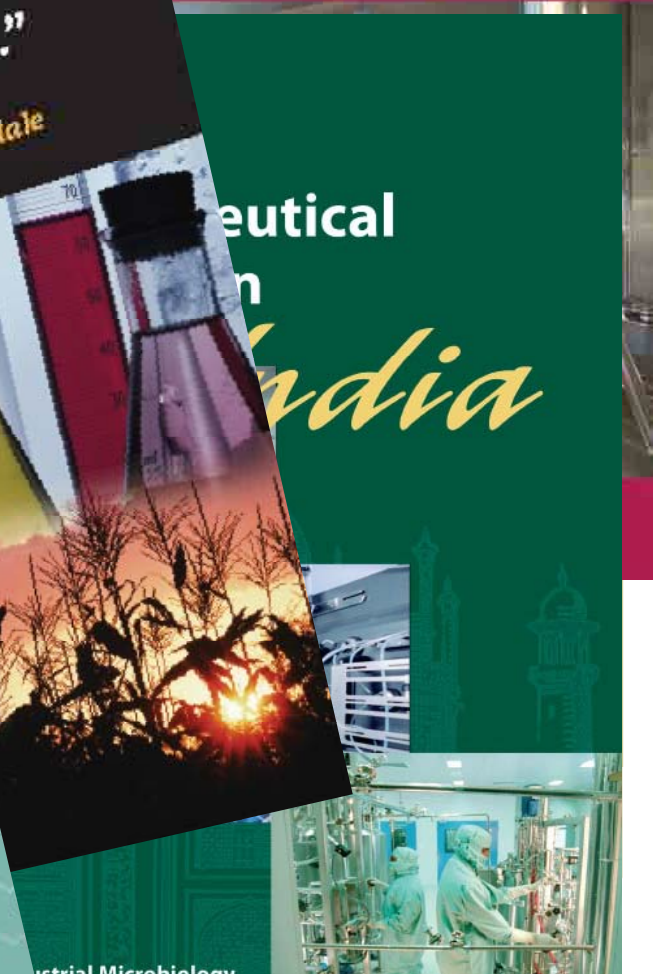
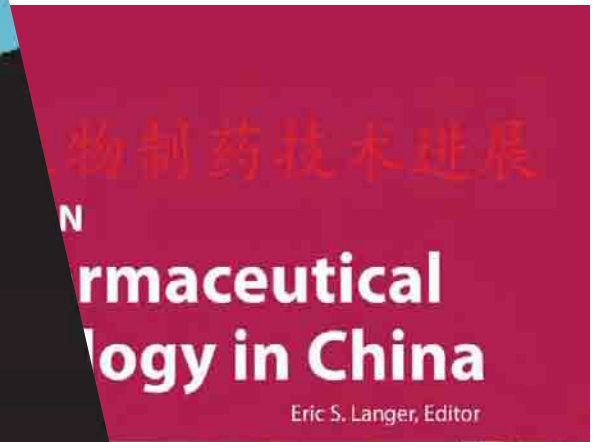
Bio-Process Systems Alliance
Advancing Single-Use Worldwide

Media Partners:



CanBiotech
Biotech Portal
& B2B Marketplace







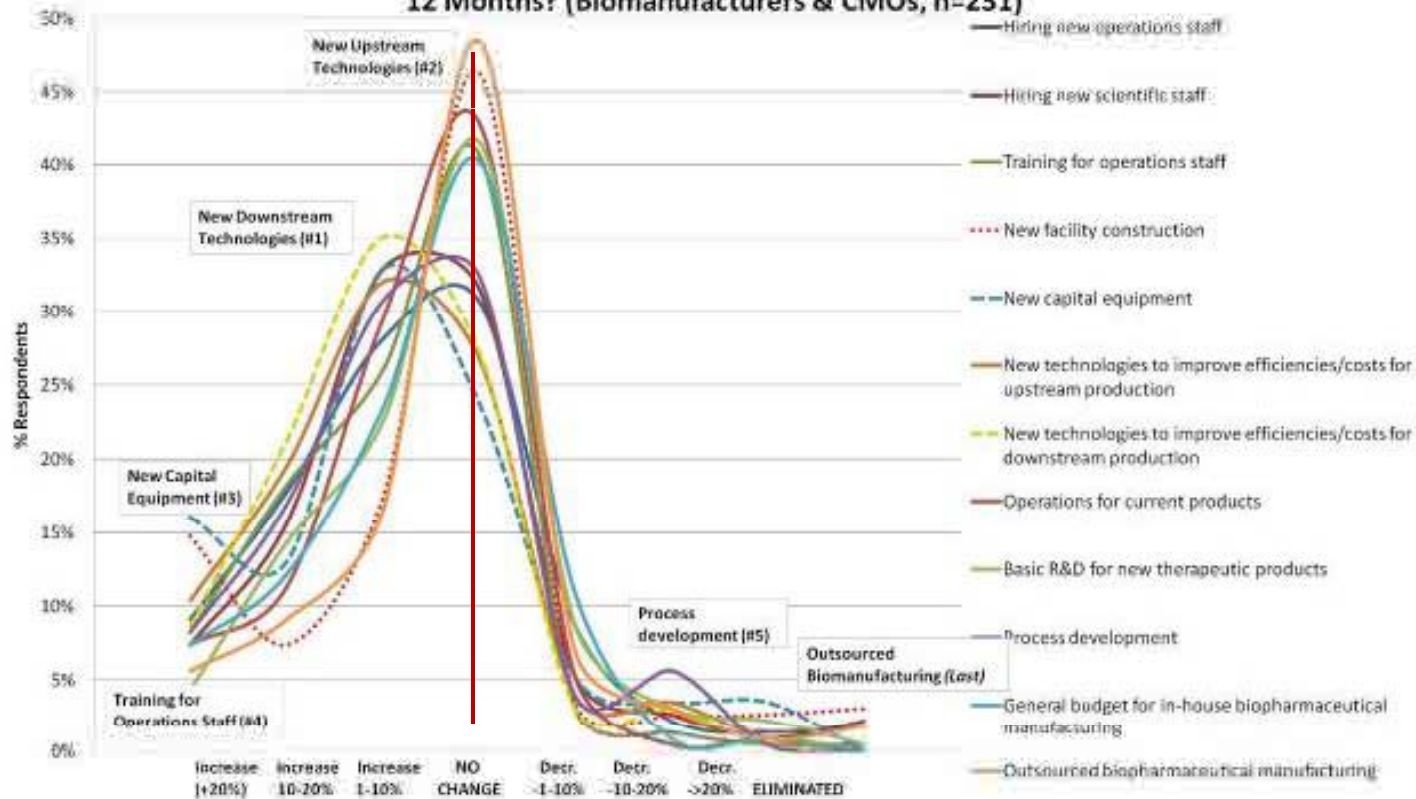
Bio/Pharmaceutical Manufacturing Trends

- **Budget Trends**
- **Operational Changes**
- **New Product Development Trends**
- **Process Improvements**
- **Capacity Constraints, 2011 and 2015**
- **Outsourcing Trends**
- **Hiring Problems**
- **Vendor Budgets, Pricing, New Product Trends**



Biomanufacturers' Budget Shifts for 2011

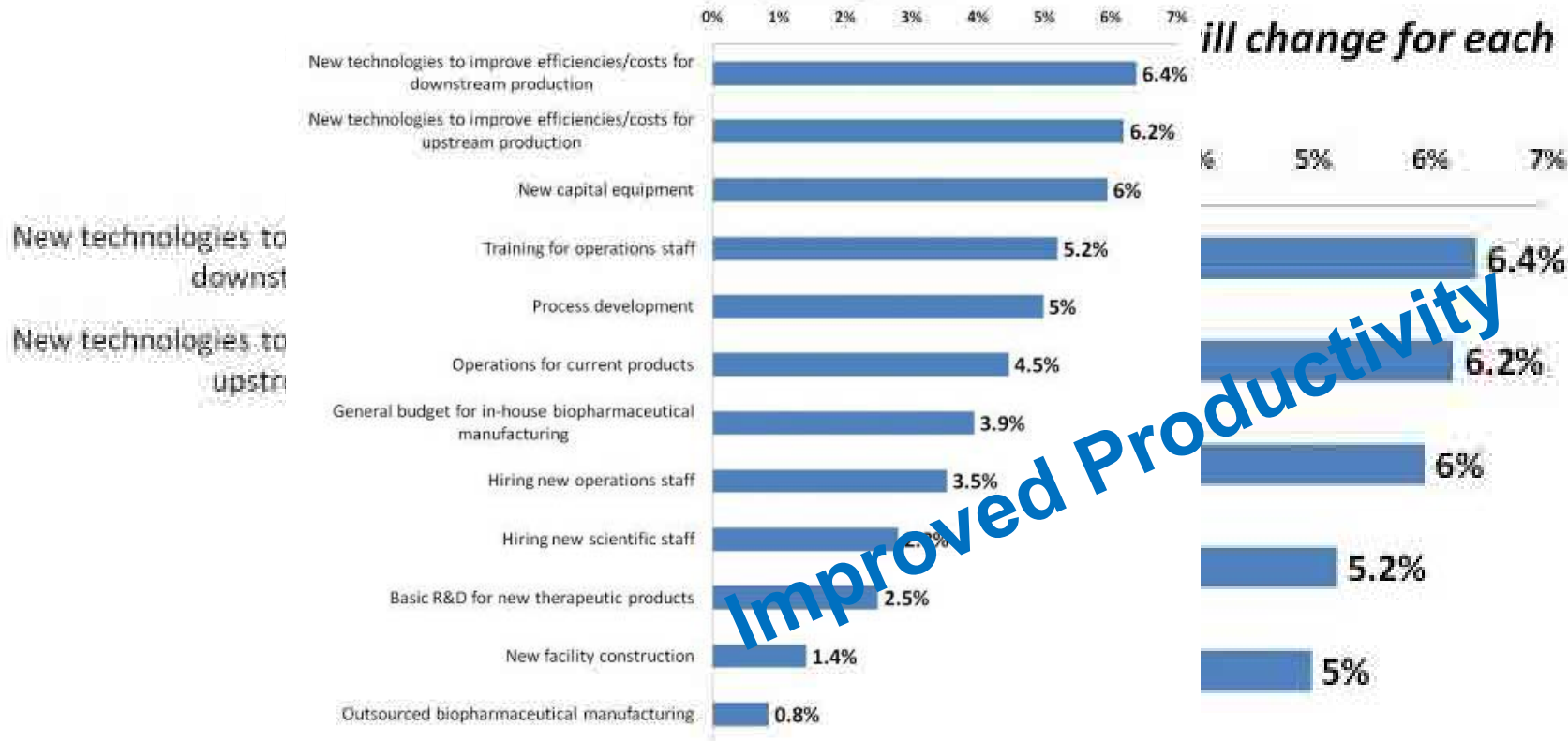
Current Economic Situation: By what % will your BUDGET / FUNDING change over next 12 Months? (Biomanufacturers & CMOs, n=231)





Change in Biomanufacturers' Budgets for 2011

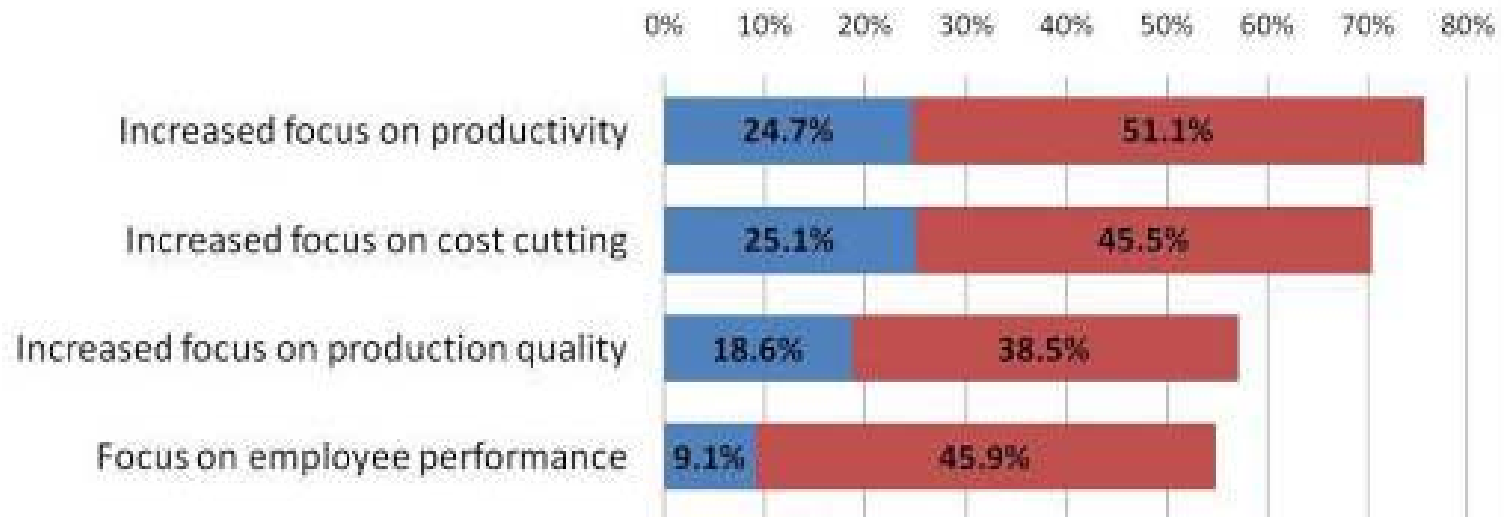
By what percent do you believe your budget will change for each of the following in 2011





Operational Changes; Global Economics

**Top Operational Changes for 2011:
% Biomanufacturers & CMOs
"Much Greater" or "Somewhat Greater"**

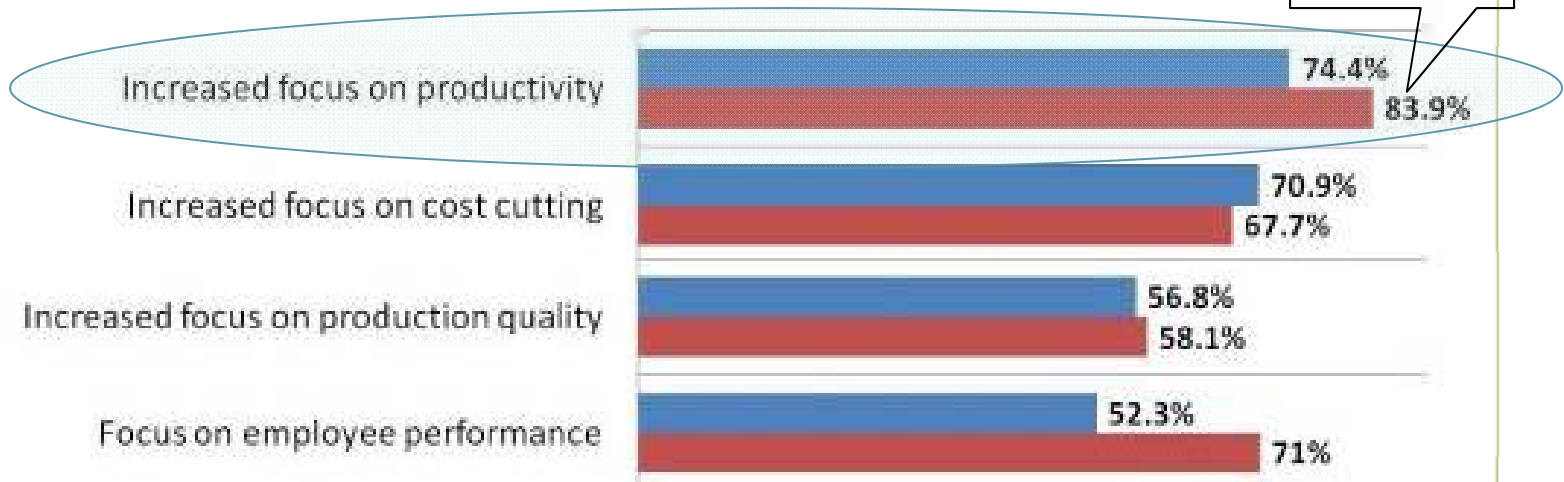




Operational Changes; Biodevelopers vs CMO's

Top Operational Changes for 2011:
"Much Greater" or "Somewhat Greater:
"Biotherapeutic Developers vs CMOs"

CMOs





Top New Product Development Needs

New Product Development

Areas of Interest *Biomanufacturers and CMOs, 2011*

(Consider new products and services suppliers develop. What TOP areas do you want your suppliers to focus their development efforts on?)



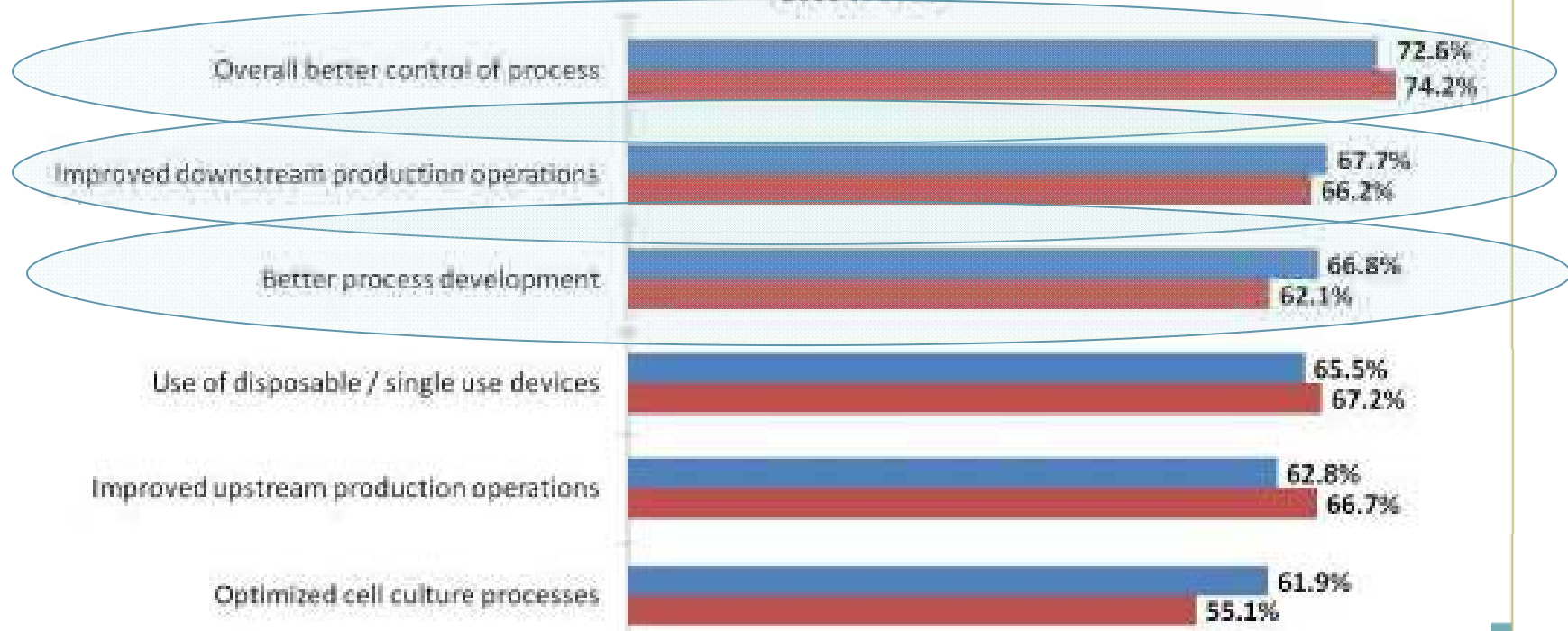


Factors in Biomanufacturing Creating Improvements

Improving Biomanufacturing Performance

Factors Creating "Significant" or "Some" Improvements

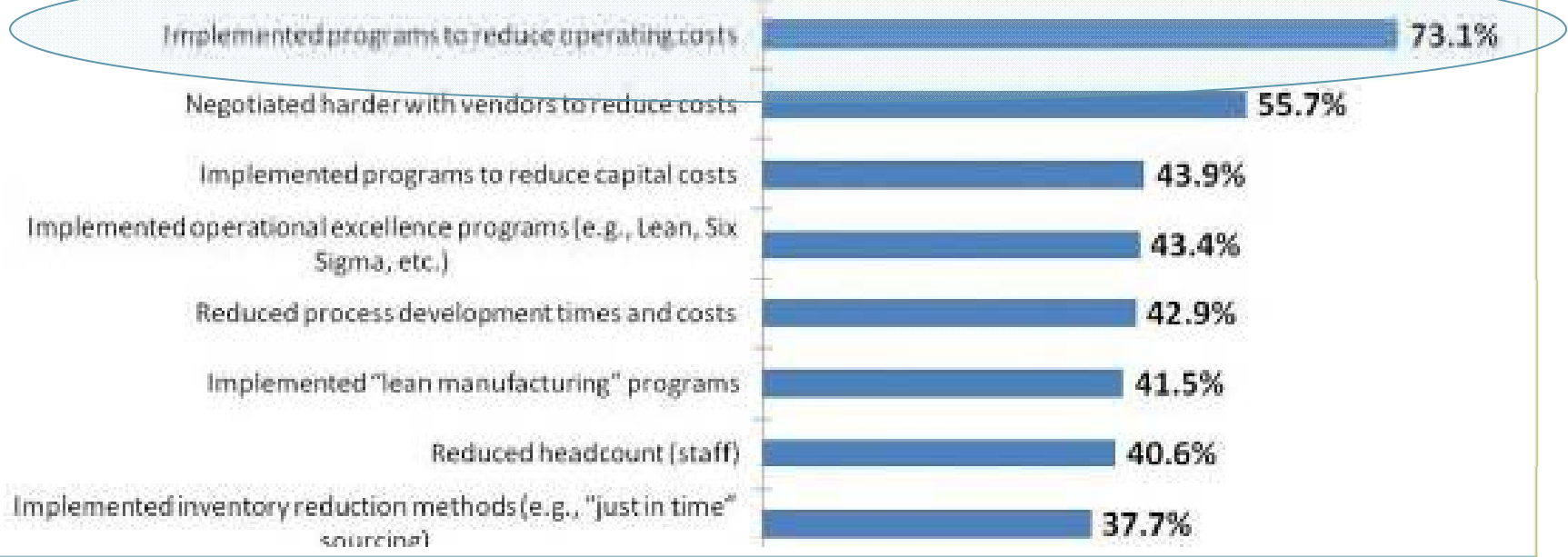
How much have each improved biomanufacturing performance over the past 12 months?
2011 vs 2010





Cost-Cutting Changes During Past 12 Months

"During the past 12 months, which actions has your organization undertaken to reduce overall costs at your facility" (n=212)



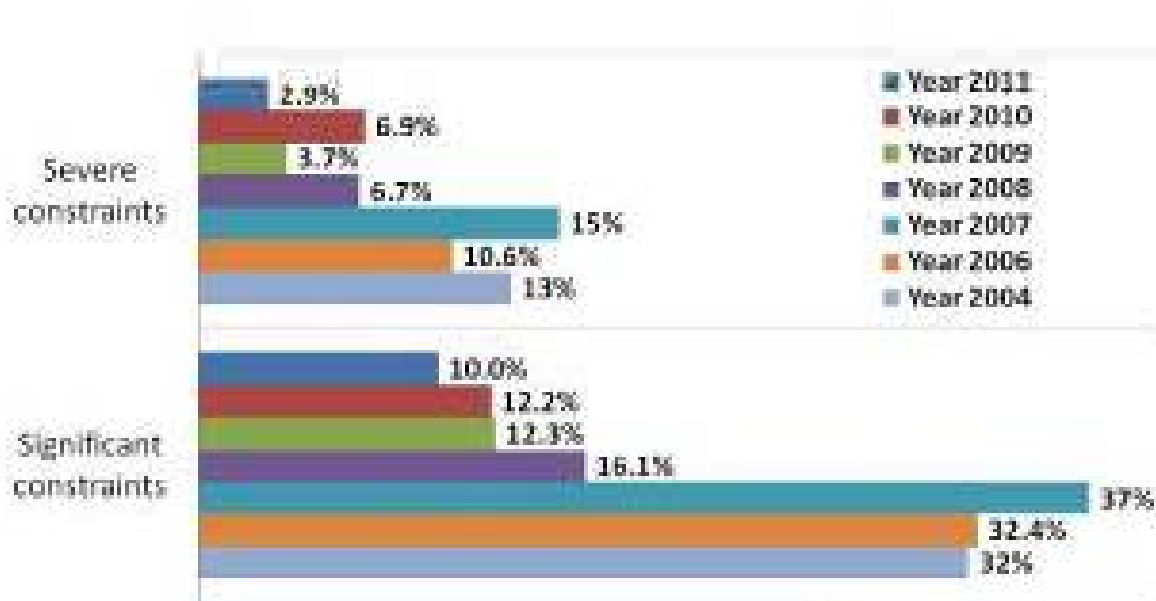


Expectations of Capacity Constraints: 5 years

Expected Capacity Constraints

I believe our facility will experience production capacity constraints in 5 years;

Responses from 2004-2011

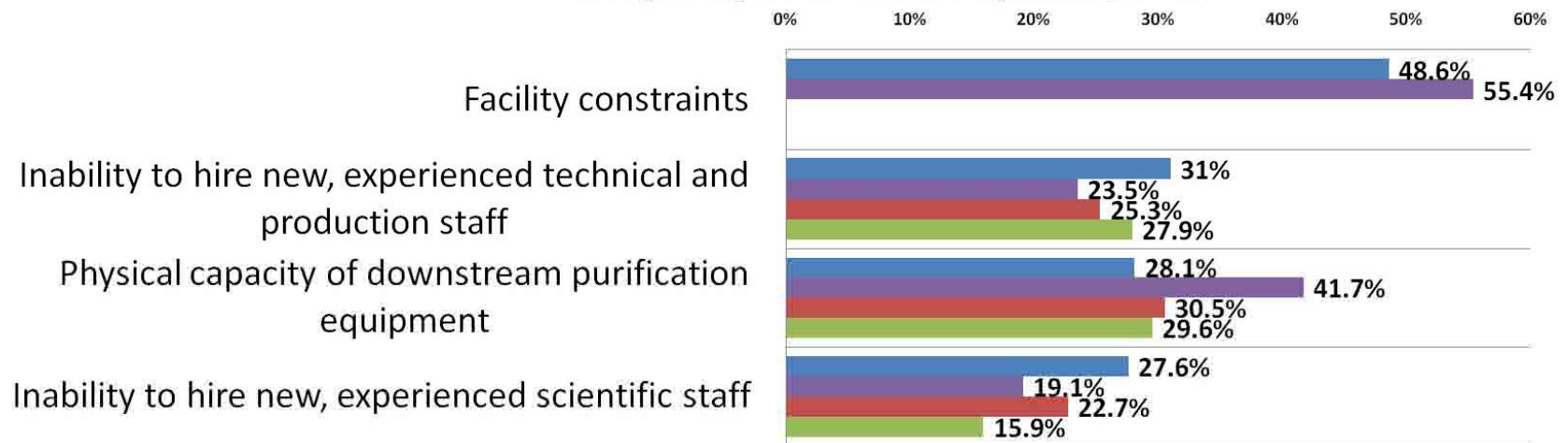




Factors Creating Capacity Constraints, 2008-11

Factors likely to create biopharmaceutical production capacity constraints in 5 years?

Comparing 2008 - 2011 responses, (n =210)

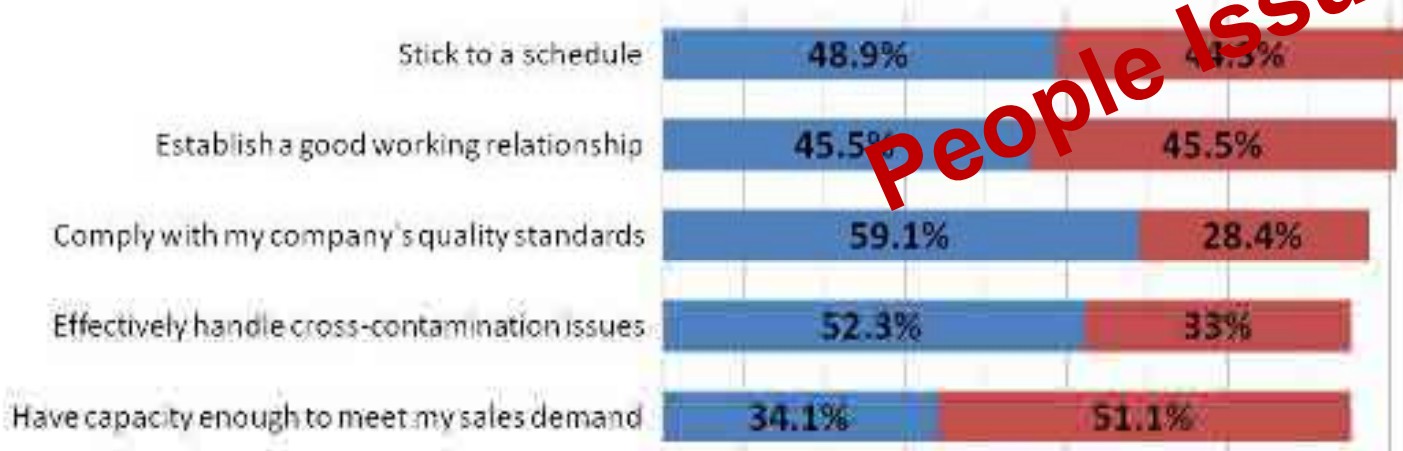




Outsourcing Issues: When Considering a CMO...

Critical Issues when Considering Outsourcing Biopharmaceutical Manufacturing to a Contract Manufacturing Organization (CMO), 2011

% Responding "Very Important" & "Important"



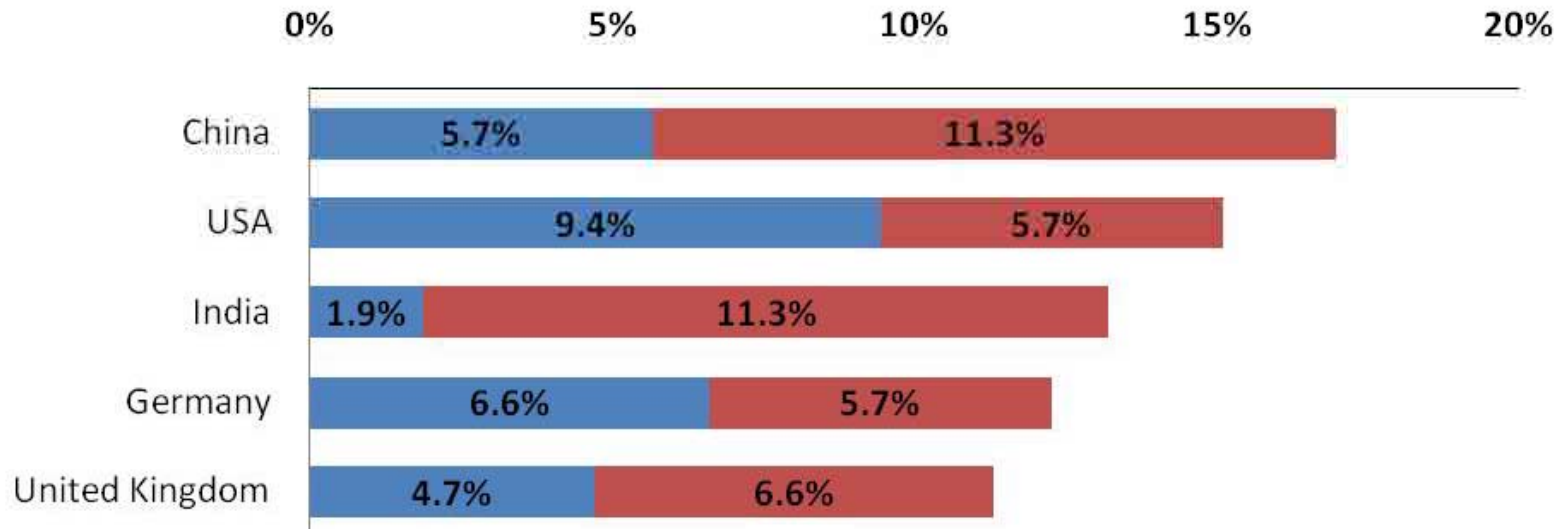


Country: Outsourcing of BioManufacturing

Destination for International Outsourcing

"Consider your facility's current plans for INTERNATIONAL capacity expansion over the next 5 years (2015)." All Respondents

"Where have you been considering production outsourcing outside your own country"

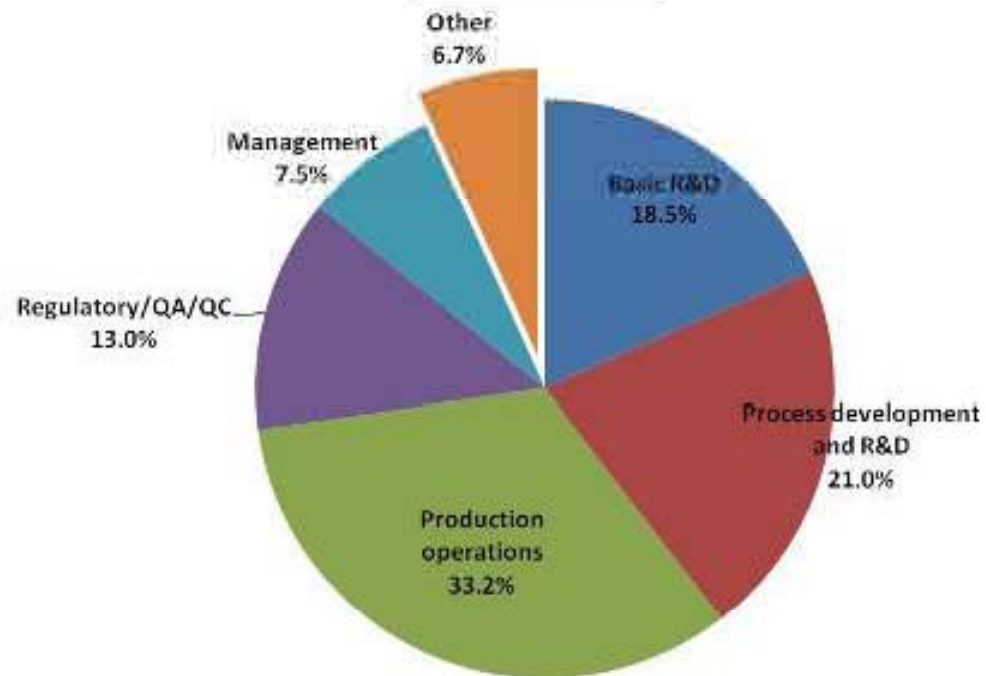




New Hires in BioManufacturing (2011)

Where Will the New Staff be Hired in Biopharmaceutical Production Facilities?

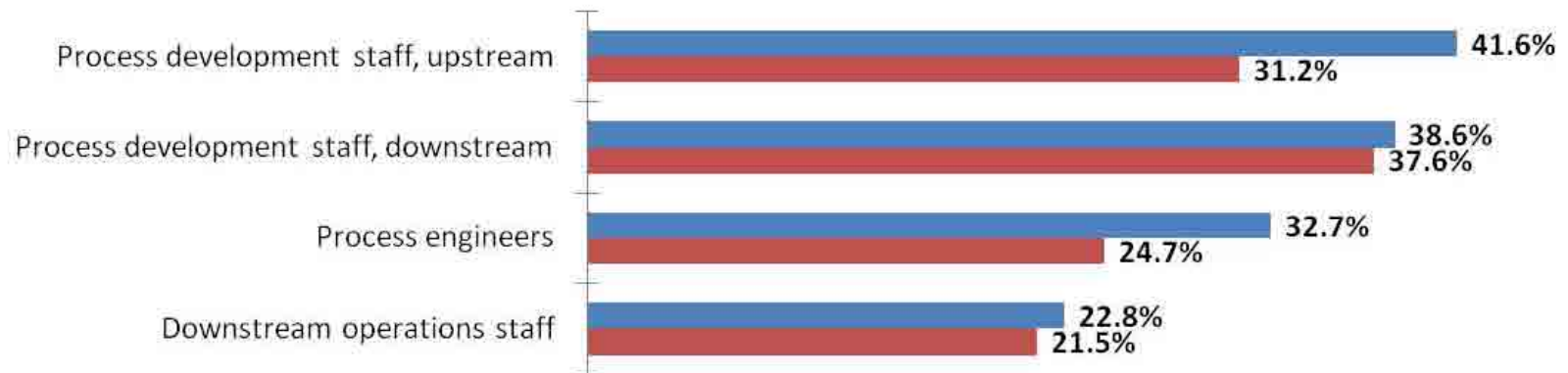
% Hires in 2011





Hiring Difficulties in Operations; 2010 vs 2011

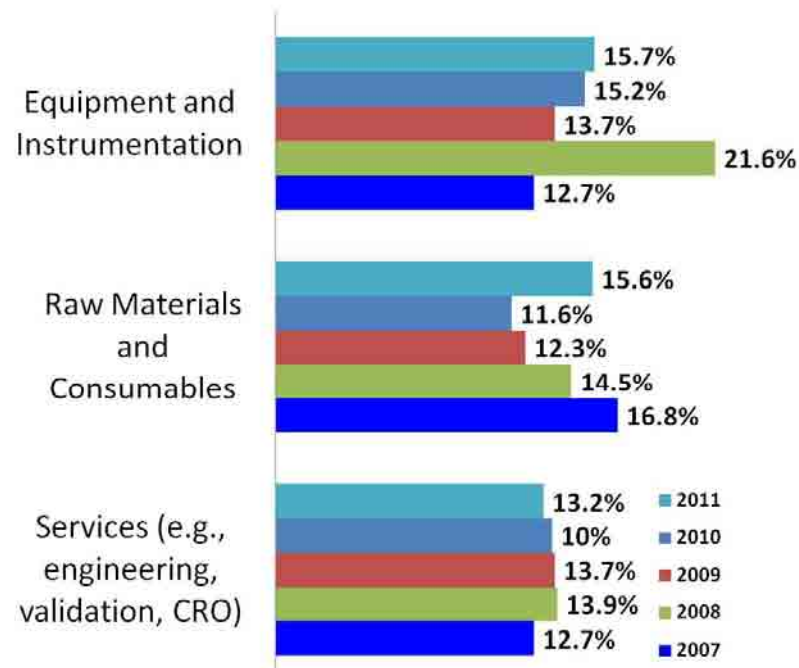
**Hiring Difficulties: "Which job positions at your facility are you currently finding it difficult to fill?"
(2011 vs 2010)**





Vendor Segment Sales Growth Rates, 2007–2011

**Supplier Segment to Manufacturers of
Biopharmaceuticals:**
Average Annual Segment Growth Rate,
2007 - 2011

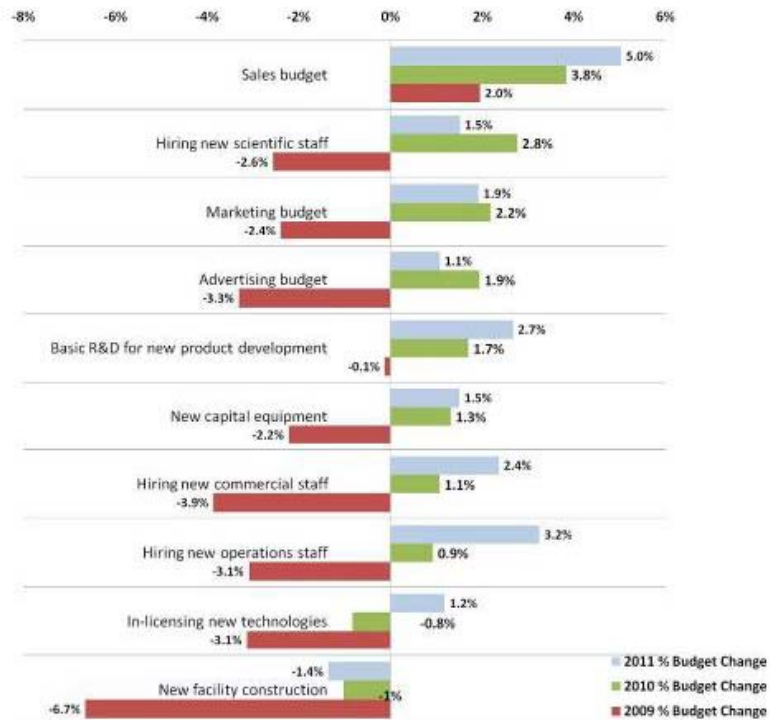




Vendors' Budget Change 2009 - 2011

Vendors' Approx Average Change in Budget 2009 - 2011

By what percent do you believe your BUDGET and FUNDING will change for each of the following over the next 12 months?





Top 14 Areas of R&D and NPD for Biopharma

R&D and New Product Development Area	% Vendors Engaged
Disposable /single-use bioreactor bags/consumables	40.5%
Bioprocess development/optimization svcs/modeling	40.5%
Chromatography, disposables	34.2%
Disposable /single-use bags/films	33.5%
Disposable /single-use filtration	30.4%
Animal-free media components	27.2%
Cell line optimization	25.9%
Disposable /single-use monitoring systems	24.1%
Chromatography, alternatives to Protein A	23.4%
Bioreactor control	22.2%
Culture media optimization services	20.9%
Expression systems and platforms	19.6%
Sensors and probes	19.6%
Culture media supplements	19.0%



About BioPlan Associates, Inc.

- Custom market analysis in biopharma and life sciences since 1989
- Publications, annual reports, peer-reviewed studies
- Commercialization programs

BioPlan Associates, Inc.

2275 Research Blvd, Suite 500

Rockville, MD 20850

www.bioplanassociates.com

301-921-5979