

# CMOs and CROs as Business Solutions Providers: A New Strategy for Contract Services Providers

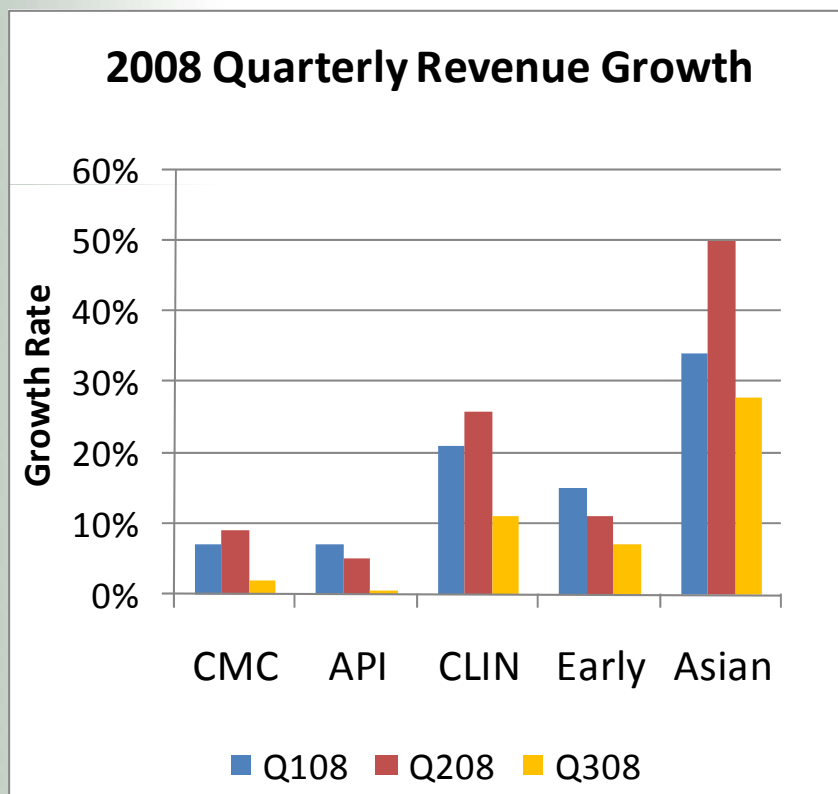
Jim Miller

*Pharmaceutical Technology* Breakfast at AAPS

November 2008

Market conditions

## Top line growth down sharply in Q3 2008



Asian companies mostly APIs, intermediates and dose manufacturing

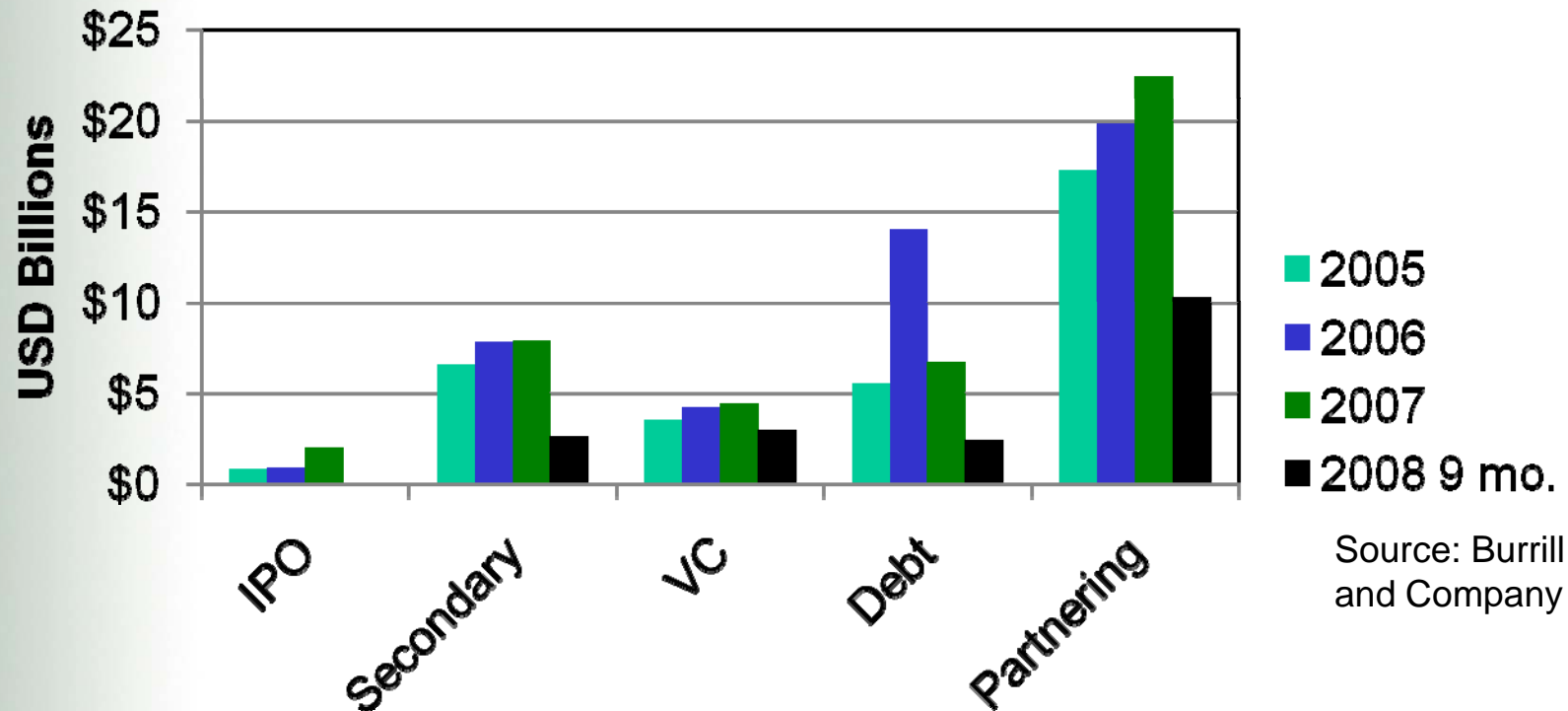
### CROs and CMOs report major demand drops

- Toxicology, clinical pharmacology, process development
- Includes Charles River, Lonza, SAFC, Cambrex
- Late development seems to be holding up

Market indicators

# Bio/pharma funding down sharply

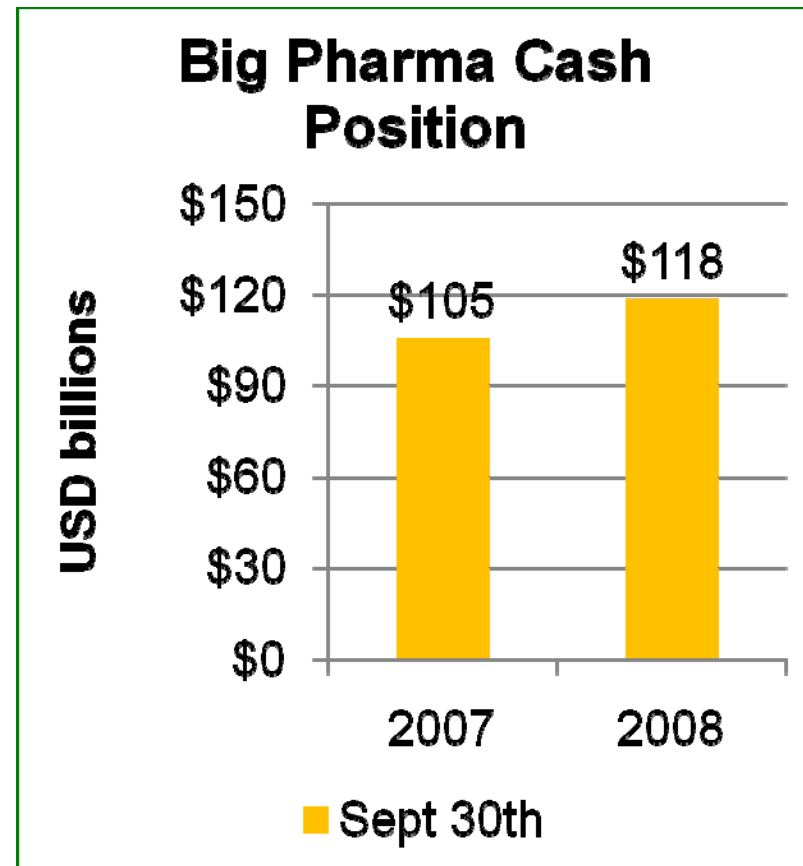
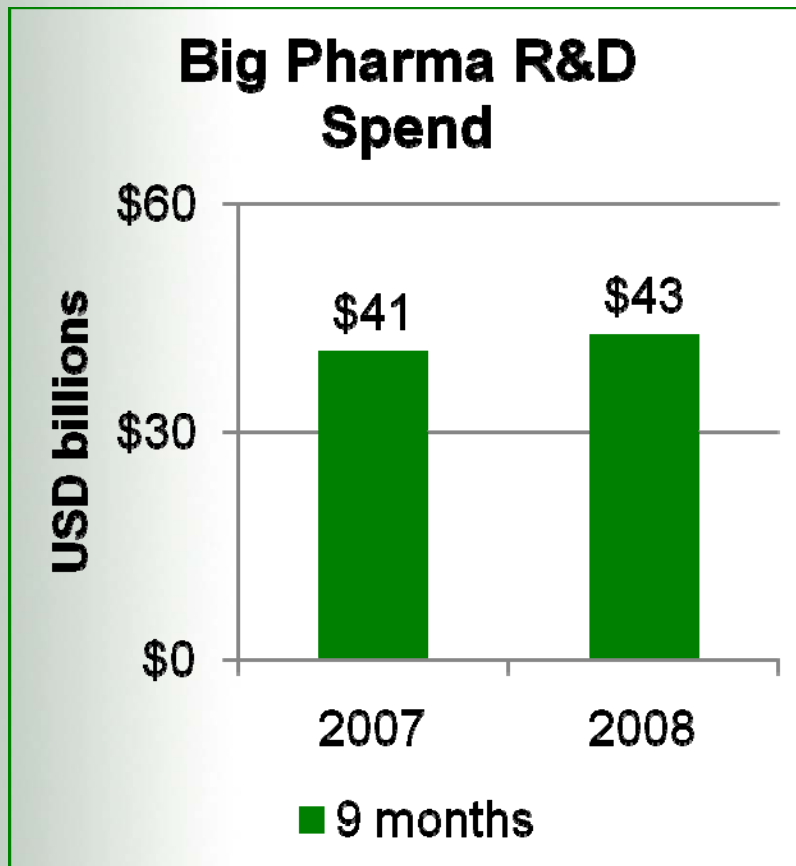
## Funding to US Bio/Pharma Companies



Source: Burrill and Company

Market indicators

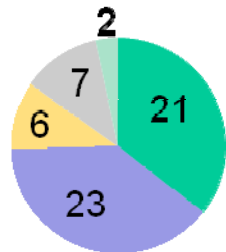
# Big Pharma holding up



Market indicators

# FDA approvals on track with past years

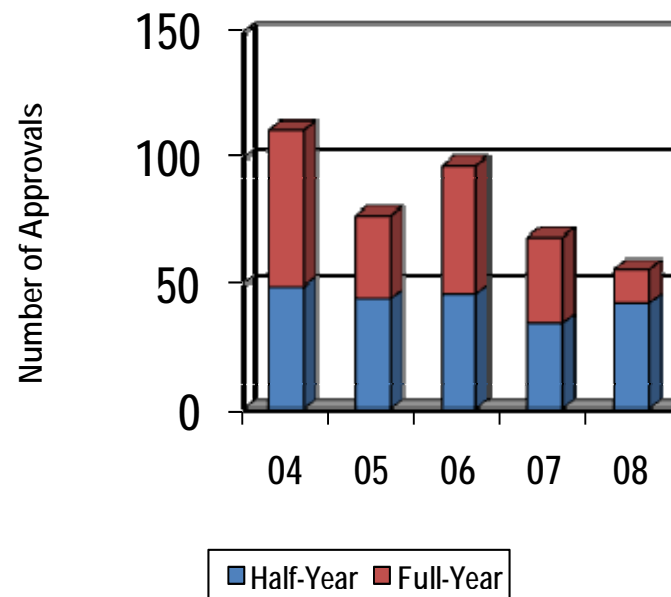
## 2008 NDA Approvals



■ Parenterals ■ Solid Dose ■ Topical  
■ Liquid, oral ■ Inhalation

- 57 Total
- 14 NMEs
- 33 global pharma
- 23 small/mid pharma

## NDA Approvals



Data through September 2008

[www.pharmsource.com](http://www.pharmsource.com)

Market conditions

## How long will downturn last?

- Big Pharma could be window dressing 2008 results
  - Delayed projects should move in 2009
  - Phase II/III studies contracted, cancellations not high
  - But portfolio restructuring is permanent
  
- VC downturn could be a year or more
  - Focus on ensuring funding for portfolio companies
  - Europe worse than US

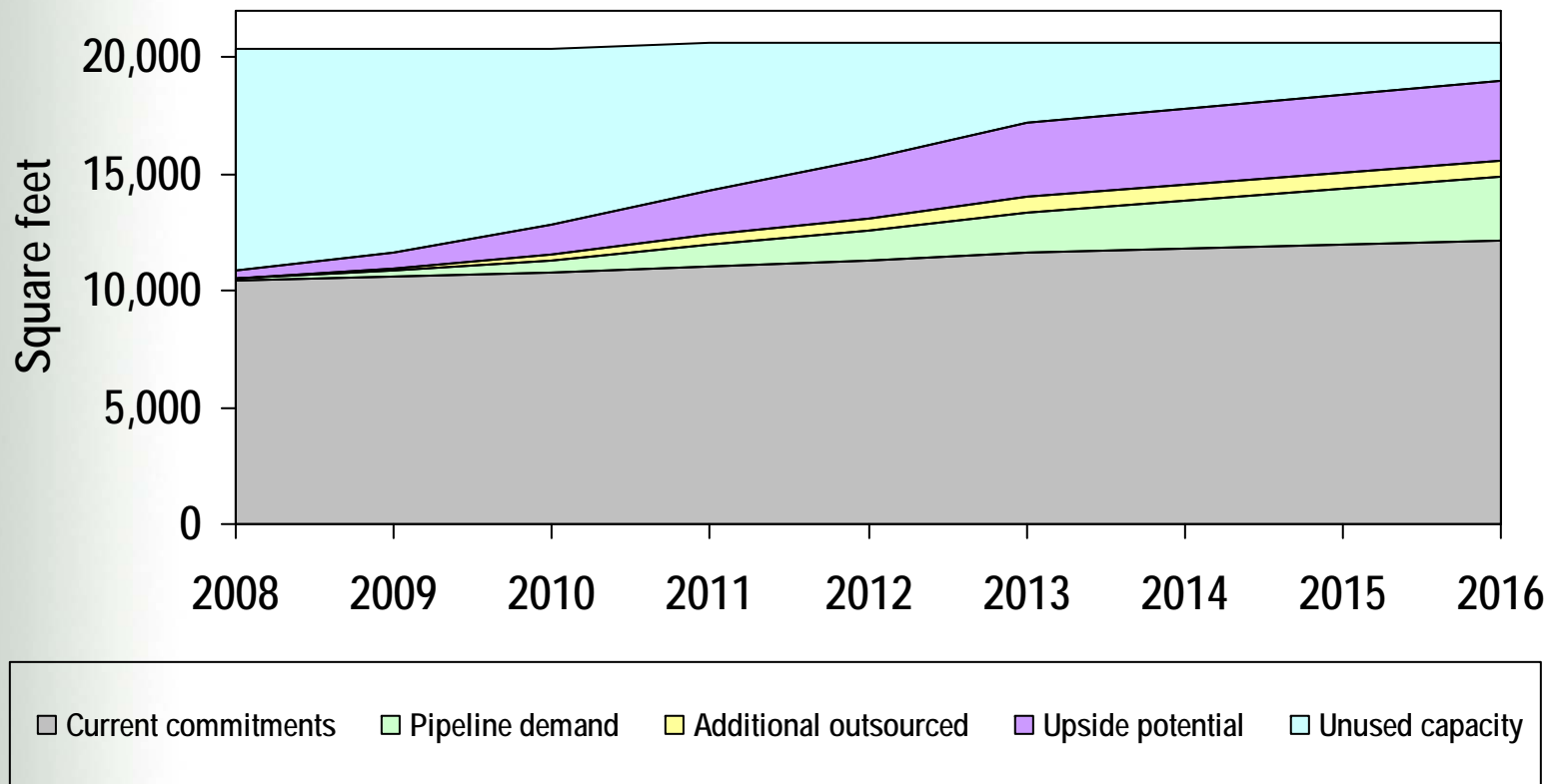
# CMOs and CROs as solutions providers

- GMP capacity is a commodity
  - Although some CMOs still get in regulatory trouble
- Pharma is in survival mode
  - Looking for broader solutions than just capacity
- Providers must move beyond capacity
  - Recast offerings as a solution to broader business problems
  - New capabilities + positioning

CMOs and CROs as solutions providers

# GMP manufacturing capacity is a commodity

GMP Lyophilization Demand / Supply 2008-2016



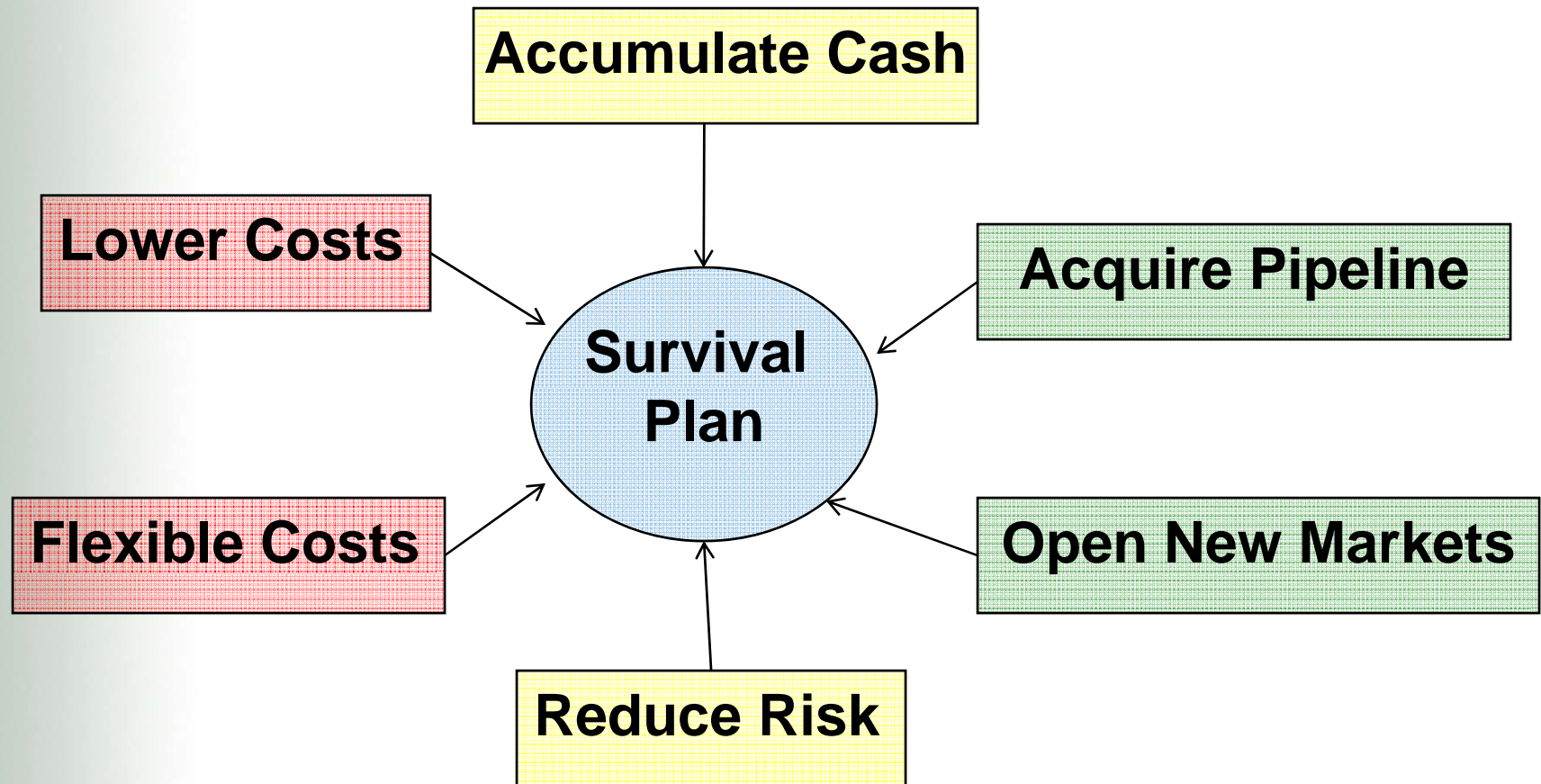
Source: PharmSource model

[www.pharmsource.com](http://www.pharmsource.com)

**PHARM**SOURCE™

CMOs and CROs as solutions providers

# Pharma is in Survival Mode



CMOs and CROs as solutions providers

## Pharma adopting alternative strategies

### Examples

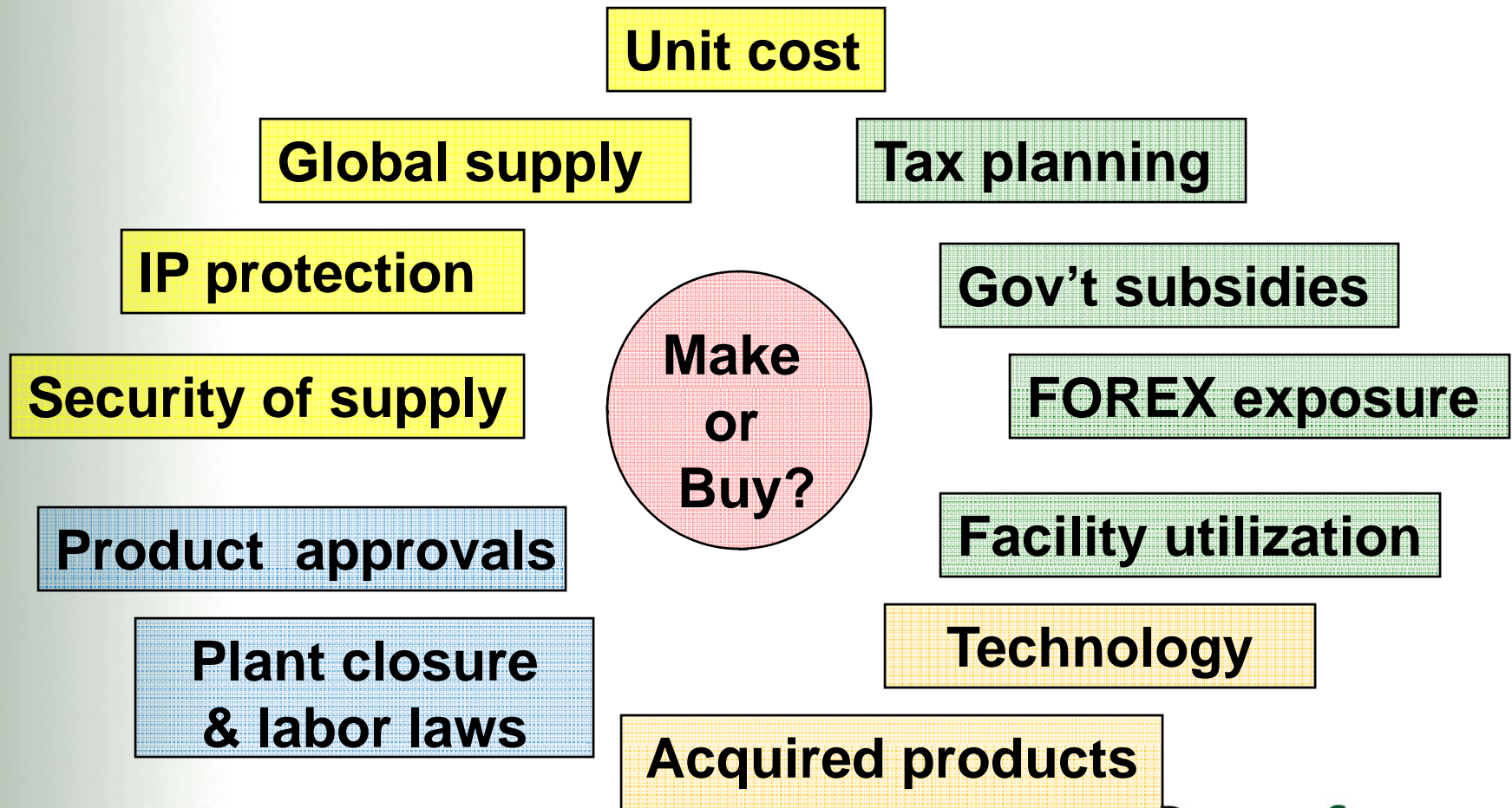
- Proof-of-concept
- M&A and in-licensing
- Discovery partnerships
- Venture capital
- Generics
- Offshoring
- Functional outsourcing
  - Central labs, data management, monitoring
  - Space reservation at preclinical facilities

### Lilly-Covance deal

- Covance buys Lilly research facility for \$50 million
- Covance gets:
  - \$1.6 billion 10-year services contract
  - New technologies
  - Experienced staff
- Lilly gets:
  - \$50 million cash
  - Lower fixed costs
  - Best-in-class performance

CMOs and CROs as solutions providers

# Manufacturing decision is very complex



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## Globalization complicates manufacturing decisions

Global Products									
North Am Regional Products		Europe Regional Products		South Am Regional Products		Asia Regional Products		Africa Regional Products	
Country Products	Country Products	Country Products	Country Products	Country Products	Country Products	Country Products	Country Products	Country Products	Country Products

### How to balance cost and compliance?

<ul style="list-style-type: none"><li>• Large batch economies</li><li>• Labor rates</li><li>• Exchange rates</li></ul>	<ul style="list-style-type: none"><li>• Shipping costs</li><li>• FDA/EU versus local GMPs</li></ul>
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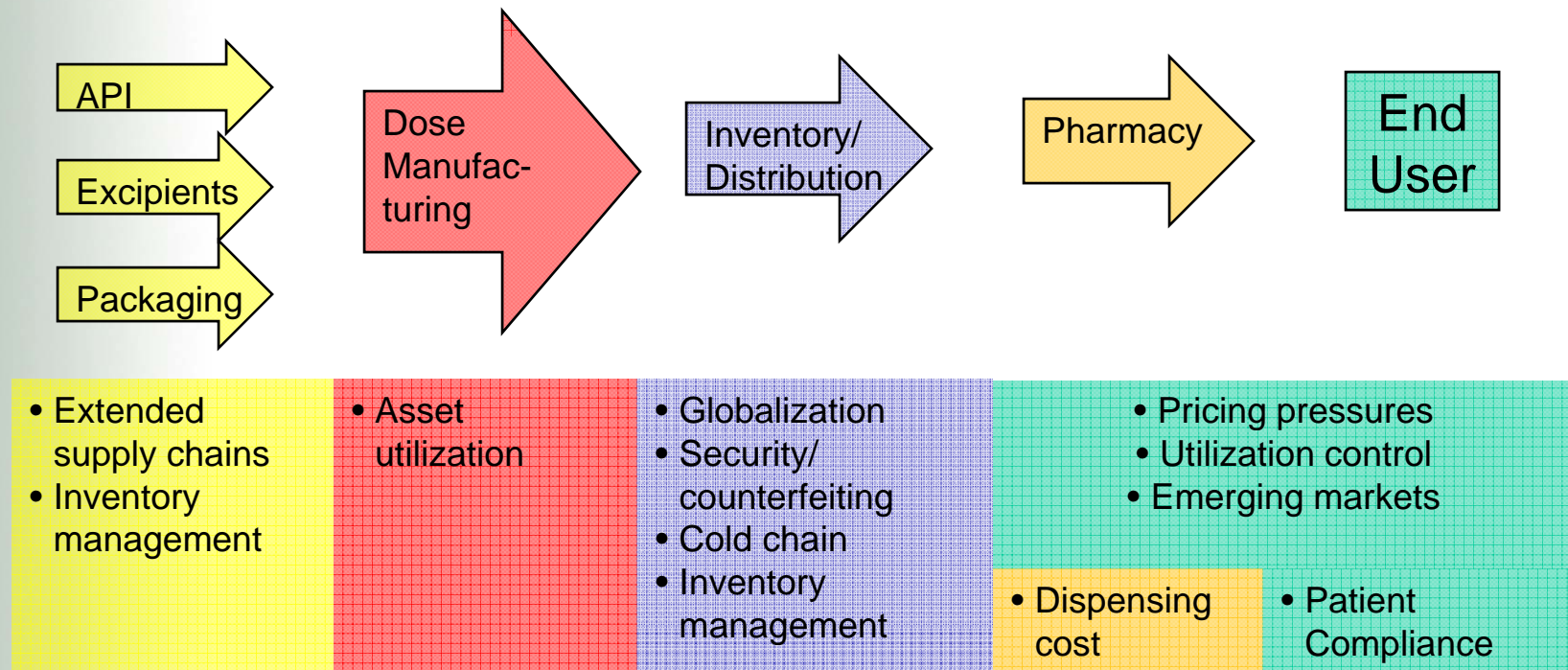
CMOs and CROs as solutions providers

## CMO's greatest value may be reducing risk

	Launch	Maturity	Decline
<b>Innovator Risk</b>	Very high	Very low	Moderate
<b>Innovator objective</b>	<ul style="list-style-type: none"> <li>Regulatory approval</li> <li>Market acceptance</li> <li>Reduce sunk costs</li> </ul>	<ul style="list-style-type: none"> <li>Build and defend market share</li> <li>Reduce CGS</li> </ul>	<ul style="list-style-type: none"> <li>Harvest profits</li> <li>Very low CGS</li> </ul>
<b>Volume</b>			
<b>CMO Value</b>	<ul style="list-style-type: none"> <li>Absorb risk</li> <li>Flexibility</li> <li>No capital expense</li> </ul>	<ul style="list-style-type: none"> <li>Process expertise</li> <li>Delivery technology</li> </ul>	<ul style="list-style-type: none"> <li>Low cost production inc. offshore</li> </ul>

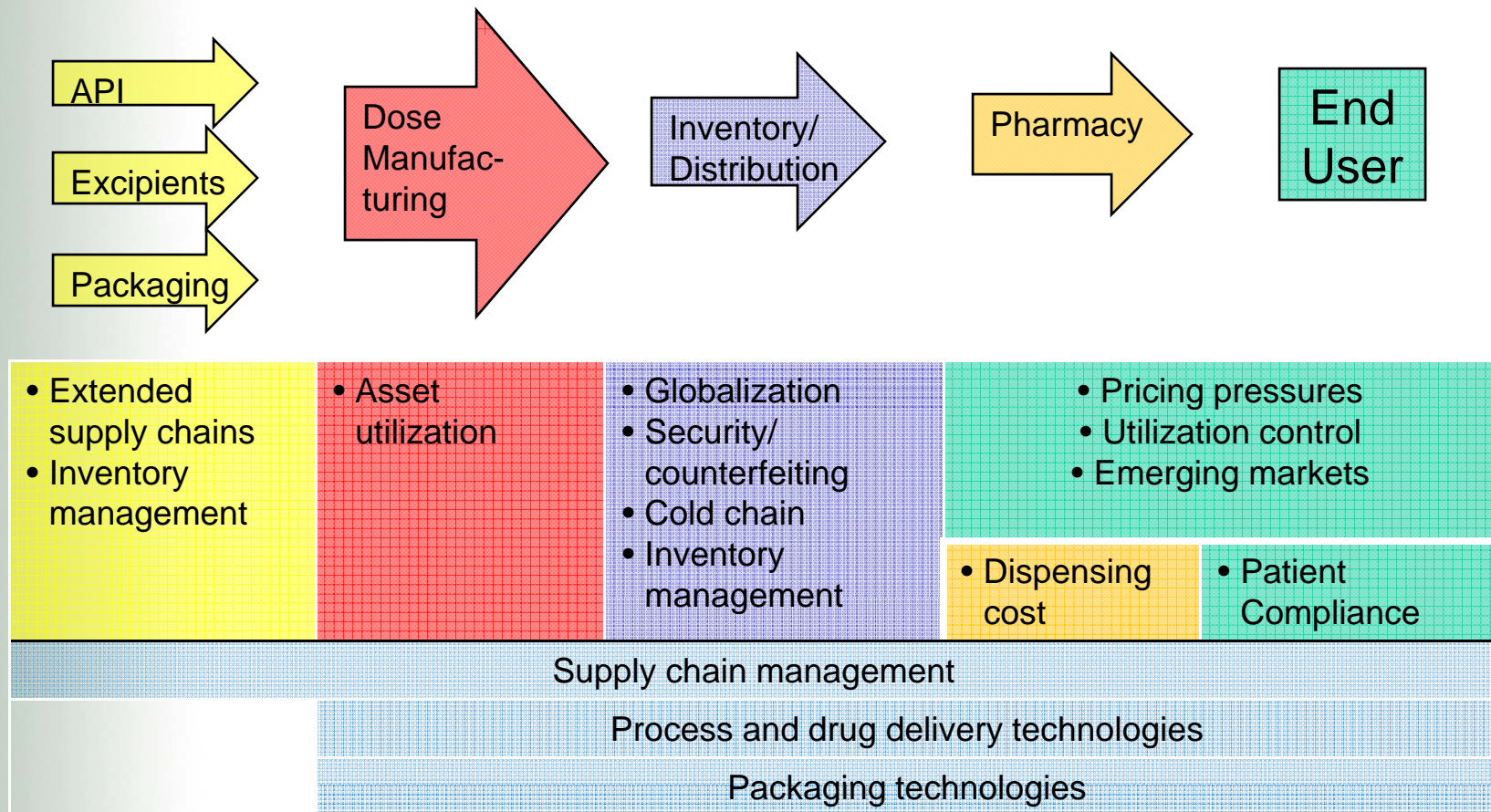
# CMOs and CROs as solutions providers

## Pivotal to solving supply chain issues



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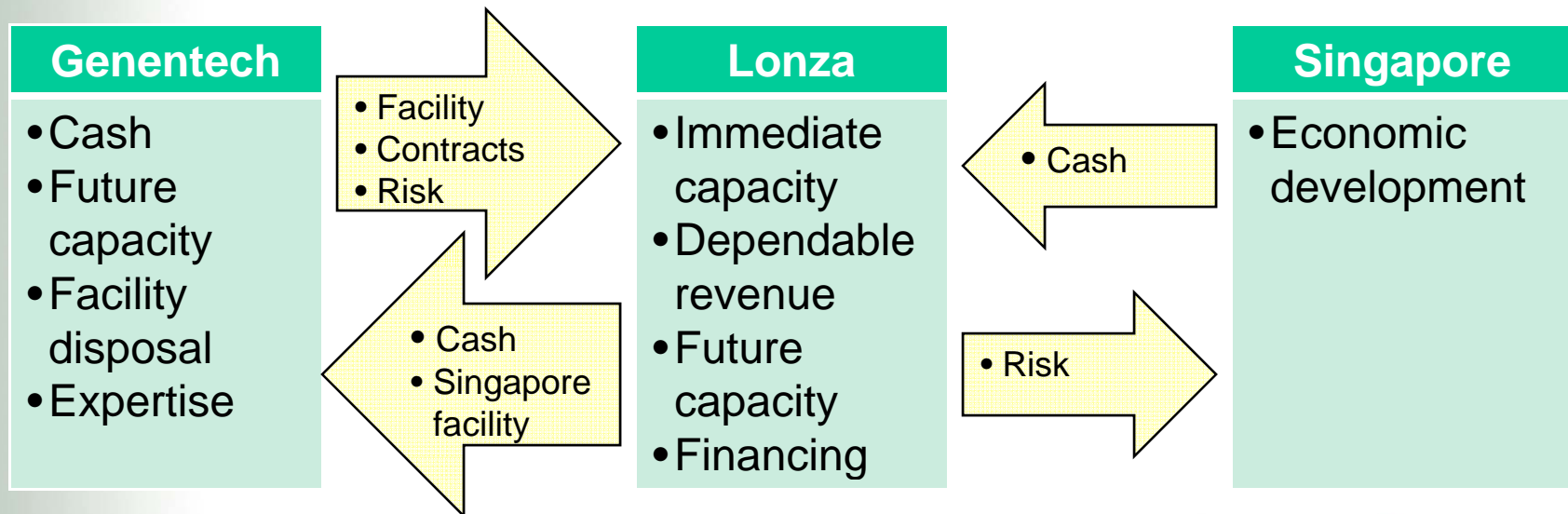


CMOs and CROs as solutions providers

# Lonza-Genentech deal transfers risk

- **Key elements**

- Lonza buys Genentech MCC facility in Spain w/contract
- Lonza builds MCC facility dedicated to Genentech in Singapore
- Singapore agency contributes investment
- Genentech option to acquire facility



CMOs and CROs as solutions providers

## Lonza – Novartis deal: risk + technology transfer

10+ year deal for biopharmaceutical development

Service	Value to Novartis	Source of Value
<ul style="list-style-type: none"><li>• Process development</li><li>• CTM manufacture</li><li>• Launch manufacture</li><li>• Facility design &amp; engineering</li></ul>	<ul style="list-style-type: none"><li>• Faster development</li><li>• Better performance</li><li>• CAPEX avoidance</li><li>• Risk mitigation</li></ul>	<ul style="list-style-type: none"><li>• 20 years experience and expertise</li><li>• Investment in GS expression system</li><li>• Diversified project/product portfolio</li><li>• Manufacturing assets</li><li>• Clever deal making</li></ul>

# Closing thoughts

- Manufacturing will become part of broader business solution
  - Think IBM, UPS, FEDEX
- Changing environment providing important new sources of value
  - Risk mitigation and arbitrage
  - Supply chain management
  - Global manufacturing networks
- New skill sets required
  - Marketing (segmentation and positioning)
  - Financial engineering
  - Global logistics
  - Just-in-time manufacturing operations