

# The Evolving CMC Development Business

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PARCS

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PHARMSOURCE™

Overview

# The Evolving CMC Development Business

## Agenda

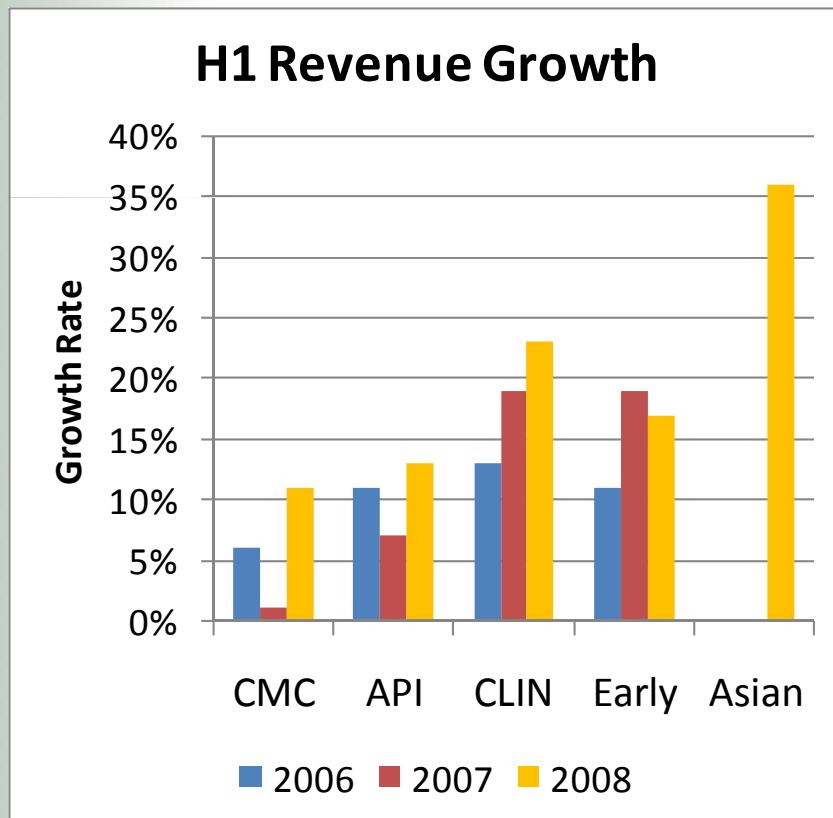
- CMC market overview
- CMC business models
- CMC challenges
- Final thoughts

## Key Points

- A robust and rapidly growing market
- Business models in flux
- Market presenting new challenges
- A buyer's market but be cautious

## CMC market overview

# Strong growth for contract services



- All segments participate

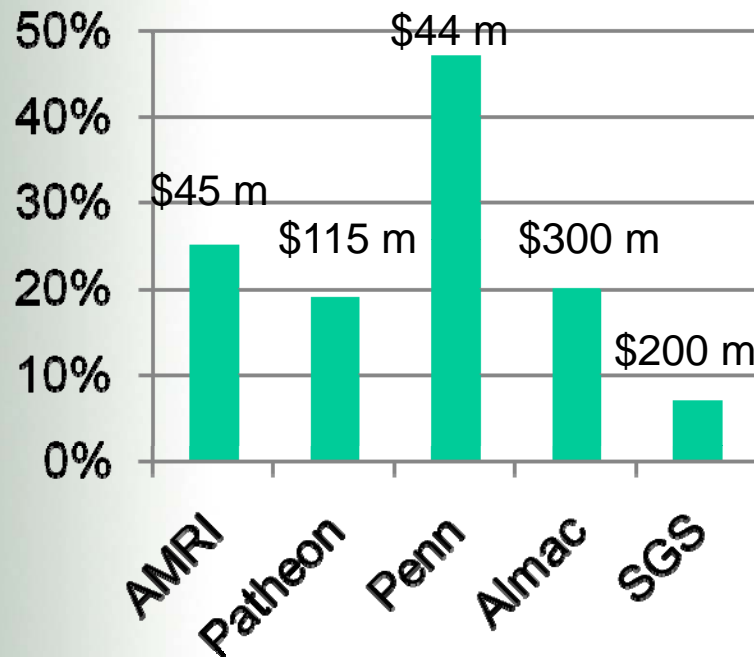
- Factors:

- Pipeline
- Big Pharma outsourcing
- Consolidation in clinical and preclinical
- Asia advantage declining

CMC market overview

# CMC development show strong growth

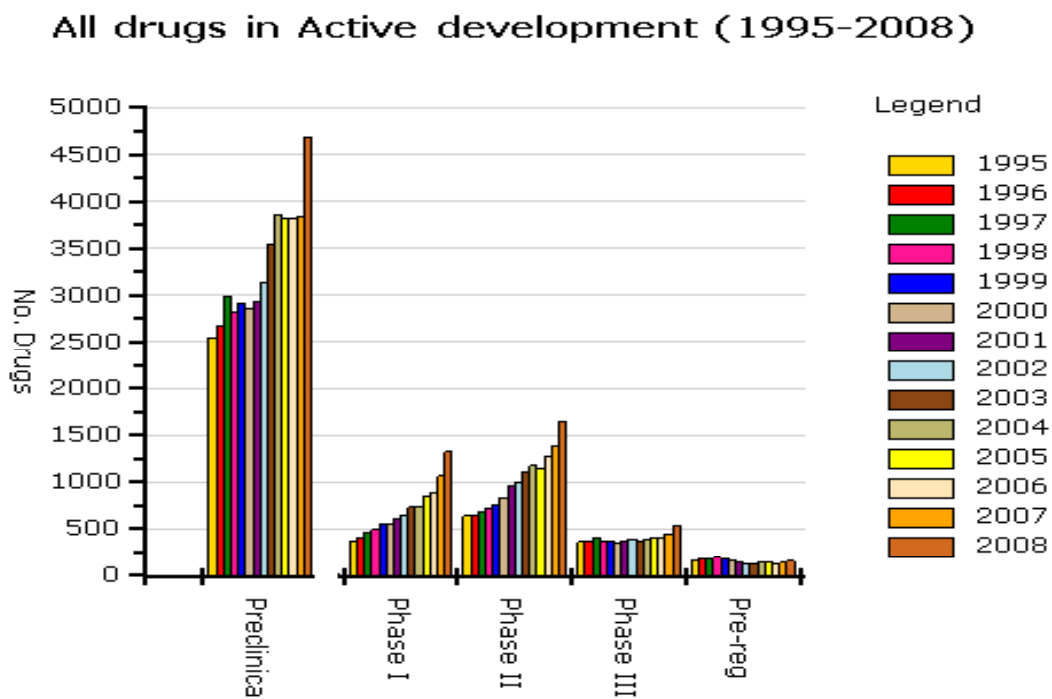
## CMC Development Services Growth



- Strong demand for
  - Process development
  - Formulation
  - CTM manufacture
  - Packaging

## CMC market overview

# Rapid pipeline growth drives performance



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- Reflects POC focus
- Rise in P3 candidates notable
- Financing could limit early stage

## CMC market overview

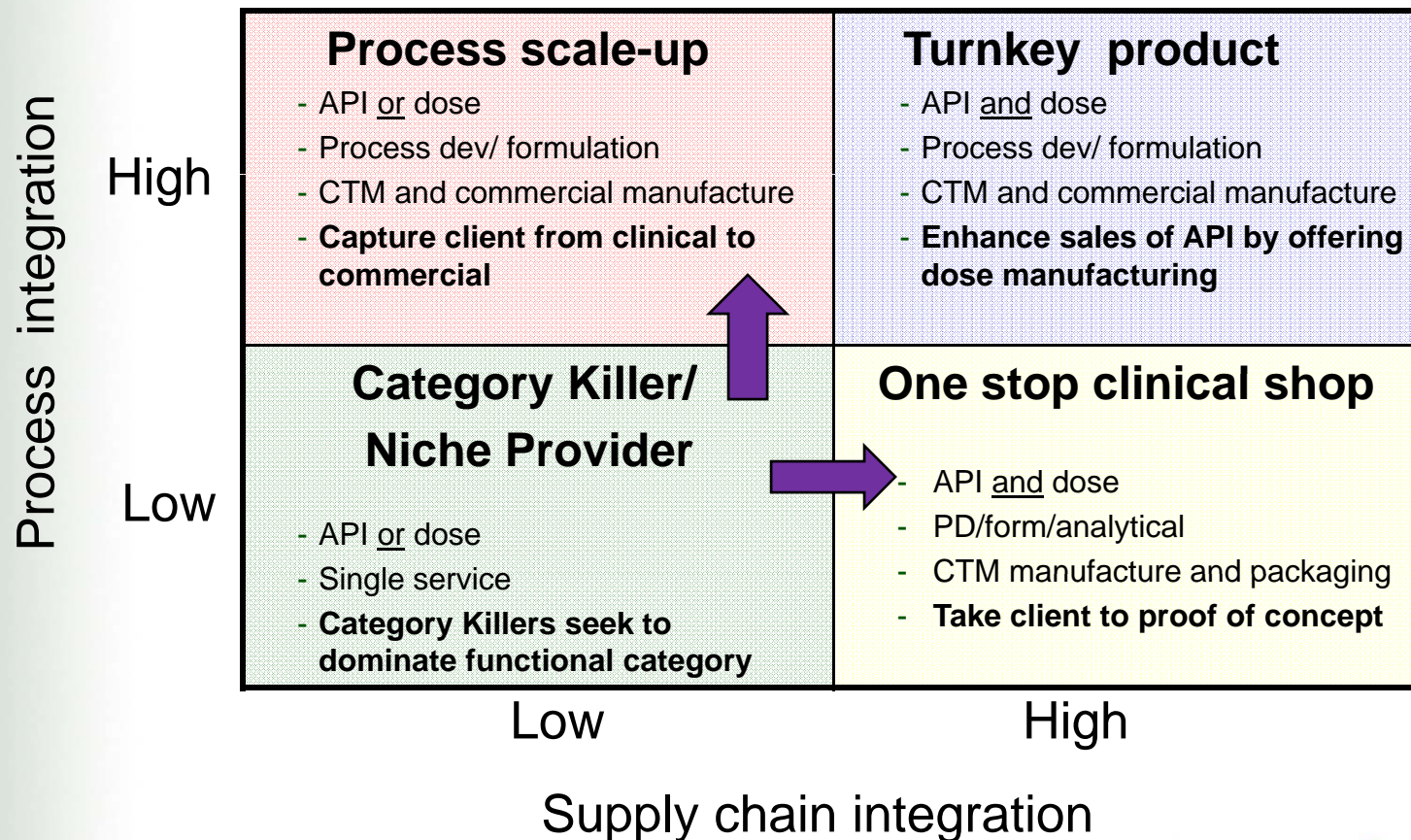
# CMC a \$5 billion market

	Formulation and Analytical	Clinical Packaging
Basis of estimate	5% of total R&D spend (per PhRMA)	5-10% of clinical study mgmt cost
Market (\$100B R&D spend) Phase 1&2 only	\$ 5 billion \$ 1.5 billion	\$1.8 billion \$ .5 billion
Outsourced share	40%	40%
Outsourced spend	\$ 2 billion	\$.7 billion
Outsourced growth rate	15%	15%
CROs/CMOs	280+	40+

PharmSource estimates

## CMC business models

# Models evolving to capture more of spend



## CMC business models

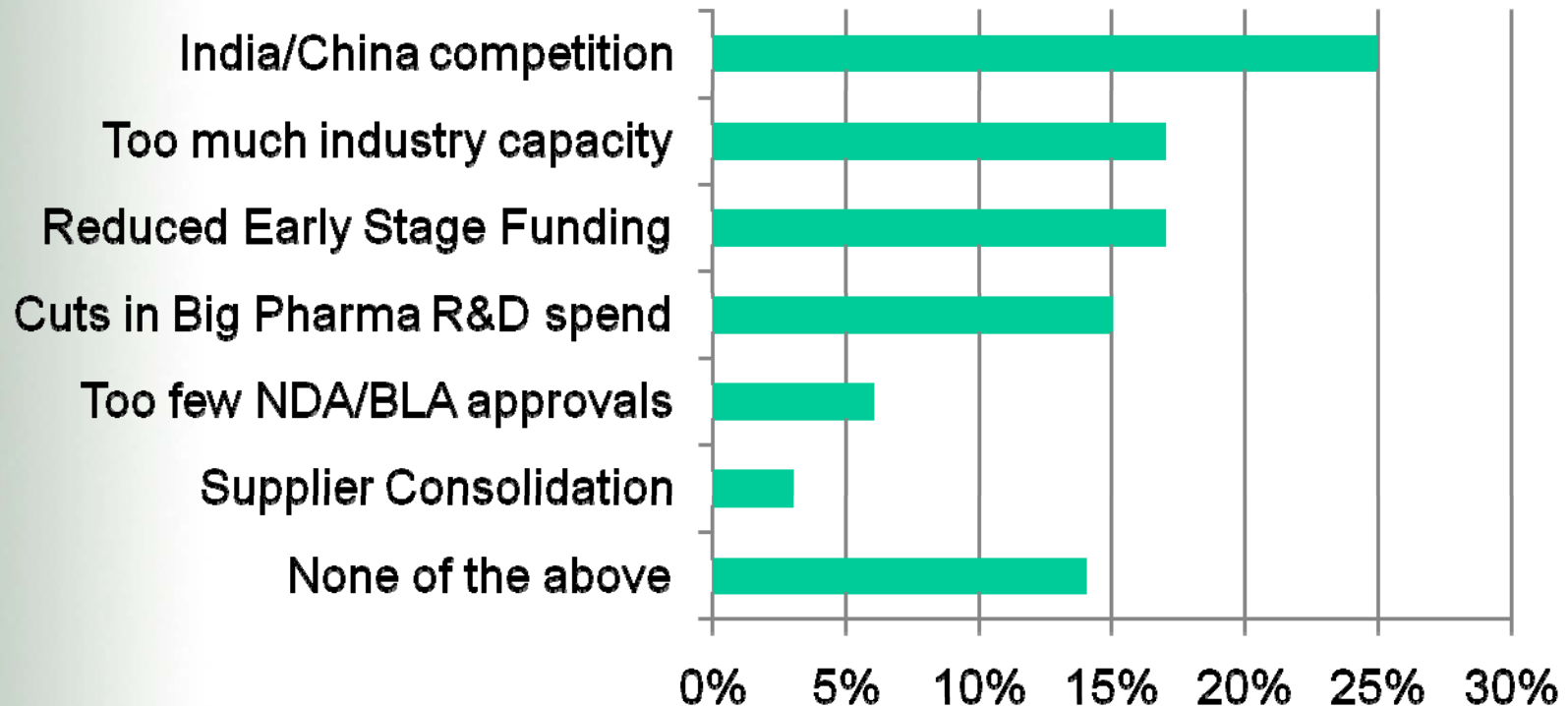
# How the major players are competing

Process integration	High	<b>Process scale-up</b> <ul style="list-style-type: none"><li>- Patheon</li><li>- Catalent</li><li>- DSM</li><li>- Vetter</li></ul>	<b>Turnkey product</b> <ul style="list-style-type: none"><li>- ??</li></ul>
	Low	<b>Category Killer/ Niche Provider</b> <ul style="list-style-type: none"><li>- Fisher Clinical</li><li>- Lancaster Labs</li><li>- Almac companies</li><li>- Most small CROs/CMOs</li></ul>	<b>One stop clinical shop</b> <ul style="list-style-type: none"><li>- Aptuit</li><li>- Azopharma</li><li>- AAIPharma</li></ul>
		Low	High
		Supply chain integration	

CMC market trends

# Challenges lie ahead

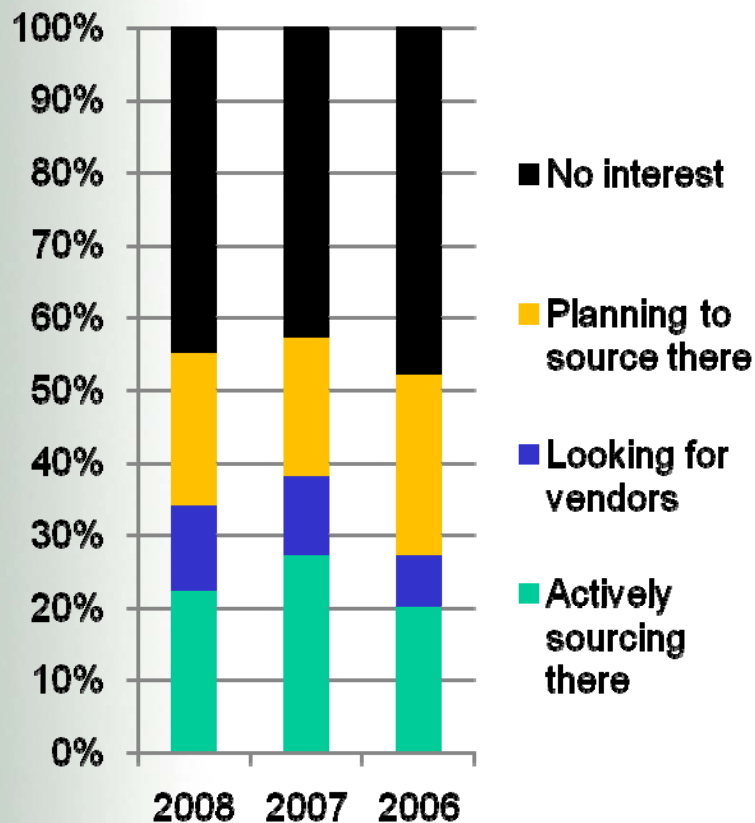
## What is the biggest risk to your business?



Source: 2008 PharmSource/Pharmaceutical Technology Survey

## CMC challenges

# Pharma interest in Asia growing



- Most interest in discovery and APIs/intermediates
  - CMC following growth in clinical trials
- Companies testing dose manufacturing opportunities
  - Initially for local market?
- CMC following growth in clinical trial activity
- Barriers to interest
  - Eroding cost advantage
  - Quality concerns

Source: 2008 PharmSource/Pharmaceutical Technology Survey

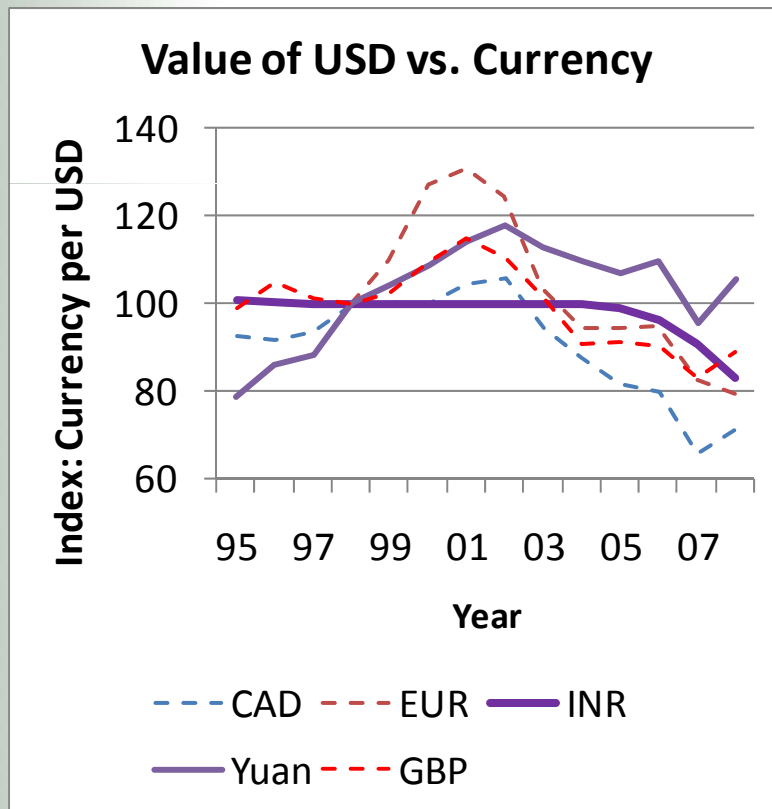
## CMC challenges

# Asian CTM supply base expanding

Company	Country	Form	S/SS/L CTM	Par CTM	Clin Pkg	Strategy
Advinus	India	X	X	X		Shared
Aptuit	India, Sing.	X	X			Dedicated
Astron Research	India	X	X	X		Dedicated
Bharat Biotech	India			X	X	Excess
Bilcare GCS	India				X	Dedicated
BioArc Res.	India	X	X			Dedicated
Cadila Pharma	India	X	X	X		Excess
Gland	India	X		X		Shared
Piramal	India	X	X	X		Dedicated
Reliance Bio	India			X		Excess
Rubicon	India	X	X			Shared
Sipra Labs	India	X	X			Dedicated
CoSci	China	X	X			Excess
Frontage Labs	China	X	X			Dedicated
WuXi Pharma	China	X	X			Dedicated
11 Fisher Clinical	India, Sing.				X	Dedicated

## CMC challenges

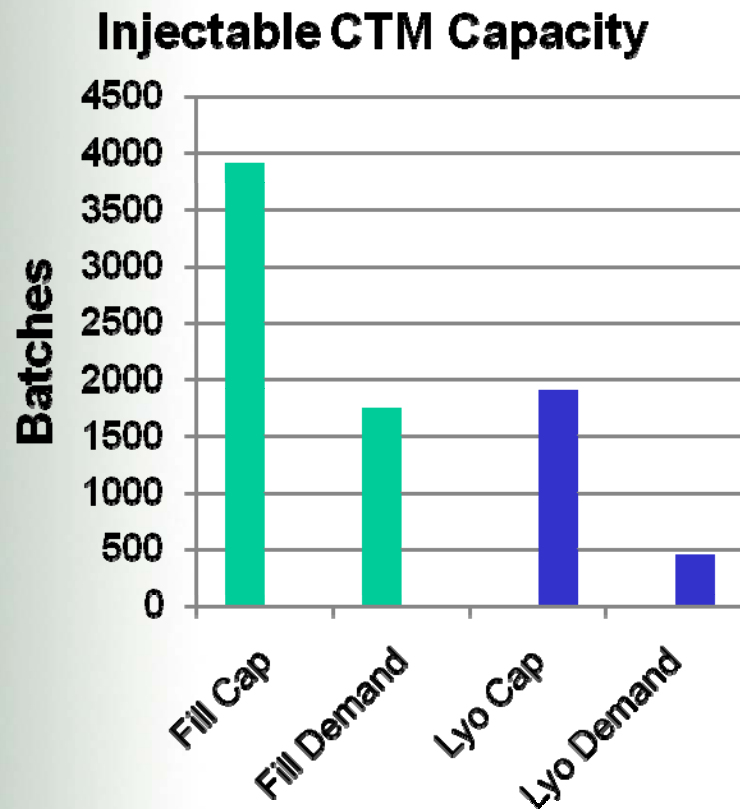
# Costs on the rise in India, China



- Rapid inflation
  - India 11%
  - China 8%
- Pharma labor rates rising more rapidly
  - Non-operator wages (e.g., QA, QC staff) at US levels in India
  - Operator rates about 25% of US, but <50% of labor cost
- Other factors
  - Rising costs for shipping
  - Exchange rates
  - Higher quality oversight

CMC challenges

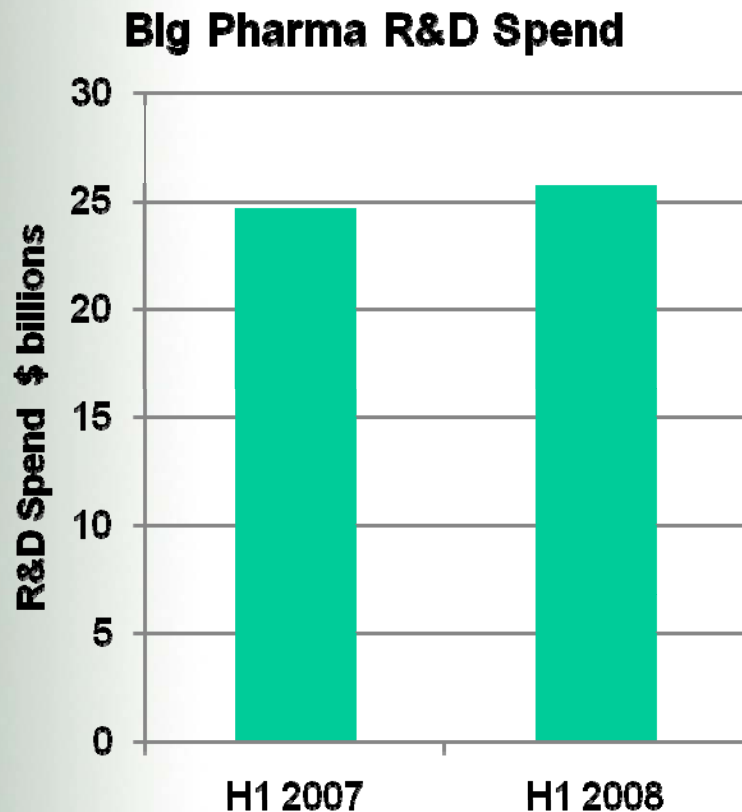
## Overcapacity a major concern



- CMOs and CROs expanding offerings
- Low barriers to entry
  - Small investment
- Most capabilities easily copied
  - e.g., solid state chemistry, High potency

CMC challenges

## Big Pharma R&D spend drives market



- 70% of revenue for big CROs
- More of spend is outsourced
  - Esp. clinical, preclinical and discovery
  - Chemistry and CMC spend behind but growing
- Supplier consolidation is the trend

CMC challenges

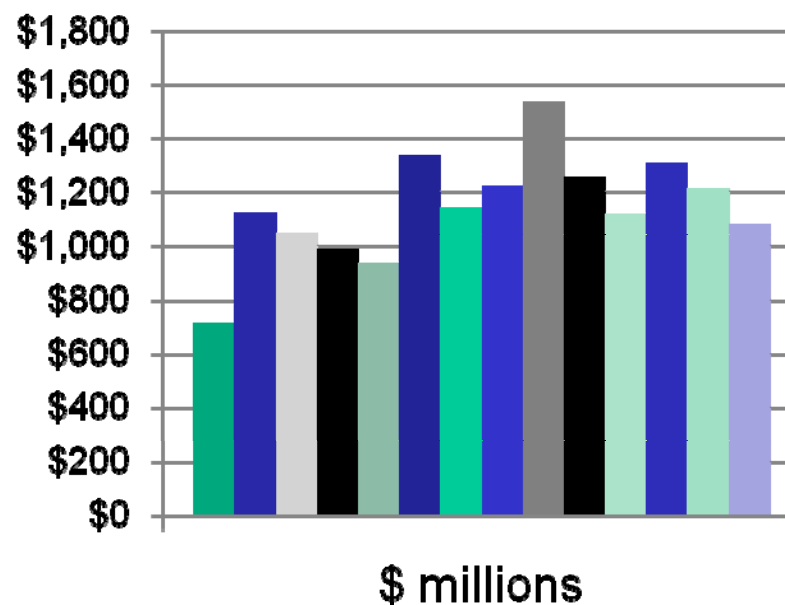
## Declining early stage financing a risk

### BioPharma IPOs

	Deals	Amount Raised
H1 2008	1	\$ 6
H2 2007	9	\$ 616
H1 2007	16	\$ 1095

\$ in millions

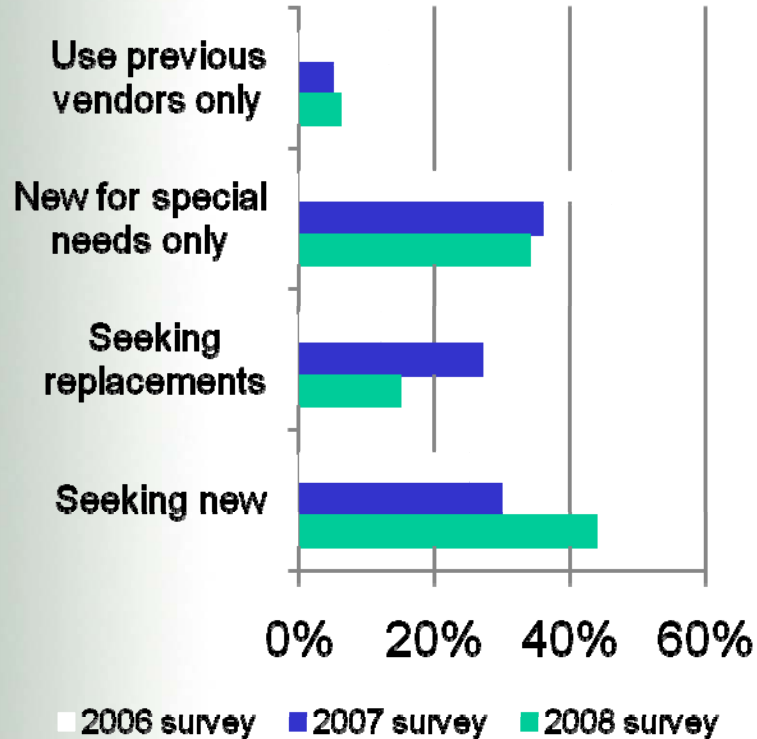
### VC Investment North American Biopharma 05Q1 – 08 Q2



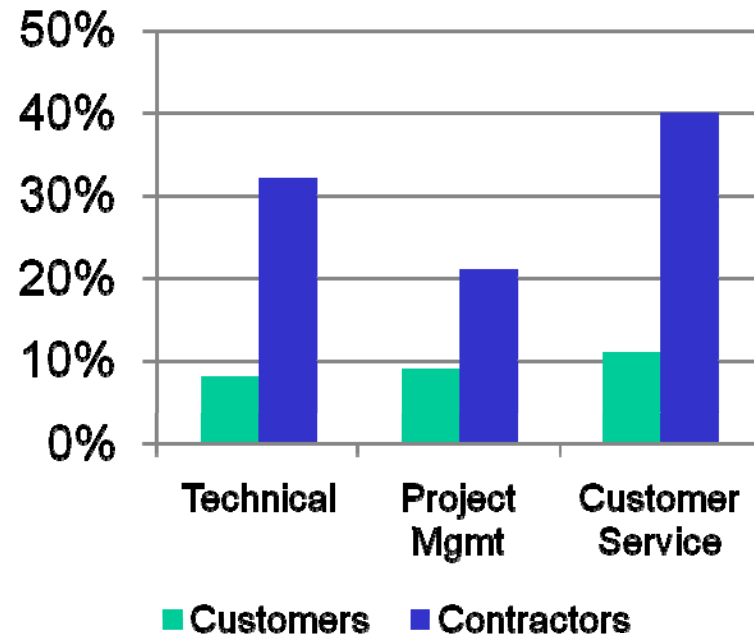
## CMC challenges

# Signs of client dissatisfaction

### Stance on New Vendors



### Share of Respondents Rating Contractor "Excellent"



# Closing thoughts

- CMC services are a buyer's market
  - Lots of capacity
  - Demand likely to slow, especially for smaller CROs/CMOs
- Careful due diligence is critical
  - Financial stability
  - Technical skill and experience
- Major opportunities available
  - Global capabilities
  - Servicing Big Pharma