



A brief look at the history of contract development and manufacture, the current market and future trends.

Richard Dennett PhD
Head of Consultancy Services



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- *‘With outsourcing beginning to feature as an increasingly inherent component in the drug development lifecycle – how can emerging biocompanies use this to their best advantage in today’s difficult economic and competitive climate?’*



Headlines

‘Credit crunch hits European Biotech’ – Pharmafocus, October 2008

‘New Biotechs facing tough financial environment’ - SCRIP market insight, April 2008

‘Biotech start-ups turn to big pharma for survival’ – Worcester Business Journal, March 2009

‘The worse is yet to come for biotech warns industry leader’ BIO, May 2009

Market analysis snapshot



US

- Of the 350 public biotech companies approximately 20 were trading with less than 6 months of cash on the books
- Capital raised by US biotechs declined from over \$2.1 billion in 4th Qtr 2007 to under \$700 million in 4th Qtr 2008 – a drop of 68%
- Biotech licensing down deals by top 20 global pharmaceutical companies declined by 28% between 1st Qtr 2006 - 3rd Qtr 2008

(Source June 2009 – Mass High tech Business news: – Inside Biotech)



EU

- 2007: nearly one billion euro investment was provided to European Biotech. First half of 2008 saw this supply almost dry up

(Source EPFR Global/Pharmafocus)

France

- 79% Fall in equity investments in French Biotech companies 2008 (694 million 2007, 143 million 2008)
- Investment in listed companies collapsed (only 12 million in 2008 – a fall of 98%)
- Investment in private companies (132 million in 2008 - fall of 27%)
- Innovation budget and tax credit cut by half

(Source Biotrinity)



In summary

- Recession still in the balance
- Financial support and Investor confidence low
- What relevance does this place in the consideration of outsourcing in 2009 ?

1980s: 'biotech baby boom'

- First biopharmaceuticals on the market in the 1980s were manufactured by the companies that developed them
- Expended effort to overcome challenges => core value driver; critical capability / strategically important
- Regulatory framework
 - Manufacturing process defines product (Analytical methodology less advanced)
 - 'Product' License Application
 - 'Establishment' License Application
- Notorious failures: product flops / white elephant facility builds



1990s

- Significant step change FDA -> BLA
- Growth of Biotech

- Emergence of CMOs
 - Residual capacity
 - Dedicated



This last decade

TRACK 1

- Lots of public interest areas/high promise: mAbs, therapeutics, stem cells, gene therapy
- High investment interest in Biotech
- European govt funding: US model – academic/start up company model, bio incubators, investment input. Formation of Bioclusters/Biopoles
- Initial lack of CMO capacity – therefore Increase in capacity of CMOs to meet explosion of start ups in line with this
- Specialisation



- Meanwhile – **TRACK 2**
- Traditional Pharma:
 - Patents on products expiring + not enough new targets
- Therefore interest in biotech products as new pipelines – particularly mAbs (more defined)



- Mergers and acquisitions of biotech companies/technologies
- Coalescence of Pharma meets Biotech



Difficult times

- Is economy to blame?
 - Partly: for decrease in ongoing forward investment
 - No: due to natural failings of Biotech products/start ups
 - *'Biotech always risky sector and already struggling – economic turmoil has only made a bad situation worse'*
(Source Pharmafocus)
- So where are we now? And why is engaging with an outsourcing partner more important than ever?



Present picture 2009

- Period of consolidation:
- Mergers, Acquisitions, Shake out: Survival of the fittest
- Combination of best elements
- Biotech finding its feet for renewed growth

- Picture not entirely bleak!
 - Casualties not as heavy as in other industry sectors
 - Investment and government support less but not zero
 - Good science will still get funding in the future

- Pharma/biotech alliance good

- KEY FOCUS: Smart, Critical Path, Focused Development. Know How. Efficient. Cost Effective => OUTSOURCING



- Outsourcing has reached maturation and is an accepted low risk model
- Solid outcome – assured, timely and better return on investment
=> Investor confidence
- CMO – as we will see:
 - Specialised
 - Well versed
 - Expertise to match product
 - Track record
 - Better guarantee
- CMOs good ones – more than just a black box that makes products
 - **Win-Win ‘Partnership’ that can add value on many levels**