Biomanufacturing 2008: a review of the state of the art in France and recommendations for improving the country's attractiveness

A national issue to support France in the world competition of medicine
Trends and perspectives of the world biomedicine market

- Weight of biomedicines in the pharmaceutical industry will increase from 10% to more than 15% between 2007 and 2012

Perspective of the biomedicine world market over the period 1994 - 2007

Source: From IMS Health, analysis Développement & Conseil, July 2008
Biomedicines in clinical studies

- An important number of biomedicines in phase 1 clinical studies in 2007

Number of biomedicines in clinical studies by phase from 2002 to 2007

Source: From PhRMA, Arthur D. Little, analysis Développement & Conseil, July 2008
Trends in the launch of new biomedicines on the market and perspectives

• 104 new biomedicines should be marketed before 2012

Source: From PhRMA, FDA, IMS Health, analysis Développement & Conseil, July 2008
The biopharmaceutical industry relies on 2 key stages of production:

- **Clinical-scale biomanufacturing**
- **Industrial-scale biomanufacturing**

Important stages of biomanufacturing of the active pharmaceutical ingredients (« bulk »):

1. **Academic and applied research**
2. **Screening**
3. **Pre-clinical studies**
4. **Clinical studies**
   - Phase I
   - Phase II
   - Phase III
5. **Industrial-scale manufacturing & Distribution**
6. **Marketing & Sales**
7. **Phase IV**
8. **Consumer Distribution network**
World biomanufacturing capabilities

- In 2008, the world total capacity reaches about 3 million liters
- Strong growth forecast in the biomedicine world market

**Evolution of world biomanufacturing capabilities between 2005 and 2011**

Between 2008 and 2011, potential increase of 25% of the biomanufacturing capacities corresponding to:
- 1 million additional liters,
- investments of 10 billions €

Sources: From Bioprocess International, analysis Développement & Conseil, July 2008
World investments for openings of industrial-scale biomanufacturing units over 2009-2012

- Similar amount of forecast investments on the 3 zones: North America, Asia and Europe
- But strong growth in the construction of new industrial-scale biomanufacturing units in Asia,
- Half of the forecast units will be built in Singapore

Investments by geographical zone (Billions €)

- Construction
- Extension

Source: Développement & Conseil, July 2008
Industrial-scale biomanufacturing units set up preferentially in the countries which possess a powerful biotechnology R&D sector and a developed clinical-scale biomanufacturing with capabilities from pre-clinical-scale to phase III clinical scale biomanufacturing.
Clinical-scale biomanufacturing in France

Only three GMP sites of biomanufacturing with limited capabilities in France, corresponding to a total of 500 l of batch culture in bioreactor.

- Impossibility for a company to subcontract, on the same site, the biomanufacturing of the preclinical-scale up to the phase III clinical-scale.

- Many companies prefer to produce straightaway in another European country.

The opening of the biomanufacturing center of Evry will fulfill this deficiency from 2009. Foreseen capacity of 1500 liters.

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New industrial-scale biomanufacturing units in Europe

No project in France, until 2011

- Pfizer in Sweden
- Biogen in Denmark
- Eli Lilly in Italy (2009)

In Europe, seven new units under construction

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How to attract in France the forthcoming investments in industrial-scale biomanufacturing?
Implantation key factors for the industry stakeholders

Major implantation key factors
- Fiscal policy of the host country
- Social policy of the host country
- Education and working experience
- Technical and scientific environment

Secondary implantation key factors
- Infrastructure of the host country
- Strategic will of the company
- Market

These factors leverage the competitiveness of pharmaceutical companies

Implantation key factors identified are macro-economical

Important role of authorities

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Source: Développement & Conseil, July 2008
Recommendations for reinforcing France's attractiveness

Christian Lajoux
Président of Entreprises du Médicament
Our recommendations

It’s necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing

1. To protect clinical-scale biomanufacturing in France

2. To promote the creation of new industrial-scale biomanufacturing units in France

3. To support a national public / private partnership research on bioprocess

4. To develop education and specific competencies

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Our recommendations

It’s necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing

1. To protect clinical-scale biomanufacturing in France

Create a fund to support clinical-scale biomanufacturing and to promote the continuity of preclinical-scale to preindustrial-scale in the respect of a continuous process, avoiding the risk and the cost of a technological transfer
Our recommendations

It’s necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing

2. To promote the creation of new industrial-scale biomanufacturing units in France

To set up fiscal incentive to facilitate new implantations:

By the creation of “free industrial zones“ particularly in health clusters

By access to the “credit impôt-recherche” for firms having a research program on bioprocess.

To allow companies, who wish to subcontract biomanufacturing, to produce the biomedicine in France, by supporting common platforms

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It’s necessary to assure the sanitary independence of France by protecting biological molecules from Research to industrial-scale Biomanufacturing

3. To support a national public / private partnership research on bioprocess

In close collaborations with the major suppliers and the french pharmaceutical companies:

- New cell line development,

- Optimization of the biomanufacturing phase, in order to decrease the biomedicine cost,
Our recommendations

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4. To develop education and specific competencies

- To offer actionable competencies to industrial actors:
  - To provide formation organisms with “GMP like” pilots, allowing them to acquire hands-on experiences

- To integrate additional programs into education:
  - Authorize other persons than the pharmacists to supervise batch delivery (in compliance with appendix 16 of EU GMP and articles 48 - 53 of the 2001 / 83 / CE directive)
Find the study Biomanufacturing 2008 on Web:

www.leem.org/espace biotech

www.leem-recherche.org

www.genopole.fr