

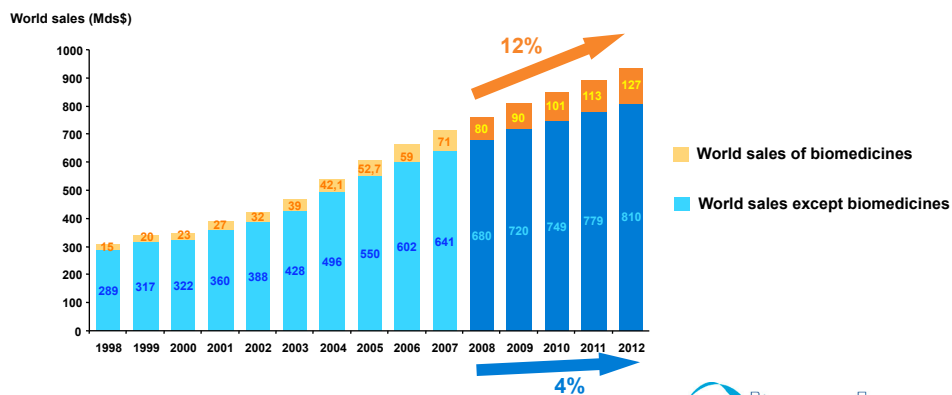
Biomanufacturing 2008: a review of the state of the art in France and recommendations for improving the country's attractiveness

A national issue to support France in the world competition of medicine

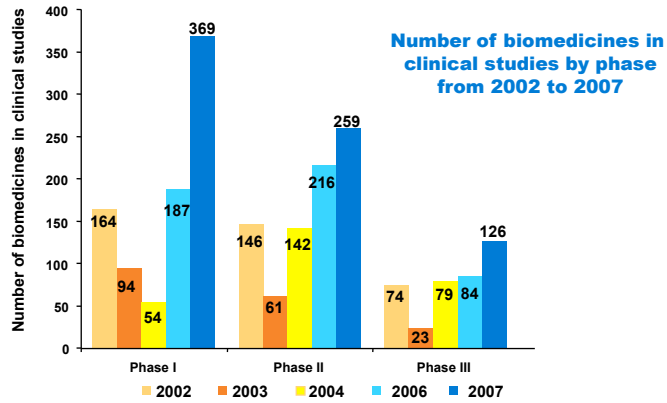
Trends and perspectives of the world biomedicine market

- 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

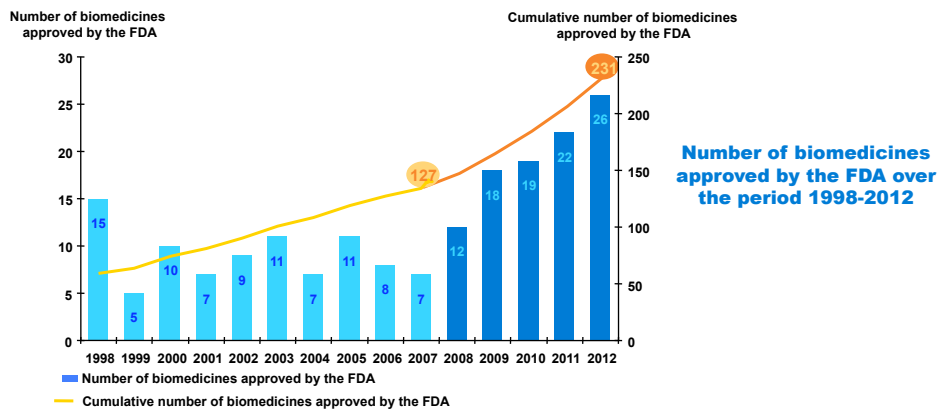


- **An important number of biomedicines in phase 1 clinical studies in 2007**



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- **104 new biomedicines should be marketed before 2012**



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The biopharmaceutical industry relies on 2 key stages of production

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

Clinical-scale biomanufacturing
Industrial-scale biomanufacturing

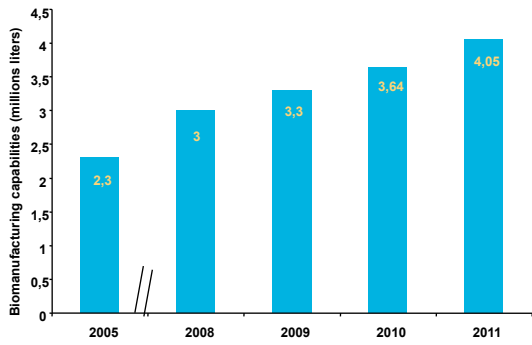


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World biomanufacturing capabilities

- 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 €

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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

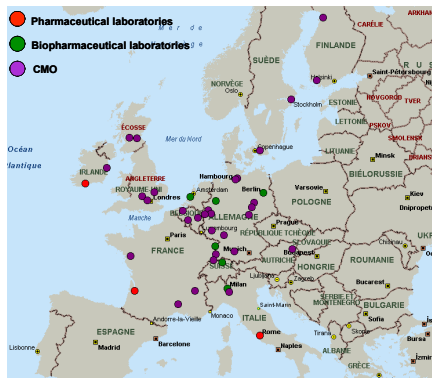
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Source : Développement & Conseil, July 2008

Biomanufacturing in Europe

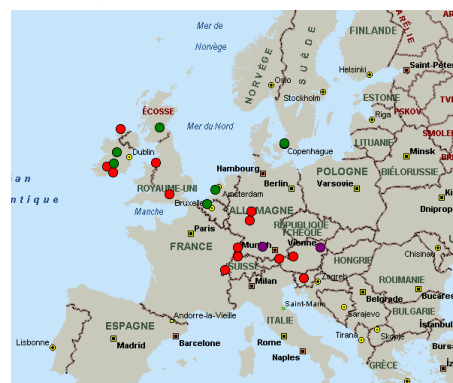
Industrial-scale biomanufacturing units set up preferentially in the countries which possess a powerful biotechnology R&D sector and a developed clinical-scale biomanufacturing with capabilities from pre-clinical-scale to phase III clinical scale biomanufacturing



Cartography of clinical-scale biomanufacturing units in Europe in 2008

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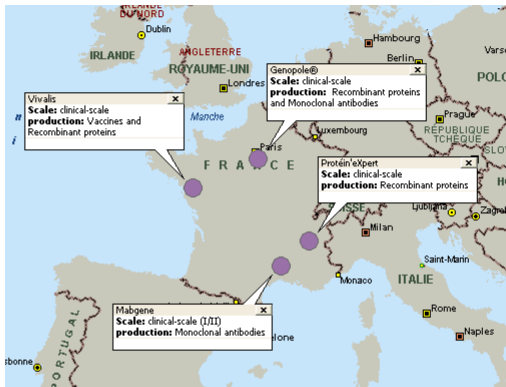


Cartography of industrial-scale biomanufacturing units in Europe since 2003

DEVELOPPEMENT & CONSEIL 8

Source : Développement & Conseil, July 2008

Clinical-scale biomanufacturing in France



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

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

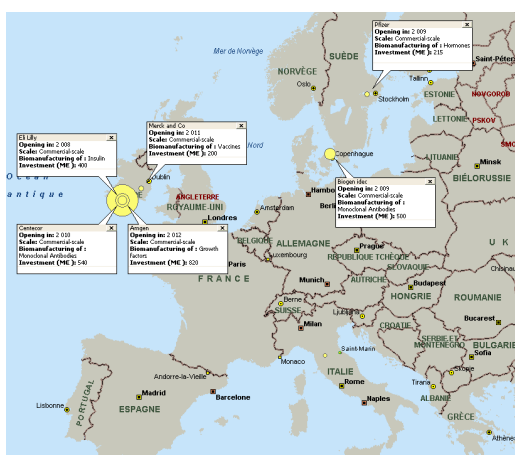
> Impossibility for a company to subcontract, on the same site, the biomanufacturing of the preclinical-scale up to the phase III clinical-scale

> Many companies prefer to produce straightaway in another european country

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New industrial-scale biomanufacturing units in Europe



In Europe, seven new units under construction

No project in France, until 2011

- 4 in Ireland : Eli Lilly (2008), Centecor(2011), Merck (2011), Amgen (2012)
- Pfizer in Sweden
- Biogen in Denmark
- Eli Lilly in Italy (2009)

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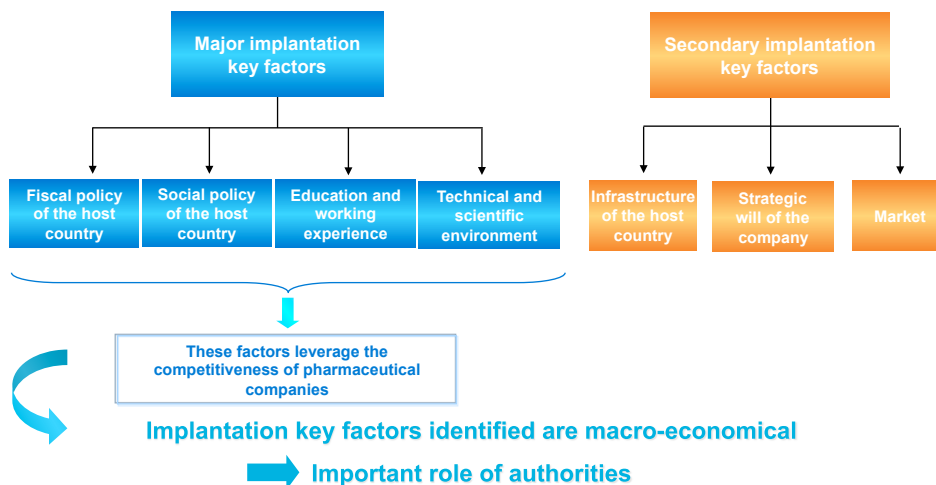
How to attract in France the forthcoming investments in industrial-scale biomanufacturing?

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Implantation key factors for the industry stakeholders



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Recommendations for reinforcing France's attractiveness

Christian Lajoux
Président of Entreprises
du Médicament

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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 Production*

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

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

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

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

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

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,*

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

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 Bioproduction 2008 on Web :

[www.leem.org/espace biotech](http://www.leem.org/espace_biotech)

www.leem-recherche.org

www.genopole.fr