

Biomanufacturing: raising the game in France

Leem presents a groundbreaking study by AEC Partners that lists the manufacturing sites for biological medicines in France. It shows that France, despite significant investments, still has some catching up to do in the European biomanufacturing race. France's shift in production towards the first monoclonal antibodies lagged behind that of its European neighbours and it can no longer afford to be behind the competitive curve.

For Leem, the promotion and development of this sector should feature in the work of the next CSIS¹ meeting. The manufacture of gene and cell therapy medicines for certain cancers and rare diseases is proving to be a key lever for competitive advantage to boost pharmaceutical production in France. A lever that should be activated without delay.

A sound industrial base, investments and jobs to boot ...

France has a strong pharmaceutical industry with 32 biomanufacturing sites generating more than 8,463 direct jobs (i.e. 19% in pharmaceutical production and 8.6% of total employment in the sector).

The map produced by AEC Partners for Leem shows a concentration of sites in the Rhône-Alpes region and the Paris Basin. Expansion plans are underway for 9 of the 32 biomanufacturing sites, 3 of which set to develop biomanufacturing sites or units in the coming years, which translates into nearly 1,000 new jobs over the next five years.

France also has four innovative facilities able to manufacture commercial batches of biomedicines for the cell and gene therapy (CELLforCURE, and Yposkesi) and viral vectors (ABL Europe and Sanofi Genzyme).

... but it's lagging far behind its main global competitors

Despite its undeniable competitive strengths, France is still struggling to keep pace with its main European and global rivals in biological medicines manufacturing. Since 2012, France has manufactured only two biomedicines (excluding vaccines and biosimilars) granted a European MA. This low ratio leaves France far behind the United States which is involved in producing nearly half of the biological active substances authorised by the EMA between 2012 and 2016 (37 of the 76 authorised substances). Producing the 191 cell and gene therapy products that have reached the clinical phase in Europe poses a strategic challenge for France in the future.

France is still too heavily dependent on the biomanufacture of vaccines

¹ Strategic Council for the Healthcare Industries (CSIS)

Another lesson to emerge from the AEC Partners study is that French biomanufacturing has a disproportionate tendency to produce mature biological substances such as vaccines, recombinant proteins and the extraction of proteins from biological fluid. Nearly one third of the biomanufacturing facilities that manufacture in-house (no subcontractors) are involved in vaccine production. The 4 facilities that manufacture only vaccines in-house (Sanofi Pasteur at Marcy l'Etoile, Neuville sur Saône and Val de Reuil, and Merial at Saint-Priest) account for 4,693 jobs, i.e. 63% of all biomanufacturing jobs in France.

Boosting manufacturing capacity in advanced therapies

The limited capacity of French facilities to manufacture commercial batches, as identified in the AEC Partners study, throws into question France's ability to attract biological medicines manufacturing. Only 3 French sites combine clinical and commercial batches of recombinant and/or extracted proteins. The same applies to cell and gene therapies, which remain the preserve of few French sites often focused on one or two types of biological products.

However, the manufacture of upcoming advanced therapies poses a major competitive challenge against the background of France's eroding pharmaceutical manufacturing base. The country's ranking has fallen in the space of a decade from 1st to 4th place in Europe². This relative decline calls for a radical reboot of industrial policy, particularly in the framework of the forthcoming CSIS meeting. By accelerating our manufacturing capacity in advanced therapies, France's pharmaceutical production will be given a unique opportunity to regain its leadership position in Europe.

"While our European neighbours have pursued the path of a coherent manufacturing strategy, competitive intelligence and regional balance, we are still picking up the scattered pieces of the French biomanufacturing puzzle", according to Patrick Errard, Chairman of Leem. The map produced by AEC Partners teaches us lessons about France's need to catch up but also about the strengths and resources it possesses to close the gap. One thing is certain, as was the case with monoclonal antibody production, there will be no second chance. The upcoming calendar of political events - the next CSIS meeting, the new health strategy, not forgetting the Action Plan for Corporate Growth and Transformation (PACTE) - should serve as a valuable sounding board to bring the central issue of biomanufacturing in France to the attention of top-level policy makers. For France to reclaim its place among the community of innovative nations. "

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² France has now been overtaken by Switzerland, Germany and Italy.