

Grifols obtains FDA approval for new sterile albumin filling plant at Los Angeles

Barcelona, 23 December, 2009. Grifols, the Spanish holding company which specializes in the hospital-pharmaceutical sector and is one of the leaders in the plasma products sector, has received approval from the FDA for its new sterile albumin filling plant in Los Angeles. This approval is the culmination of a three-year project to transform the entire process of obtaining, purifying and filling albumin vials at Grifols Biologicals Inc. (Los Angeles).

“The albumin production method at the Los Angeles plant was complex and inefficient,” explains Willie Zuñiga, president of Grifols Biologicals Inc. “Now the plants in Barcelona and Los Angeles will manufacture the same albumin. The method used in Barcelona is much better both from a production and a technical perspective. This approval, obtained in record time, completes one of the many projects which Grifols currently has underway in the United States.”

Approximately two months ago, Grifols also obtained FDA approval for its new plasma fractionation plant, known as “Minifrac”. With a capacity to process 700,000 liters of plasma, this brings the total fractionation capacity of the Los Angeles plant to 2,200,000 liters/year. “Now, in addition to other smallscale projects, we are focusing on completing construction of the new IVIG purification plant (for Flebogamma[®] DIF) to complete the full modernization of the facilities at Grifols Biologicals. This new Flebogamma[®] DIF plant is the sister plant of the one in Barcelona, and we hope to complete it during the third quarter of 2010. The immense complexity of this plant, which measures 10,000m² and includes over 50 reactors and advanced facilities for “viral filtration” and filling, means that we will take around two years to complete the validation, inspection and approval processes for the US and European health authorities. We plan to start production in the first quarter of 2013,” explains Dr. Javier Jorba, president of Instituto Grifols S.A. and global head of plasma product manufacturing.

A second plasma analysis laboratory

In addition to the work in Los Angeles, Grifols is also constructing a second plasma analysis laboratory in the United States. The new laboratory will be located in the city of San Marcos (Texas), 25 km from the central laboratory in Austin. Grifols hopes to start operations there at the start of 2011.

GRIFOLS

About Grifols

Grifols is a Spanish holding company specialized in the pharmaceutical-hospital sector and is present in more than 90 countries. Since 2006, the company has been listed on the Spanish Stock Exchange (“Mercado Continuo”) and is part of the Ibex-35. Currently it is the first company in the European sector in plasma derivatives and the fourth in production worldwide. In upcoming years, the company will strengthen its leadership in the industry as a vertically integrated company, thanks to recent investments. In terms of raw materials, Grifols has ensured its plasma supply with 80 plasmapheresis centers in the United States and in terms of fractionation, its plants in Barcelona (Spain) and Los Angeles (United States) will allow the company to respond to the growing market demand. Nevertheless, the company is preparing for sustained growth in the following 8-10 years and has launched an ambitious investment plan.