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Production of advanced therapy products: Should it be scaled up to industry processes?

Development of advanced therapies medicinal products represent a major challenge for companies or institutions who choose to manufacture and promote this type of medicines. ATMPs production requires a deep understanding of GMP, as well as a strong technical qualification. Facilities and equipment are unusual compared to the manufacture of conventional drugs, which increases the manufacturing complexity. From the viewpoint of quality control, analysis techniques are not very robust and some of them very complex. However, these medicines have become in the last 10 years in a hopeful alternative for some incurable diseases. This has led to extensive development of medicinal products for Gene and Cell Therapy for many indications, having conducted numerous clinical trials with these therapies. Currently, most of these therapies are experimental, with good safety and promising signs of efficacy. Only four products are approved by regulatory agencies and marketing stage, although it is estimated that in the coming years to increase the number of registrations of new ATMPs.

Biography

Eva Martin Becerra studied Biological Sciences at the Complutense University of Madrid (Spain) and is a Master in Management of biopharmaceutical companies. She is experienced in the management of both non-clinical and clinical studies for the development of biotechnological products, including *In vitro* diagnostics of medical devices and advanced therapy medicinal products (ATMPs), and has been involved in technology transfer processes between public centers and private companies. She started her career as a researcher at the Spanish Council for Scientific Research, and then changed to the biotechnological industry, getting specialized in project management. She worked as Intellectual Property and Clinical Research responsible in Fina Biotech (formerly Indas Biotech) for 4 years. After this experience, she joined Sanifit Laboratories (Palma de Mallorca, Spain) where she worked as Project Manager for 3 years. Finally, she founded the consultant firm Kinrel on May 2013 and she currently works as Regulatory Affairs consultant at Gradocell Group (Gradocell Consulting and Gradocell Pharma SL) since June 2014.

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