Raw materials for production of cell-based and gene therapy products

Hundreds of raw materials are used in the production of cell based and gene therapy products (which includes advanced therapy medicinal products - ATMPs). However, a large number of these biologically active raw materials are only available in research or in-vitro grades, which means it is difficult to assure their quality, safety and consistency.

In recent years, an increasing need for guidance for the quality requirements of raw materials used in the production of cell based and gene therapy products has been recognised both by manufacturers of such products and regulatory authorities. In order to meet the needs of the field, the European Pharmacopoeia Commission decided in November 2011 to elaborate a text covering the quality of these raw materials. The purpose of this text will be to assist stakeholders in identifying the quality requirements of raw materials and to harmonise the current variable practices.

Programme Overview

On Wednesday, 03 April 2013, the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM) and the European Medicines Agency (EMA) will bring together users and manufacturers of such raw materials and other interested parties in order to discuss issues of mutual interest and to exchange experiences. This will enable the RCG Working Party to develop quality requirements for these raw materials for inclusion in the European Pharmacopoeia.

Who should attend?

This symposium should be attended by professionals using raw materials to produce cellular and gene transfer products, professionals who are responsible for the manufacture of such raw materials, their representatives, national regulatory bodies and other interested parties.

We look forward to meeting you in Strasbourg.