
**21 December 2015, Strasbourg, France**

## NEW PH. EUR. GENERAL CHAPTER ADOPTED: RAW MATERIALS OF BIOLOGICAL ORIGIN FOR THE PRODUCTION OF CELL-BASED AND GENE THERAPY MEDICINAL PRODUCTS (5.2.12)

During the last European Pharmacopoeia Commission session, held in Strasbourg on 17-18 November 2015, a new general chapter was adopted for *Raw materials of biological origin for the production of cell-based and gene therapy medicinal products (5.2.12).*

This general chapter is for information only and not legally binding. It includes sections on the risk, origin, production of and quality requirements for raw materials of biological origin used for the production of cell-based and gene therapy medicinal products for human use. The chapter aims to assist stakeholders in ensuring raw materials are of suitable quality and to foster harmonisation in the qualification practices and standards to be applied.

The chapter is based on the outcome of the Symposium on Raw Materials for Cell-Based and Gene Therapy Products, organised by the EDQM and the European Medicines Agency (EMA) in April 2013, and takes account of comments received from stakeholders during the Pharmeuropa 26.4 enquiry in October 2014. The Working Party is very grateful to all the stakeholders for their contribution to the elaboration of this important chapter.

The Chair of the Working Party, Dr Jaana Vesterinen, from the Finnish Medicines Agency said *"While, at present, only a few cell-based and gene therapy medicinal products are authorised in Europe, many more are in the late stages of development and the standards for raw materials provided in this chapter will facilitate product development and contribute to their quality and safety."*

This chapter will be published in the 9th Edition of the European Pharmacopoeia and will become effective on 1 January 2017.

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**Note for the Editor:** Further information is available on the internet site **www.edqm.eu**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in Member States[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union. There are twenty-eight observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, Israel, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Republic of Moldova, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*