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Cell therapy regulations – a critical factor in translational medicine

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The current state of cell therapy regulations in Europe is presented from the perspective of a manufacturer in a university hospital who also is a member of the hospital´s recently founded Interdisciplinary Centre of Cell Therapy (IZZTKUM). An overview of Good Manufacturing Practice (GMP) and other standards will be given, focusing on the manufacture of sterile medicinal products in a class 100 (A) cleanroom. Links to the application of these products in clinical trials according to Good Clinical Practice (GCP) will be identified. Measures for quality assurance such as accreditation are considered useful tools to demonstrate compliance with laws and regulations. Recent developments in cell therapy – specifically the Advanced Therapy Medicinal Products (ATMPs) - have prompted a cascade of new regulations which will be outlined. Conversely the latter have challenged current methods and concepts such as testing product identity or sterility after culture and other manipulation procedures. The large spectrum of methods required for manufacturing and quality control of ATMPs results in the involvement of other partners and the need of written agreements. Coping with all these standards and regulations remains critical in the implementation of new options in cell therapy.

Biography

Beate Wagner earned her doctoral degree from Ruprecht Karls University of Heidelberg. She is a specialist in internal medicine and transfusion medicine and works as Senior Consultant and laboratory director in the Department of Transfusion Medicine & Hemostaseology, University Hospitals of Munich. At 2 sites she implemented cleanroom operation and sterile manufacture, which she is the Qualified Person of. She also is a member of the hospital´s recently founded Interdisciplinary Centre of Cell Therapy (IZZT^{KUM}).