

5th International Conference on

Tissue Engineering & Regenerative Medicine

September 12-14, 2016 Berlin, Germany

Development of the cell-based medicinal products from the regulatory perspective

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Development of an advanced therapy medicinal products and their shift from the basic research to the clinical application is very difficult task. The legislation and regulatory requirements are in force but the research at this area is so rapid that we are facing new and new challenges. On one hand, it is necessary to define the rules so that the regulatory field is transparent, consistent and the decisions are predictable. As a consequence, there are some situations when the requirements seem to be too restrictive. On the other hand, there is a strong wish to have effective treatment on the market as soon as possible. Regulators need to balance both point of views. The national regulatory authorities and especially European Medicine Agency (EMA) offer different procedures that can be used by the product developers. These procedures such as classification of the borderline products, certification and scientific advices can be very helpful for the planning of development and saving time and resources, if used appropriately. At the beginning of the planning of cell-based product development, it is important to know what the regulatory framework for the specific product is, what are the procedures that can or should be used and what is the manufacturer goal (national hospital production or European market). The risk-based approach should be used to define risk and other important aspects but also the requirements that are not relevant for this particular case. Those findings must be taken into consideration during the whole development phase.

Biography

Ivana Haunerova is a Quality Assessor for biotech and advanced therapy medicinal products in the State Institute for Drug Control in the Czech Republic. She has completed her graduation in Biochemistry at the Institute of Chemical Technology, Prague. Since 2009, she is a Member of the Committee for Advanced Therapies at EMA.

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