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## Stem cell based medicinal products from a regulatory view

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Stem cell based advanced therapy medicinal products offer big hope for patients that currently have no alternative efficient therapy. The patients are even willing to travel outside the EU for stem cell based treatments. However, there are considerable potential risks linked to the usage of this type of products. Therefore, it is a legal and regulatory challenge to establish rules that enable rapid development of safe and effective medicinal products. New regulatory procedures have been introduced in the EU to support and accelerate the development of medicinal products. Currently, there is a high number of stem cell based medicinal products in the clinical phase of development. However, till now only two of them gained an approval of the centralized marketing authorization application. The development of stem cell based products requires very good strategy planning via using a risk-based approach based on multidisciplinary evaluation. Additional aspects such as future logistic activities with respect to the potential market or technical possibilities should be considered. Especially for academia which is involved in this field it can be an enormous load and therefore the awareness of potential pitfalls and the knowledge of regulatory procedures (such as scientific advices, certification, PRIME and others) that could facilitate a development is essential.

### Biography

Ivana Haunerová 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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