

## 4<sup>th</sup> International Conference and Exhibition on **Cell & Gene Therapy**

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### **Transition from the bench to the bedside: Considerations for ensuring a safe and successful entry into the clinic for cell based medicinal products**

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In 2007, the European Regulation on advanced therapy medicinal products (ATMPs, including cell and gene therapies) was adopted, aiming to provide a common framework for marketing of therapies and to ensure a high quality and therefore safety profile of ATMPs in Europe. The Regulation was implemented in 2009, and over the last 5 years, we have seen 5 ATMPs obtain a positive recommendation from the European Medicines Agency (EMA) for marketing authorization, including the first stem cell based product, Holoclar, in December 2014. While there have been some marketing approvals, the number of marketed products remains lower than anticipated, reflecting the difficulties that developers experience in transitioning products from both the laboratory to the clinic, and the clinic to the market. In this presentation the author will provide an introduction to the regulation of cell based products in Europe, and include a review of the distinction between cell based therapies that are regulated as medicinal products as compared to those that are not. In addition, the key manufacturing and pre-clinical requirements to both maximize the likelihood of investment following due diligence, and ensure a smooth transition without regulatory challenges from the laboratory to the clinic will be examined. Finally, the author will outline methodology and practical implementation of the risk-based approach to the development of cell based medicinal products, which aims to ensure that the development programme is tailored to the known affects and safety risks of these complex products.

#### **Biography**

Natalie Thomas is a regulatory affairs consultant with Clinical Network Services, specializing in technical and regulatory advice on biopharmaceutical medicinal products including cell based therapies. She is a PhD biochemist/molecular biologist who has worked as a scientist in pre-clinical/early stage clinical drug development, before transitioning to regulatory affairs. She is particularly involved in early stage drug development with academic spin-offs and small, medium enterprise, and is on the editorial board for the journal "*Regulatory Rapporteur*".

#### **Notes:**