SYMPOSIUM SWEDEN 2018

1–3 October 2018
Globe Hotel,
Stockholm,
Sweden

In partnership with the Swedish Medical Products Agency Sweden

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

TIME OF TRANSFORMATION

IMPLEMENTING INTERNATIONAL REGULATORY CHANGE

A regulatory update in a day for Small and Medium sized Enterprises

3 October 2018

This one-day conference is for small and medium-sized enterprises (SMEs) and provides the opportunity to understand regulatory challenges specific to them. This year there is a particular focus on the development of Advanced Therapy Medicinal Products (ATMPs) (both Human and Veterinary) plus sessions on Early Access schemes and Clinical trials. Hear from speakers from the Medical Products Agency, the Commission and the European Medicines Agency and other agencies and industry.

MORNING SESSION: FOCUS ON ATMP

Introduction to Advanced Therapy Medicinal Products (ATMPs)
This session will provide an introduction to ATMPs and their associated regulations as background to the next session on ATMPs, the future. Use will be made of examples of products that are authorised (where available) to demonstrate the types of ATMPs: cell based therapies CAR-T: gene therapies and more; opportunities for interaction with EMA and some of the considerations during development and post authorisation that are specific to ATMPs.

ATMPs (Cell- and Gene Therapies, the future?)
After 10 years with the ATMP Regulation, there are only a handful of approved products on the market. With a great number of products in the pipeline there are still challenges to overcome, especially for SMEs and Academia. In this session we will hear about plans and activities to facilitate for developers of ATMPs. Speakers include representatives from the Commission, the MPA and an SME.

Or optionally:

Veterinary Advanced Therapies
The development of advanced technologies in veterinary medicines requires a well adapted and adequate regulatory framework and guidance. Projects are often initiated by SMEs with limited experience in the regulatory arena. The session provides an insight on recent experiences and discusses the challenges for both industry and regulators, to make advanced veterinary therapies available for the market.

In addition to the above delegates can opt instead to attend sessions on:

The Regulatory role in Early Access Schemes to Patients
What are early access schemes and how do these link to regulatory strategies in Europe? This session will shed some light to the current mapping of available early access schemes in EU Member States and how these play an important part in the voyage between medicines regulation and patient access.

Clinical Trial Regulation
With an implementation date of July 2019 for the EU clinical trial portal and after a transitional period of 1 year it will be mandatory to use the portal and database for all new clinical trials in the EU, and after 3 years all trials must be transferred. This session will share the hands-on insights of testers from industry, Agencies and Ethics Committees on the portal and database functionality, as well as experience gathered by the Swedish MPA and Ethics Committees with their national Clinical Trial Application (CTA) pilot. We will discuss transition guidance documents and the challenges of practical implementation of the legislation.

Veterinary Antimicrobial resistance
EU authorities are developing innovative approaches to ensure adequate dosing and efficacy and to control risk profiles of antimicrobials. The outcome and perspectives of these initiatives will be presented. The specific legal proposals related to antimicrobials will be presented, and the future opportunities for handling of infectious diseases will be discussed.

AFTERNOON SESSION: SME UPDATE

This session will give small and medium-sized enterprises (SMEs) the opportunity to understand regulatory challenges specific to them. Support by the SME Office at the European Medicines Agency (EMA) will be explored and experiences by SME companies shared.

SME Office at the EMA • Activities of the Agency's SME Office • Experience of EMA scientific advice process and centralised procedure • Support to SMEs Experience of a Swedish SME • SME challenges • Experience of drug development • Regulatory and administrative assistance • Incentives and support

For more information visit

www.toprasymposium.org/smeday18