Session 2: Identification and production of active pharmaceutical ingredients

Production of active pharmaceutical ingredients: general aspects and sphingosine-1-phosphate as an example

Dr. Ralf Zuhse
Geschäftsführer der CHIRACON GmbH
Biotechnologiepark,
D-14943 Luckenwalde

In this talk I like to give an introduction to a production process of sphingosine-1-phosphate with a view on the regulatory aspects related to it. Chemical processes are usually originated in a small scale in the laboratory. In many cases the first synthesis was developed by academic groups to test the product for pharmaceutical or biological mode of action. These groups care about the finding of new drugs, discovery of new biological interaction or just new ways of synthesising complex chemical structures.

Starting at the moment of the finding a new potential drug, the need of a sufficient and economic process for synthesis is raised.

The development is normally carried out by conducting the reaction steps successively larger before transferring to full size production for commercialization.

While the importance of drug impurity profiles has been recognized since the beginning of pharmaceutical drug therapy, regulatory considerations of stereochemistry has really only come to the force in the last decades. Increasing regulatory attention to stereoisomeric drugs is due to both technological advances in stereoselective analytical methods and the increased commercial practicality of stereoselective synthesis.