

Interview of Dr. René Bommer, PharmAccel Consulting, Germany

1- At Aerosol Forum 2011, you will make a presentation dealing with Regulatory Environment for Aerosols in EU and US.

Why it is relevant to address this topic during this meeting ?

Companies who exhibit at Pharmapack are manufacturers of pharmaceutical primary packaging and partly also contract manufacturers for the pharmaceutical industry. People attending the exhibition and conference are the respective clients of the exhibitors, namely the pharmaceutical industry. Whether exhibitor or customer, they all have in common a major interest to develop and market a product. Necessarily a successful product development has to be in line with the regulatory guidelines. Particularly aerosol products are challenging in terms of their regulatory compliance. Pharmaceutical aerosol drug products are a combination of two key elements, the drug formulation itself and the respective device. Aerosol devices for pharmaceutical applications are distinguished by the applied technology, the resulting performance and the regulatory compliance. The regulatory authorities' main focus is safety for the patient. As a consequence the aerosol device manufacturer has to be prepared to respond accordingly to the regulatory guidelines. But also the pharmaceutical companies who are the customers of the device manufacturers and who will have the responsibility for the submitted documents for approval of a drug product should be able to understand these essential regulatory necessities.

2- What are the key points you want to make the audience aware of ?

Aerosol devices are the vehicle to transport a medication to the intended target site. The regulatory requirements of these functional packagings are more demanding than for a standard pharmaceutical packaging as for example a tablet blister. The key points are the characteristics of the performance and the choice of materials. The materials have to be clean and not interactive with the formulation during storage and during the period of usage. The performance has to be reliable in acceptable tolerances. The objective is to provide primarily a common basis of understanding of the complex regulations for the aerosol drug products.

Dr Bommer thank you very much for this exchange!

Sylviane Robinet