Session 5: Clinical development

Optimizing your development plan through scientific advice processes

Dr. Jürgen Regenold
Dr. Regenold GmbH
International Regulatory Affairs
Am Berg 4
D-79410 Badenweiler

Constantly evolving needs and demands related to the safety and efficacy of new medicines contribute to the increasing volume and complexity of drug development programs and a successful development program has to meet numerous criteria and targets in order to deliver a valuable medicinal product.

To meet regulatory needs is one of several key success criteria and has big impact on timelines and costs of a development program. Therefore, regulatory needs should be understood and implemented in the development program from the beginning.

Scientific advice from a regulatory authority in relation to the development of a new medicinal product can contribute to the understanding of scientific and regulatory expectations a medicinal product has to meet prior to receiving a marketing authorization. Scientific advice may be requested at any time during development of the medicinal product and may cover questions related to pharmaceutical quality (including biological and biotechnological aspects), design and conduct of preclinical investigations and clinical trials, including biostatistics.

Scientific advice meetings are an important element of the process to enable a dialogue to take place with a national and/or international competent authority or advisory committee and they should be considered an essential part of the development strategy. Whilst such a dialogue may help the future applicant to understand regulatory requirements, it does also contribute to the competent authority's understanding of the science and technology of the new medicinal product which they may have to review during the marketing authorization process.

Selection of the most appropriate competent authority or advisory committee and careful preparation of a scientific advice meeting, both from a scientific, documentational and organizational perspective, is of great importance. Whilst competent authorities are usually happy and interested to give scientific advice, they expect the applicant to seriously consider and implement advice given. Minutes from an authority's scientific advice received during development of a new medicinal product need to be submitted with the marketing authorization application and will contribute to the authorities review and approval.