

Session 2: Identification and production of active pharmaceutical ingredients

The regulatory framework for preclinical research

*Dr. Thomas Zapf
Bundesinstitut für Arzneimittel und Medizinprodukte
Georg-Kiesinger-Allee 3
D-53175 Bonn*

In modern drug regulatory the common target in mind is a high safety potential of market drugs. This is the target of the regulatory authorities and the pharmaceutical entrepreneurs.

The progress in scientific disciplines needs an increasing number of requirements/criteria in the assessment of drug safety and drug quality to ensure a good risk/benefit ratio for patients. Nevertheless, one target of each drug development by a pharmaceutical entrepreneur is to be successful with an approval for the marketing of the developed drug within the planned time scheme.

Guidelines for the assessment criteria of the regulatory authorities can be a good guidance on the pathway from the idea to a marketing authorization for minimizing economic risk by a rational approach to development activities.

