

Workshop Regulatory Affairs

For the first time the workshop is an integral part of the main program. This is reflecting that dialogue between regulators, industry and scientist has become more and more important. The workshop will be chaired by Prof. Dr. Knöss, BfArM (Federal Institute for Drugs and Medical Devices), Bonn. The workshop „Regulatory Affairs“ has a long history in the annual meetings of GA. It is providing a platform to focus on selected topics in the field of regulatory affairs related to herbal medicines. Moreover, the workshop offers options to establish networks and bring together regulators, industry representatives and scientists.

The objective is to stimulate an extensive dialogue between science and regulation. At this year's workshop participants will get insight into recent advances of analytical methodology and the impact and challenges with respect to regulation. The presentations will cover different aspects such as PCR-related techniques, hyphenated methods, chemometric approaches etc. Participants shall learn and understand the different aspects and actively join the discussion about the following questions: What can regulators learn from science? What can scientists contribute to regulation? How can research support regulation? What is the current status of new methodology in regulation of herbal and traditional medicines? Which are the challenges of the future?

PROGRAM

Regulatory Affairs and new analytical methodology – status and future

Monday, 2nd September 2019

14.35 – 14.50	Werner Knöss (BfArM, Germany) Welcome and introduction New analytical methodology and regulatory affairs
14.50 – 15.15	Dr. Caroline Howard (De Montfort University, Leicester, UK) PCR, NIR, Chemometrics, Pharmacopeia perspective
15.15 – 15.40	Dr. Stefan Schönbichler (Bionorica research GmbH, Austria) Hyphenated methods, development, industry perspective
15.40 – 16.15	Coffee Break
16.15 – 16.40	Prof. Dr. Johannes Novak (University of Vienna, Austria) PCR-related methods
16.40 – 17.15	Panel discussion