Session 4: Aspects of Formulation

Regulatory aspects of pharmaceutical quality with dermatics

Dr. Britta Tofern-Reblin and Prof. Dr. Usfeya Muazzam
Federal Institute for Drugs and Medical Devices
Kurt-Georg-Kiesinger Allee 3
D-53175 Bonn

The regulatory framework for the quality assessment of marketing authorization procedures of drug products is outlined. An overview of the quality dossier is presented.

The pharmaceutical development of topical dermatological products should include characterization of the properties of the active substance with focus on those attributes which may influence performance, efficacy and safety of the drug product. Compatibility between active substance and excipients should be ensured. The choice and function of excipients should be explained. The need for antioxidants and preservatives should be justified concerning the quality and stability of the finished product as well as regarding the patient groups (e. g. paediatric use). For novel excipients, detailed information concerning manufacture, characterization of structure, physical properties, chemical properties, purity, specifications, validated analytical procedures as well as data to support the safety of the novel excipient need to be provided. Formulation development should be described. Overages need to be justified. Physicochemical and biological properties should be characterized, and parameters critical to the quality of the drug product should be identified. The development of the manufacturing process should be described. Critical manufacturing steps and process conditions should be outlined.
The suitability of the container closure system for storage of the drug product should be shown. The possibility for leachables of primary packaging components into the drug product as well as the possibility of sorption phenomena should be addressed.
The microbial requirements for topical dermatological products and demonstration of antimicrobial efficacy are discussed.
Tests of the final drug product and stability tests are outlined.

Issues of the quality documentation which can be optimised are summarized.