**Specific challenges for CMC Statistics after approval**

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‘During the development of a new drug the application of Chemical, Manufacturing and Control (CMC) statistical methods are usually more than helpful to enable the submission within short time and to achieve a successful approval by the authorities. After getting the marketing authorization the situation is changed with the company’s focus now on continuously assuring the quality of the product and continuously supplying the market. This change has impact on the expected support of CMC Statistics including the choice of appropriate statistical methods which might be different from the ones in the development phase. E.g., any (even minor) post approval change of the drug product or manufacturing process requires an adequate equivalence statement. This talk is about the challenges for CMC Statistics in the product life cycle phase after approval and during marketing authorization and includes aspects such as changing the perspective from UQL to AQL testing, equivalence testing, continued process verification and monitoring of ongoing stability studies.’