

Fit-for-purpose pharmaceutical analytical methods

Analytical Quality by Design explained with Capillary Electrophoresis methods as examples

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In this presentation, a practical and pragmatic overview is given, translating the new ICHQ14 guideline and Analytical Quality by Design (AQbD) into a method development workflow. The AQbD process workflow will be illustrated with examples from capillary electrophoresis CE methods, but naturally the AQbD workflow application is applicable to all method development, even outside the realm of pharmaceutical analytical chemistry. This will include a demonstration that AQbD encompasses a lot more than Design of Experiments (DoE) method optimization or robustness testing.

Although originally designed for the pharmaceutical industry, the usefulness or not for applying AQbD outside the pharmaceutical industry will be discussed, as well as what or what not (aspects of) AQbD can contribute to analytical science.

Prof. Dr. Cari E. Sanger – van de Griend is founder and scientific consultant at Kantisto in The Netherlands and she is associate professor at the Division of Analytical Pharmaceutical Chemistry, Department of Medicinal Chemistry, Faculty of Pharmacy at Uppsala Universitet in Sweden.

In her daily work, Cari supports industry and institutes in the field of pharmaceutical analytical chemistry, Analytical Quality by Design (AQbD), and in the Capillary Electrophoresis (CE) technologies. The handouts of her yearly “Advanced CE method development, validation, and troubleshooting course” are considered the CE bible for method development.

Cari received her MSc from Universiteit Leiden and her PhD and habilitation from Uppsala Universitet. She previously worked for TNO (the Netherlands Organization for Applied Scientific Research), Astra Pain Control, AstraZeneca, Solvay Pharmaceuticals, and Abbott Healthcare Products.

In her spare time, Cari is Associate Professor Analytical Pharmaceutical Chemistry at the Faculty of Pharmacy, Uppsala Universitet, and lectures and supervises currently in Sweden, Germany, Poland, and Switzerland. She is chair of the EDQM CE working party and member of the EDQM AQbD working party, Associate Director at CASSS, and on the CASSS organizing committees of Analytical Technologies Europe and The Netherlands Area Biotech Discussion Group.

Cari won the prestigious CEParm award 2015 for sustained and significant contribution to the practical application of Capillary Electrophoresis to the analysis of biotechnology and pharmaceutical products. Quotes from the committee: “Cari advocates tirelessly for scientifically sound CE method development and for the use of CE to ensure the quality of pharmaceutical products. She enabled acceptance of CE in the pharmaceutical industry and provides essential input to the community by teaching and otherwise sharing knowledge.”