

The Use of Capillary Electrophoresis in the Biotechnology and Pharmaceutical Industry

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The workshop will comprise of a series of short presentations by leading industrial experts on their experiences encountered during the routine application of CE methods in the pharmaceutical/biopharmaceutical industry.

The presentations will highlight uses of CE in various areas of pharmaceutical product development e.g. product characterisation, QC lot release, ICH conform stability testing, etc. all areas requiring robust analytical test methods.

Examples for efficient method development, method validation and QC batch release (e.g. for small molecule pharmaceuticals as well as biopharmaceuticals) are given. Validation parameters (including precision, accuracy, linearity), acceptance criteria and results of CE assays used in QC batch release testing of (bio)pharmaceutical compounds will be discussed.

The workshop will be open for all attendees to raise questions and will allow for open discussions of specific techniques and/or applications.

Industrial experts:

Steffen Kiessig, Solvias AG: QC N-Glycan Analysis of therapeutic glycoproteins

Oscar Salas-Solano, Genentech, Inc.: CE-MS for N-glycan characterization and CE-SDS, cIEF

Fabian Stapf, Solvias AG: Chiral Separation

C.E. Sanger-van de Griend, Solvay Pharmaceuticals BV: Small Molecules

W. Nashabeh, Genentech, Inc.: Regulatory Aspects of CE Methods