

CE in biopharma science: it's more than GCE and cIEF - Unexploited applications from the sewing box.

Maria. A. Schwarz, Claudia Michael*, Cristina Montealegre*, Solvias AG, Switzerland

Solvias AG, Römerpark 2, CH-4303 Kaiseraugst, Switzerland

Solvias is a Contract Research Organization (CRO) near Basel (Switzerland), focus on innovative solutions for the complex challenges that the customers face in the pharmaceutical, cosmetic and medical device/medtech industries. In the CE-field, Solvias offers profound know-how and expertise to fully leverage the benefits of CE during all stages of method design – from feasibility, over method development and pre-validation, to validation and routine analysis.

GCE-SDS and cIEF are powerful and well accepted analytical techniques for a wide series of methods used in the biopharmaceutical industries. With the rise of additional modification of biopharmaceuticals such as ADCs or pegylation or the trend to monitor additional characteristics of the product such as glycation or post-translational modification, the challenge to separate differently modified proteins and peptides variants has increased. While some generally do not cause problems, for others it is necessary to go back to the drawing board and have a deep look into the sewing box for a suitable separation strategy. While HPLC and the above mentioned CE techniques are power horses for standard test, there are several problem and limitation for them. With increasing demand for more detailed analyses, either as a specific customer request or because of a lack of an analytical method, the need for special applications also increases.

We will present some examples showing “alternative” CE methods to address some actual questions in biopharmaceutical analysis as **pegylated peptides, monoclonal antibody glycation, or deamidation**. For each of these examples we will outline the specific underlying problem for either HPLC or the most commonly used CE method and why CZE is a suitable technique. This showcasing of different CE applications should spark the innovation for novel analytical methods.