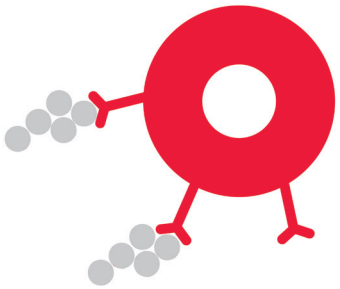
EXPERT INSIGHTS

TOSOH

ROCHE DIAGNOSTICS GmbH
PHARMA TECHNICAL DEVELOPMENT ANALYTICS

Tosoh Bioscience: Could you give us a short summary of your activities within the Roche group?

Dr. Ruppert: Our group is responsible for release analytics, stability testing and extended characterization for biologics tox and clinical supply. Another important focus area of our work is the evaluation of new technologies as well as implementation and validation of new methods for Quality Control and extended characterization.



You presented a poster at the CASSS 2017 about UHPLC analysis of bi-specific antibodies. What was the key driving force to develop a UHPLC method for this target molecule?

To ensure high safety standards of our products, it is of absolute importance to reliably monitor product related impurities. As our product pipeline contains more and more advanced and complex antibody formats, there is a need to constantly improve our repertoire of methods to assess potential new product related impurities with highest possible resolution and sensitivity. Our new SE-UHPLC method is exemplary for this approach, enabling us to increase the sensitivity for detection of product related impurities during quality control while providing shorter run time and increased robustness.

You evaluated two UHPLC columns for this project: a TSKgel UP-SW3000 column and an UHPLC column from another supplier. Why did you end up selecting the Tosoh column as your standard UHPLC column?

We were testing several columns from different vendors with a variety of our pipeline products. Although, several columns showed a comparable resolution, the Tosoh TSKgel UP-SW3000 column (2 µm, 4.6 x 30 mm) convinced us in terms of robustness, especially the high lot-to-lot stability, an absolute requirement for quality control under GMP conditions.

What do you think will be the key challenges for analytics of biomolecules in the future?

1. The need for increased analytical throughput: automated solutions for the entire analytical workflow (from sample preparation to data evaluation), shortened run time.
2. Requirement for increased sensitivity and resolution to enable separation of product variants and impurities with subtle molecular differences.
3. High effort to screen the constantly increasing market for bioanalytical solutions meeting the above mentioned requirements.

Members of the team involved in the project:

From left to right: Alexander Knaupp, Dr. Friederike Winkhaus, Georg Hafenmair, Dr. Michael Leiss, Dr. Raphael Ruppert

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