

## INVITATION TO VWR BIO-CHROMDAY

### NUMBERS ARE LIMITED!

To reserve your place, please email [marcomsuk@vwr.com](mailto:marcomsuk@vwr.com) with "BIO-CHROMDAY" in the subject.

### Date:

Tuesday, 19th September

### Time:

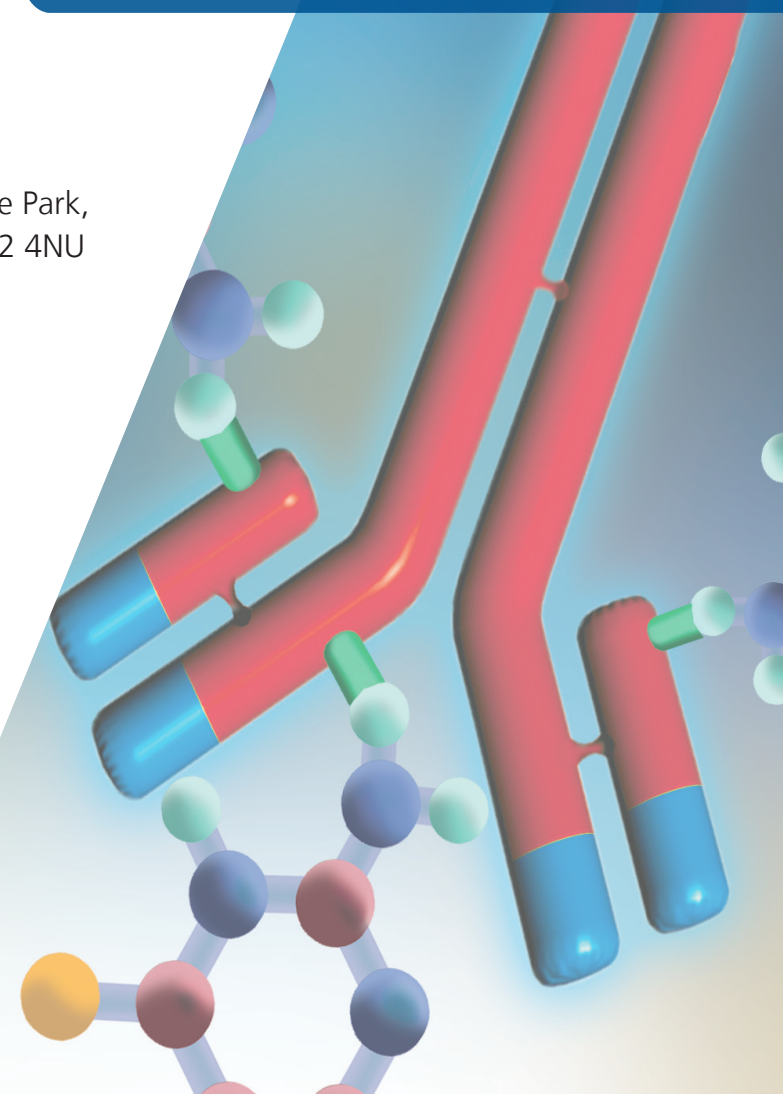
10:00 am to 4:30 pm

### Location:

University of Chester,  
Conference Room 245,  
Building 49, Thornton Science Park,  
Pool Lane, Ince, Cheshire, CH2 4NU

### Agenda:

|               |  |  |
|---------------|--|--|
| 9:00 - 9:55   | Registration, Refreshments & Exhibition    |  |
| 9:55 - 10:00  | Welcome                                    |  |
| 10:00 - 10:35 | Gemma Lo (Hichrom)                         | A Review of Biomolecule Characterisation Techniques  |
| 10:40 - 11:15 | Robert van Ling (Thermo Fisher Scientific) | Peptide Mapping - An Innovative Approach to Simplify a Workhorse Application                             |
| 11:15 - 11:45 | Exhibition & Refreshments                  |  |
| 11:45 - 12:20 | Egidijus Machtejevas (Merck Millipore)     | New Global Trends and Challenges in Biomolecule Separations: Chromolith WP                               |
| 12:25 - 13:00 | Robert van Ling (Thermo Fisher Scientific) | High Molecular Aggregates and Charge Variants – Characterising Two Critical Quality Attributes           |
| 13:00 - 13:45 | Lunch & Exhibition                         |  |
| 13:45 - 14:20 | Peter Bridge (VWR)                         | Automated HPLC Method Development for Monoclonal Antibodies  |
| 14:25 - 15:00 | Alex Obiakor (Tosoh Bioscience)            | Sophisticated Chromatography Solutions for Downstream Processing and Analysis of mAB Related Targets     |
| 15:00 - 15:10 | Break                                      |  |
| 15:10 - 15:45 | Robert van Ling (Thermo Fisher Scientific) | New Reversed Phase Chromatography for LC and LC-MS Characterisation of Intact and Sub-unit mABs and ADCs |
| 15:50 - 16:25 | Tomas Kostelec (BIA Separations)           | Enabling Biologics: Macroporous Monoliths for Virus, Vaccines and Phage Purification                     |
| 16:25 - 16:30 | Close                                      |  |



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## Biomolecule Characterisation Techniques

With an increased interest in the area of biotherapeutics and more regulations focused on these pharmaceuticals, possible methods to characterise biomolecules are required. Choosing the most appropriate method for your biomolecule can be a challenge. Chromatographic modes such as size exclusion, ion-exchange, hydrophobic interaction and affinity chromatography will be outlined for intact biomolecules helping you to choose the best approach.

## Automated HPLC Method Development for Monoclonal Antibodies

Software can often be an overlooked component to the bigger picture of chromatography. Recently there have been some good developments in software, which can enhance user experience and improve efficiency in the laboratory. This short presentation, with a focus on method development, aims to give an enlightening overview of the possibilities that exist when software is considered to be a key tool in chromatography.

## Peptide Mapping - An innovative Approach to Simplify a Workhorse Application

Peptide mapping is a fundamental technique employed in biopharmaceutical applications. Typically proteomics oriented protein digestion protocols are used to prepare the sample and, despite its widespread use, protein digestion still proves to be an analytical challenge. The optimum digestion requires conditions that unfold the protein/proteins of interest, cleave the proteins after every lysine and arginine and reduce autolysis effects. This can be a lengthy and complex process and often leads to poor reproducibility. In this presentation we describe an innovative and simplified digestion platform for biotherapeutic proteins. This novel workflow removes uncertainties associated with conventional solution-based tryptic digestion protocols. Applying immobilised and heat-stable trypsin technology combined with optimised buffer conditions results in reduced user-dependency, higher reproducibility and superior sample characterisation.

## New Reversed Phase Chromatography for LC and LC-MS Characterisation of Intact and Sub-unit mABs and ADCs

Mass spectrometric analysis of antibodies at the protein and sub-unit level is becoming more and more important during development and production of biopharmaceuticals. In particular the analysis of antibody sub-units often provides additional and complementary information with the advantage of requiring very little sample preparation. Reduction is an optional step in the sample preparation and when combined with enzymatic digestion with IdeS results in ~23-25 kDa subunits. Subunits in that molecular weight range are most amenable to top-down analysis and can provide the highest sequence coverage. This presentation will focus on the separation and MS detection of multiple commercially available mABs, under different reduction conditions, for unambiguous determination of accurate intact masses of the subunits.

## Enabling Biologics: Macroporous Monoliths for Virus, Vaccines and Phage Purification

Increasing demand for biomolecules as therapeutic drugs and gene therapy vectors has incentivised the development of new purification tools. As one of the most common techniques in downstream processing, chromatography is increasingly moving from particle-based resins to membranes and monoliths. This type of rigid resin, while operating under the same basic principles for particle-resin interaction, introduces mass-transport characteristics suited to the size of the particles. BIA Separations is pioneering in the production of monolithic columns which enable efficient and robust downstream processes at an industrial scale. The talk will look at the properties of monolithic chromatographic columns in the context of purification of biomolecules, covering basic principles as well as applications.

## Sophisticated Chromatography Solutions for Downstream Processing and Analysis of mAB Related Targets

In this presentation we talk about Tosoh's new solutions to affinity-based capture of mAB, Fab and svFv and look at salt-tolerant ion-exchange resins for mAB polishing. We conclude by sharing some tips and tricks for (U)HPLC analysis of mAB.

## New Global Trends and Challenges in Bio-molecule Separations: Chromolith WP

Biotherapeutics such as bio-engineered drugs, peptide therapeutics and the complete field of biotechnology represents the promise of new medical treatments for the new millennium. That implies a demand of suitable analytical methods for process monitoring and quality control of biomolecules with therapeutic purposes. HPLC is the most widely used analysis method with the properties of the column being extremely important. As a rule of thumb it is widely accepted that in order for the separated molecules not to be influenced by size exclusion processes the pore should be at least 10 times bigger than the molecule. Therefore a 100 kDa molecule would require around 300 Å pores. Chromolith columns already shown great potential and superiority compared to standard silica particles. In contrast to conventional packed particle columns, wide pore (300 Å) monolithic silica columns are made of a single continuous-bed rod of high purity porous silica that is then bonded with C18, C8, C4, epoxy and Protein A. Monolithic columns remove backpressure as the primary consideration in method development and give back the flexibility of choices in flow rates for much higher throughput, column lengths for superior resolution and solvent choices for optimum selectivities. Because they have no individual particles to shift or break the column performance is very consistent over much longer lifetimes. This makes them ideal for relatively "dirty/ matrix rich" sample analysis. Their high permeability also makes them very forgiving of shortcuts and timesaving in sample preparation as well as easier to aggressively flush out to re-equilibrate. This presentation will guide you through the world of monolithic silica materials. Benefits will be demonstrated with many application examples including pharmaceutical and bioanalysis separations (proteomics, peptidomics, etc.), calibration curves, recovery calculations, and method robustness overviews. Numerous real life application examples will be provided to show the usability and advantages of monolithic wide pore silica materials. New possibilities of modifying epoxy activated columns will be highlighted, for example creating online column reactors.

## High Molecular Aggregates and Charge Variants – Characterising Two Critical Quality Attributes

With the continued development of mAB-based biotherapeutics, multiple key quality attributes need to be measured and controlled to guarantee their safety and efficacy. Aggregates are typically dimers, trimers, or larger order structures of antibody molecules. Protein aggregation has been implicated as the cause of adverse immunological reactions that result in serious safety and efficacy issues. mABs can also exhibit changes in charge heterogeneity during production and purification which can impact stability and activity and cause adverse immunological reactions. In this presentation we will discuss the chromatographic possibilities to optimise and simplify chromatographic techniques such as size exclusion and ion exchange to target these specific critical attributes.

## HOW TO FIND US:

Thornton Science Park is the former Shell Technology and Research Centre. It is situated close to J14 of the M56 or J10 of the M53. On-site parking will be available for delegates attending this event. A visitors pass and directions to the car park and seminar room will be provided at the gatehouse.

This seminar is FREE and lunch will be provided. However, spaces are limited!

To reserve your place, please email [marcomsuk@vwr.com](mailto:marcomsuk@vwr.com) with "BIO-CHROMDAY" in the subject.