Interview with John Rontree,

Director of Marketing, Pharma & Biopharma,

Thermo Fisher Scientific Inc.

As a former life scientist with a Ph.D. in LS/MS in Pharmaceuticals from Swansea University (UK), and a career immersed in the field of analytical solutions for pharmaceutical development and testing, I am excited by the paradigm shift in the industry with the reinvention of biotherapeutics. My expertise lies in holistic LS-MS solutions for clinical and pharma laboratories and my focus has been providing technology solutions to the scientific community. My interests in developing and marketing analytical solutions have spanned numerous markets including pharmaceutical and biopharmaceutical, clinical diagnostics, OMICS, biotechnology, geochemistry, academia environmental food analysis, nuclear, planetary sciences, toxicology, drugs of abuse, environmental monitoring, proteomics and metabolomics.

1. How did you get into the ADC field?

Thermo Fisher Scientific has been a leading supplier of chromatography and mass spectrometry (MS) in the field of proteomics for over two decades. With these technology platforms, scientists have been able to conduct fundamental research of the proteins in biological pathways and the identification of protein biomarkers. Many of those who have worked in this field are now utilising their skills and knowledge in the application of proteomics in the biopharma industry for drug targeting and complete protein characterization of monoclonal antibody (mAb)-based drugs. The power of chromatography and MS to completely and reproducibly characterise mAbs has made the analysis of ADCs a natural progression for our company.

2. What is the most exciting project you are working on?

The resolution and specificity of Ultra High Performance Liquid Chromatography (UHPLC) combined with the High Resolution Accurate Mass (HRAM) capabilities of the Thermo ScientificTM OrbitrapTM-based MS systems has afforded scientists the unique opportunity to confidently measure complex mixtures of proteins. The masses of ADCs and their conjugated variants can be identified in their intact native forms and measured to within a few Daltons. Hydrophobic Interaction Chromatography (HIC) and reversed phase (RP) chromatography are suitable for the separation of ADCs since attachment of the toxic payload alters the hydrophobicity of the mAb. By separation of the individual ADCs we can accurately determine the drug : antibody ratio (DAR) of the molecules that make up the therapeutic. We have worked hard to build a tailored suite of chromatography stationary phases. Our bespoke Thermo Scientific™ MAbPac™ HIC columns and MAbPac™ RP columns are designed to efficiently and reproducibly separate individual DAR variants and their isomers.

3. What do you see are the biggest challenge in ADC development?

Robust and uniform linkage of the payload with the analytical methods to characterise the linkage still needs further advancement if we are to drive these technologies into routine quality control environments in biopharrma.

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4. What changes have you seen in analysis approaches over the last 12 months?

Development of new HIC column chemistries and polymeric RP chemistry to pick out the DAR ratios have allowed the quality of results to be significantly enhanced. Further developments in 2-dimensional UHPLC to look at the free payload present in the ADC samples is also emerging. We strive for simplification and inherent robustness of methods to allow us to adopt these technologies in a high throughput manner to drive these technologies into the QA/QC space within biopharma.

5. What impact do you see these technologies having in 2016?

Wider adoption of integral chromatography and MS workflows will afford scientists increased confidence and throughput in ADC analysis. Further developments in MS, particularly in high mass native analysis will also impact the advancement of characterisation of native forms of ADCs.

6. What are you hoping to get out of World ADC Berlin?

The forum provides a concerted look into advances in ADC design and the requirements for the analysis of ADCs, both now and in the future. Many of our customers attend this event providing an important opportunity to receive feedback on our current product capabilities and the potential for new product advancement.

A huge thank you to John for taking the time share his experiences with us.

If you enjoyed reading about John's experience and the current work at Thermo Scientific, his colleagues will be on-site at World ADC Berlin for discussion around current needs and challenges on ADC characterization.

World ADC Berlin Summit 2016, February 8th -10th

For more details go to: **www.worldadc-europe.com**