SPEAKER INSIGHT FROM **JOHN SMERAGLIA**

John Smeraglia,
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John is Senior Director of Bioanalytical Sciences in Non-Clinical Development at UCB with laboratories in the UK and Belgium. He has responsibilities for bioanalytical sciences to enhance and revolutionise the way that the quantitative bioanalysis and biomarker assays are performed from pre-clinical development to post marketing for NBE's and NCE's. He is also responsible for providing bioanalytical leadership for the quantification of mechanistic biochemical biomarkers to advance drug development. John has held bioanalytical leadership positions in the US and EU with innovator drug development companies and CROs. Achieving his first degree in Medical Technology (B.Sc.) and his second degree in Biomedical Sciences (M.Sc.). He has developed his experience in bioanalytical sciences for the last 26 years.

What issues faced the biomarkers industry in 2017?

Recently there has been a big push by the agencies around the c-path initiative and what is required to develop and validate biomarker assays. I think that's a key element to how we think about these assays and how we link them to clinical efficacy and clinical utility, so we truly understand both the context of use and how the analytical tools will be able to match up closely to that context of use.

So, the focus has been very much on that in 2017, effectively responding to the regulatory agency and their expectations, to ensure that the analytical tools link very closely to the clinical development paradigm and ultimately getting out biomarkers that are appropriate for disease modification and disease progression.

What will be the biggest technology impact for 2018?

In the area that I work in, which is targeted protein quantitation, there are a couple of key developments that have come through. One is on the utility of mass spectrometry in targeted protein quantitation and effectively it's a progression of the technology, specifically to look at low-abundance proteins and using tools such as nanoflow LC along with antibody capture techniques. One of the challenges is to do with how fast that's moving in the pharma industry. Secondly, I'd say the advancement of low-abundance immune-analytical tools and there are a range of platforms that focus on very low-level sensitivities.

Why did you choose to work within this industry?

I think this industry really links up the interests I have in analytical technology, but then also linking that up closely to what it means from a patient value perspective and when you then develop clinical designs and clinical strategies, along with biomarker strategies that truly help us to either aid our knowledge about disease progression or disease modification, that's where the interest lies for me.

What inspires you within your current role?

Currently, we are merging a lot of the clinical development strategies with analytical tools and therefore, working with our clinical staff to understand what the actual context of use is, to help develop the analytical tools to get to more appropriate markers and characterisation of disease. I think that's what inspires me, the link between analytics and what patient value really looks like ■

This interview is an excerpt from our Speaker Insight videos, in which experts at our events answer questions on the state of the industry. Follow the link below to hear from:

- Claire Huguet, Head of Biomarkers, Randox
- John Allinson, Vice President, Biomarker Services, Biologics Development Services
- David Henderson, Director - Statistical Genetics, Axio Reach
- Oliver Poetz, Head of Protein Analytics, University of Tuebingen
- Erik Bennink, Key Account Manager, Luminex
- Daniel Garcia West, Biomarker & Protein Specialist, Merck
- Ben Chaffey, Scientific Business Development Manager, Newgene