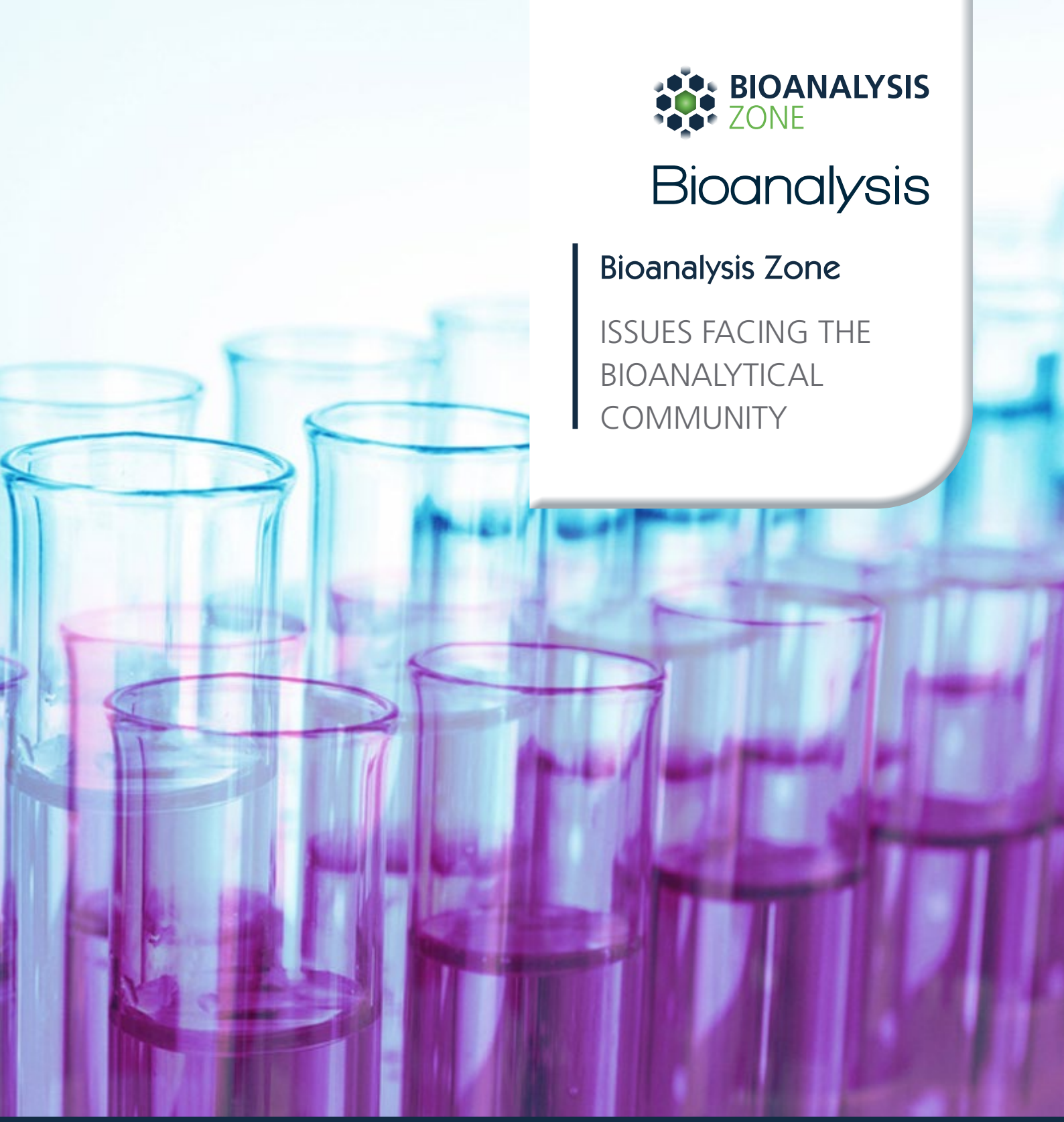

BIOANALYSIS ZONE

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ISSUES FACING THE BIOANALYTICAL COMMUNITY

Issues Facing The Bioanalytical Community: Highlights From The Bioanalysis Zone Round Table Discussion

fsg CONNECT

FOREWORD

Dear colleague,

It is my pleasure to welcome you to this special Bioanalysis Zone interactive supplement, which has been created to bring you the highlights from our recent Bioanalysis Zone Round Table Discussion on Issues Facing the Bioanalytical Community.

Bioanalysis Zone and *Bioanalysis* organized an independent Roundtable Discussion on 20 April 2016 at Hilton Orlando Lake Buena Vista, Orlando, Florida, USA, in which bioanalytical experts from Pharmaceutical Companies (Pharma) and Contract Research Organizations (CROs) were brought together to discuss topical issues faced by the quantitative bioanalytical community.

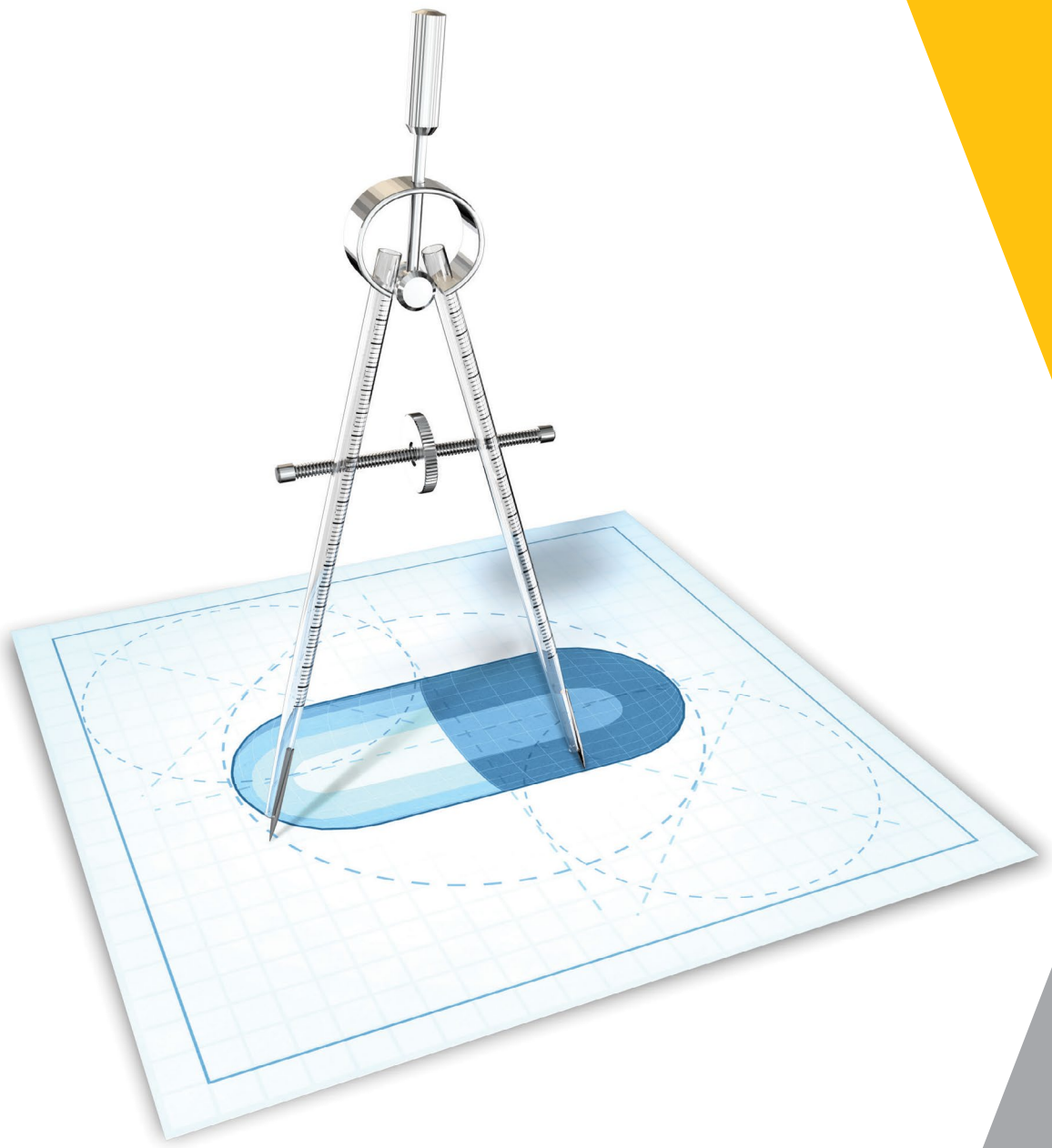
Chaired by Neil Spooner (Senior Editor, Bioanalysis), the discussion focused on three key areas. First, the panellists assessed the current situation of outsourcing in bioanalysis, and discussed the direction of outsourcing of regulated bioanalysis in the future. Next, discussions on the divide between investments being made by Pharma and CROs in new bioanalytical techniques and technologies were discussed. Finally, the growing skills gap in bioanalytical laboratories was discussed covering aspects such as: the reality of the skills gap; technical areas is which the skills gap is most apparent; where the skills gap occurs; and how can it be overcome.

Having been part of the organizing team, witnessing the discussion unfold was highly informative. It helped my understanding of the depth of issues facing the bioanalytical community and future opportunities to overcome these issues. I am therefore delighted to be able to share this free supplement where you will find highlights from the resulting Round Table Discussion Report published in *Bioanalysis* and links to footage of the discussion, hosted on Bioanalysis Zone.

I hope you also enjoy this supplement and would love to hear your thoughts on the subjects discussed, so email, tweet or comment on the associated articles and videos.

Sankeetha Nadarajah

Commissioning Editor, *Bioanalysis*



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HIGHLIGHTS FROM THE BIOANALYSIS ZONE ROUNDTABLE REPORT

Click here to watch Part 1 of the Round Table Discussion

OUTSOURCING STRATEGIES

The CRO participants were keen to understand the outsourcing strategy of Pharma to help them put together their business plans. The consensus was that for small molecules, the bioanalytical work is considered more routine and hence has, to some extent, become commoditized. Therefore, the strategy for most Pharma companies is to outsource the majority of small-molecule regulated preclinical and clinical work, with some degree of support from internal Pharma bioanalytical groups. However, for the increasing numbers of biopharmaceuticals and the novel constructs that are coming through different company pipelines, outsourcing by Pharma depends on the ability of CROs to invest in the equipment and staff required to support the analytical challenges and more complex assays that are arising from these molecules.

It was noted that smaller biopharmaceutical companies and large Pharma may have quite different requirements for bioanalytical outsourcing. Small companies may have little capability in this area and so are more reliant on the CROs for all aspects of method development, validation and study support, using them as a virtual laboratory. Whereas larger Pharma are likely to have some in-house bioanalytical capability that is capable of supporting some, if not all of these aspects. In addition, it was observed that smaller biopharmaceutical companies tend to place the support of a larger proportion of their early phase (discovery) studies out to contract. These studies often tend to be on the critical path for project progression and so the timelines for delivery of analytical data are often more aggressive than those for later development phase studies.

The panelists held the opinion that there is an increasing requirement and value in being able to work with CROs who offer an integrated approach, particularly for preclinical studies where the hand-offs between study directors and principle investigators for the in-life and bioanalytical aspects can become very complex, particularly when they are on different sites, or are part of different companies.

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INVESTMENT IN NEW TECHNOLOGIES

There was a general perception from Pharma panelists that it is difficult for them to outsource the bioanalysis of new molecular constructs, or analyses involving novel workflows, particularly when investment in new analytical approaches and equipment is required. In addition, it was observed that some CROs prefer to invest in more headcount, rather than the implementation of routine sample handling automation. The discussion confirmed that this was often the reality and that CROs are traditional followers, rather than leaders when it comes to the implementation of novel approaches. They tend not to have spare resource to invest in the research required to be an early adopter of new technologies. It was observed that Pharma clients often want workflows to be performed in a certain way, while CROs find it easier to make capital investments if they can be used across a broad range of clients, so technology has to be flexible. However, some Pharma companies are open to their suggestion and preferred workflows being used by other clients of the CRO. It was considered that this can be particularly beneficial in the discovery environment, where it can help drive down costs.

Pharma often ask CROs to invest in the identical platform to that being used in the Pharma company's own laboratories. In these cases, there is generally very little leeway for the CRO to suggest alternative approaches, or instrumentation that might attain the same endpoint. Different Pharmas often ask for different approaches, so the CRO needs to consider the cost benefits carefully. There was some openness by Pharma to consider alternative approaches to achieve the same goal.

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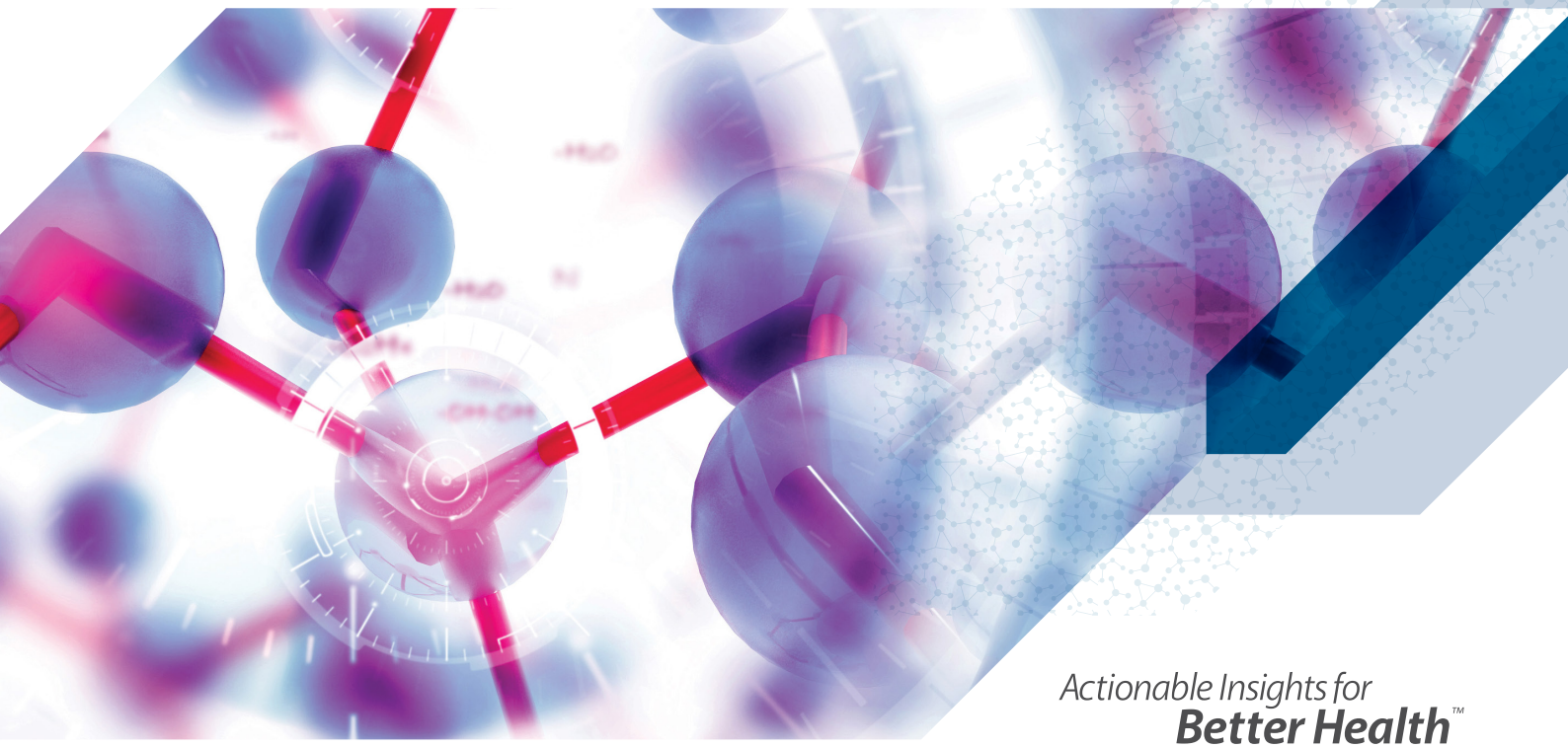

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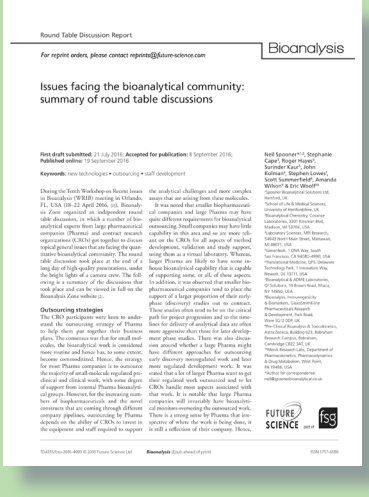
Click here to watch Part 3 of the Round Table Discussion

You can view the full Round Table Discussion Report published in *Bioanalysis* online (Spooner N, Cape S, Hayes R *et al.* Issues facing the bioanalytical community: summary of roundtable discussions. *Bioanalysis* 8(21), doi: bio-2016-4993 (2016) (Epub ahead of print).


Round Table Discussion Report

Bioanalysis

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Issues facing the bioanalytical community: summary of round table discussions

BIOANALYTICAL SKILLS GAP

This part of the discussion centered on whether there is a growing skills gap for bioanalytical scientists in both Pharma and CROs. Whether the impact of such a gap is leading to difficulties in developing suitable approaches and innovative workflows for the analysis of novel construct molecules, including ease of assay transfers and technology between laboratories were explored. Scientists with a strong chemistry and some biology background were traditionally sought by bioanalytical laboratories, where the drug entities could be defined as small molecule white powders that could be analyzed routinely by simple sample preparation followed by LC–MS/MS. However, these skills are no longer considered to be enough now that Pharma are increasingly moving toward novel molecular constructs and modes of action.

It was stated that there is a growing realization that staff need to be trained, rather than recruited with the required skills already in place. This requires that Pharma and CRO companies make a longer-term investment in their staff and provide them opportunities to develop as bioanalysts and in broader aspects of drug development and scientific leadership, and reward them for success in these endeavors. This led to a discussion around possible routes forward for staff training. It was proposed that bioanalytical groups in Pharma and CROs could work together to develop industry training courses, building on the success of current offerings from meetings such as WRIB, AAPS and so on. Another idea was that CROs could offer a hands-on training service for other bioanalytical laboratories. This could be reciprocated with Pharma companies opening their doors to CRO staff to enable them to learn the broader aspects of drug development and where bioanalysis fits into the jigsaw puzzle.

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PANEL BIOGRAPHIES

NEIL SPOONER
SPOONER BIOANALYTICAL SOLUTIONS LTD

Neil Spooner (Ph.D., C.Chem., M.R.S.C.) is the Founder and Director of Spooner Bioanalytical Solutions, a consultancy based in Hertford, UK. Neil is also a Senior Visiting Research Fellow at the School of Life and Medical Sciences, University of Hertfordshire (Hertfordshire, UK) and the Deputy-Chair and Secretary of the Reid Bioanalytical Forum. He has published extensively, with over 50 peer reviewed manuscripts and more than 30 podium presentations at international Conferences and Symposia.

Neil has extensive experience in the quantitative bioanalysis of drugs, metabolites and biomarkers in the pharmaceutical industry and contract research organisations in the UK and USA. In over 20 years of industrial practice at GlaxoSmithKline, he has led groups operating in the discovery and regulated arenas of clinical and pre-clinical quantitative bioanalysis and metabolite identification. Neil has extensive experience of successfully leading inter departmental and cross functional initiatives, including implementation of new technologies and workflows (such as microsampling), outsourcing quantitative bioanalysis, development and implementation of automation approaches and design of new scientific facilities.

AMANDA WILSON
DIRECTOR AND GLP TEST FACILITY MANAGER
ASTRAZENECA

Amanda is the Director and GLP Test Facility Manager for the pre-clinical bioanalysis and toxicokinetics (BA/TK) department in the Drug Safety and Metabolism function at AstraZeneca.

Amanda started her career as a bioanalytical scientist at Fisons Pharmaceuticals and has spent over 20 years in the pharmaceutical industry working in multiple DMPK disciplines supporting both small and large molecule projects.

Amanda, in her current role, has the responsibility for the delivery of bioanalysis and toxicokinetic data for non-GLP investigational toxicology and early pivotal toxicology evaluation of small molecules and nucleotide therapeutics. The BA/TK team also provide scientific and regulatory compliance guidance to the AZ externalization and Early Clinical Development functions.

ERIC WOOLF
DIRECTOR CLINICAL REGULATED BIOANALYSIS GROUP
MERCK RESEARCH LABORATORIES

Dr. Woolf currently directs the Clinical Regulated Bioanalysis Group of Merck Research Laboratories, West Point, PA. He received his B.A. in Chemistry from LaSalle College in 1982, and a Ph.D. in Analytical Chemistry from Seton Hall University in 1986. From 1986 to 1990 he was a member of the Drug Metabolism/Pharmacokinetics Dept. of Berlex Laboratories.

He joined Merck Research Laboratories in 1990 as a research fellow. Dr. Woolf and his group have supported numerous clinical development projects that have led to the successful registration of Merck compounds. Since 1986, he has authored or co-authored over 50 research papers pertaining to bioanalysis and pharmacokinetics. His major research interests include the utilization of novel HPLC approaches in bioanalysis and the bioanalysis of unstable compounds.

JOHN KOLMAN
EXECUTIVE DIRECTOR HEAD OF TRANSLATIONAL MEDICINE
QPS

John Kolman is the Executive Director and Head of Translational Medicine at QPS. He has over 20 years of experience in the pharmaceutical R&D industry, and has held multiple leadership roles. He is also well known throughout the industry for his scientific leadership, as evidenced by recent speaking engagements at fora such as the World PGx (Pharmacogenomics) Summit (San Francisco), the International Conference on Biomarkers and Clinical Research (Philadelphia), and the PDA/FDA (Parenteral Drug Association/Food and Drug Administration) Advanced Technologies for Virus Detection in Biologicals Conference (Bethesda). Kolman received his Ph.D. in Molecular Biophysics and Biochemistry from Yale University and his published works have appeared in such noteworthy periodicals as Science and Biologicals, and are pending with Applied Microbiology and Biotechnology, the Journal of Pharmaceutical Science and Technology, BioProcessing Journal, and in the PDA Press. His experience in biomarkers, biologics, pharmacogenomics, genetics, and bioinformatics has earned him recognition as an expert in these fields.

ROGER HAYES
SENIOR VICE PRESIDENT AND GENERAL MANAGER, LABORATORY SCIENCES
MPI RESEARCH

Roger Hayes, PhD, is Senior Vice President and General Manager, Laboratory Sciences, at MPI Research. Before joining the company in 2011, Dr. Hayes has held numerous leadership positions in the global life sciences industry and academia, leading teams in the development of state-of-the-art bioanalytical and analytical techniques, including mass spectrometry, chromatography, and automation in bringing medical and chemical products to market.

For nearly two decades, he has led strategic and research initiatives for large pharmaceutical companies that included both GLP and non-GLP preclinical studies and clinical trials. At Merck Research Laboratories, Dr. Hayes directed the regulated bioanalysis group in support of preclinical and clinical safety trials and also advanced efficiencies for method development and validation. At Parke-Davis Pharmaceuticals, he managed the instrumentation support department, headed the bioanalytical groups for both safety and discovery research, and performed cutting-edge work as the leader of the drug metabolism mass spectrometry group.

Before 1993, Dr. Hayes spent several years at Procter and Gamble, where he developed new analytical technology and processes. His career is rooted in academia, beginning at the University of Adelaide in Australia, where he received his PhD in 1985 and performed innovative research in gas phase ion chemistry. From there, he went to the University of Nebraska-Lincoln, where he served as an assistant director/assistant research professor and continued his groundbreaking research, with an emphasis on advancements in the use of mass spectrometry. Most recently, he served as President of Bioanalytical Operations, at Cetero Research where he focused on establishing overall corporate direction for bioanalytical and analytical services.

Dr. Hayes has published extensively and has taught numerous aspects of LC/MS method development. He is an active member of the American Society for Mass Spectrometry and the American Association of Pharmaceutical Scientists.

STEPHANIE CAPE
ASSOCIATE DIRECTOR OF BIOANALYTICAL SCIENTIFIC OPERATIONS
COVANCE

Stephanie Cape, PhD, is the Associate Director of Bioanalytical Scientific Operations at Covance, Madison, WI.

She received her B.S. in Chemistry from University of IL- Urbana/Champaign in 2003 and her PhD in Analytical Chemistry from the University of Wisconsin-Madison in 2007. Dr. Cape's graduate research was focused on developing high resolution mass spectrometric methods to enable discovery, characterization, imaging, and quantitation of neuropeptides.

Dr. Cape joined the field of regulated Bioanalysis as a method development / validation chemist initially at PPD and subsequently at Covance. Within the Covance Bioanalytical team, she has held a variety of leadership roles including oversight of bioanalytical study direction, validation, and method development. Additionally, Dr. Cape serves as the primary operational lead for on-site regulatory inspections and participates in aligning global SOPs and best practices to industry standards.

SURINDER KAUR
ASSOCIATE DIRECTOR/SENIOR SCIENTIST IN BIOANALYTICAL SCIENCES
GENENTECH/ROCHE

Dr. Surinder Kaur is an Associate Director/Senior Scientist in BioAnalytical Sciences at Genentech/Roche in South San Francisco, California. She has twenty plus years of biotechnology experience across diverse large molecule and small molecule bioanalytical areas, with multiple successful regulatory filings, publications and patents. She received her B. Sc. in Chemistry from Durham University, England and a Ph. D. from the Chemistry Department at Bristol University, England. Dr. Kaur conducted post-doctoral research at the University of California, San Francisco in the laboratory of Al. Burlingame.

Dr. Kaur established the mass spectrometry core laboratory at Chiron Corporation to develop analytical methods for biotherapeutic process development and small molecule drug research. In 2001 she joined Lumicyte Inc. as a Proteomics Director, developing mass spectrometry biochip methods for biomarker discovery. She joined Genentech, Inc. in 2004 to establish a multi-disciplinary immunoassay and mass spectrometry group of approximately fifteen scientists and research associates responsible for the bioanalysis of antibody-drug conjugates (ADCs) through nonclinical and clinical development. Dr. Kaur's group is responsible for bioanalytical strategies and assay development/validataion for ADCs, including pharmacokinetic assays, immunogenicty assessment, in vitro biological characterization and metabolism/ catabolism strategies. She is also responsible for a mass spectrometry core facility establishing innovative approaches for biotherapeutics development and is a Pharmacology team leader for an oncology program.

STEPHEN LOWES
SENIOR DIRECTOR – SCIENTIFIC, BIOANALYSIS AND ADME
Q^2 SOLUTIONS

Prior to joining Q^2 Solutions in 2011, Dr. Lowes was an executive management scientific leader of Advion BioServices. Dr. Lowes started his industrial career at VG Biotech in the UK that became the LC/MS instrument entity of Waters Corporation. In 1995 Dr. Lowes joined the CRO group that became Advion and focused his career on regulated bioanalysis with particular emphasis on LC/MS. He has remained very connected on regulatory developments in bioanalysis and is a founding member of the Global Bioanalysis Consortium (GBC) and a past-chair of the AAPS Bioanalytical Focus Group. At Q^2 Solutions, Dr. Lowes leads the scientific disciplines around LC/MS bioanalysis for both small molecule and biomolecule applications including biomarker assays. Dr. Lowes has over 40 peer reviewed publications on bioanalysis and is a frequent speaker at national and international conferences.

Dr. Lowes earned his Ph.D. in analytical chemistry from the Open University, United Kingdom.

SCOTT SUMMERFIELD
WW HEAD OF BIOANALYSIS
GLAXOSMITHKLINE

Having studied for a PhD and post doctoral fellowship in proteomics Scott moved into the field of regulated Bioanalysis in 1997 when joining SmithKline Beecham. In 2001 Scott moved to Neuroscience Drug Discovery to lead a bioanalytical team supporting PK, in vitro DMPK and metabolite id work. In 2009 he returned to the regulated bioanalytical group, initially as a Section Leader and subsequently as Site Head and currently as WW Head of Bioanalysis at GSK. Scott has experience of small and molecule bioanalysis as well as leading both bioanalytical and discovery and development project teams across GSK.

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Sarah Bishop
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Subscriptions and Institutional Trials
Dominik March
✉ d.march@future-science.com

Editorial
Ayan Ali
✉ a.ali@future-science.com

Sankeetha Nadarajah
✉ s.nadarajah@future-science.com

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