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Reflecting on *Bioanalysis* with the Senior Editors

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A previous Senior Editor, and the present Senior Editor of *Bioanalysis* reflect on their journeys in the field of bioanalysis, and with the journal. They discuss the evolution and progress of journal since its launch 10 years ago, and where they would like to see it heading in the future.

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Howard M Hill (ResolvPharma)

Please introduce yourself & explain how your career in *Bioanalysis* began

My first job in bioanalysis was as a post-doc with the Wellcome foundation at the Middlesex Hospital working on the pharmacokinetics of pseudoephedrine and triprolidine. At the end of 3 years, I moved to Hoechst Pharmaceuticals in the UK as a team leader in bioanalysis working on fluorescent techniques for the measurement of drugs in biological fluids. This technique was rapidly superseded by HPLC using fluorescence detection systems. After almost 5 years, I moved to Germany in charge of the bioanalytical laboratory supporting a largely Phase I clinical operation of the Iphar Institute near Munich. We were one of the first laboratories to test volunteers prestudy for drugs of abuse; as it turned out largely cannabis and cocaine.

Following a period setting up a laboratory in Spain for the same company, but as part of a largely preclinical operation, I moved back to the Bios (UK) as a bioanalyst. In 1985, I moved to BioResearch Laboratories in Montreal as Head of Bioanalytical R&D, developing methods for mainly clinical pharmacokinetics. There then followed a period of international ping pong. I moved to Hazleton, UK, in Harrogate before returning to Canada to head up the Analytical Chemistry at Phoenix International. I then returned to Hazleton where I became head of Bioanalysis of a newly designed laboratory built for 80 analysts, just before LC–MS/MS swept the bioanalytical world. In 1999, I moved to Huntingdon Life Sciences as head of Chemistry (encompassing many of the chemistries used in drug development). In 2003, I became global head of the chemistries including our laboratory in NJ, USA.

Please explain your involvement as Senior Editor with the Journal

In 2008, I was invited to become joint editor of the Journal with Brian Booth (US FDA). I saw it as a major player in the bioanalytical field tying together all the technologies used in bioanalysis which hitherto had been represented by a myriad of journals. It also provided an opportunity to discuss regulatory issues pertaining to one of the most regulated sciences in the Pharmaceutical Industry and I am delighted to say remains. In 2013, after 5 years in the role and as my interests developed around the strategic issues as to how the healthcare systems were developing and how best could CROs play a role in this movement, I resigned from the role to allow those more intimately involved in the field of bioanalysis to carry on the role.

What role has *Bioanalysis* played in the field since its launch in 2009?

Bioanalysis – the Journal – has filled a major niche in the development of the role of bioanalysis. *Bioanalysis* sits within the boundaries of science, regulatory issues and support of drug development within the Pharma Industry. It involves a wide range of technologies which are published in a diverse range of journals, *Bioanalysis* has provided a focal point bringing them together under one roof independent of technology. Together with its involvement in

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regulatory issues it has become the go to journal for bioanalysts worldwide. This is exemplified by the numerous regulatory discussions initiated by the European Bioanalytical Forum and reported at some length via White Papers and other discussion documents. In addition, the development of Bioanalysis Zone by the Journal has reinforced this approach providing a forum allowing technical seminars to be accessed by all who want to. The production of the Glossary of bioanalytical terms is another area where *Bioanalysis* has filled a niche – ideally such initiatives should be maintained and sustained in order to ensure *Bioanalysis* maintains its relevance within the industry. Its role is best described in its own words “*our mission is to advance the field of bioanalysis by increasing subject understanding and the sharing of knowledge across barriers, to unite the bioanalysis community.*”

In which direction would you like to see the Journal heading over the next decade?

I think it is important that *Bioanalysis* champions all technologies used in the bioanalytical field, including their impact on regulatory issues. Perhaps most importantly, I would like to see analysts at all levels understand in detail the context in which they are working, always asking themselves why am I doing this and hopefully *Bioanalysis* the Journal can fulfill a role in this area. Understanding the data generated and understanding why I am doing this should not be carried out in a contextual vacuum. Obviously, it should maintain its current role in terms of expanding the coverage of relevant technologies and how they relate to developing regulatory requirements in order to maintain its role as a one stop shop for bioanalysts.

What have been the milestone developments over the last decade?

This is difficult as few milestones appear out of the blue and are largely presaged by early versions of the successful innovation. Some of the innovations can be equated with regulatory innovations as outlined below. Major developments in ligand-binding assays have been driven by the increases in the development of biological drugs as well as the desire to identify and measure biomarkers, many of which are macromolecules. Hopefully, the identification of pivotal biomarkers will improve, as an understanding of drug mechanisms develops, this is largely a virtuous circle iterating to the goal of understanding drug action. The role of dried blood spots looked as though it would replace the concept of using large volumes of plasma in all aspects of bioanalysis but unfortunately that has not proven to be the case – while it has found a role in niche areas such as pediatrics and small animal studies, it has yet to gain wide acceptance by the regulators. Again, this has been an area that has been bubbling for many decades, used by clinical chemists for over 50 years before bursting on to the bioanalytical field in around 2010 and at the time was perceived by some as the biggest step change in bioanalysis since LC–MS–MS. As the niche applications increase, it is likely it will become a major biological fluid of choice.

How has the regulatory landscape evolved in bioanalysis over the last decade?

There have been a number of pivotal regulatory changes and I am pleased to say that bioanalysis played no small part in them. Although the FDA has been a leader in the development of Bioanalytical Guidelines, largely in support of Bioequivalence studies, other regulatory agencies have perceived a need to develop their own bioanalytical guidelines. This has been largely driven by the EMA and a wide range of authorities such as Brazil (ANVISA) and Japan through the MHLW. It has resulted in a number of initiatives that have extended the guidelines beyond the scope of Bioequivalence studies. However, attempts have been made to ameliorate this approach by proposing a tiered approach to method development – largely risk based but still requiring an understanding of the context in which regulatory studies can be carried out, for example, is the drug there or not? studies where bioanalytical data have no relationship to drug plasma levels. Although pleasingly the application of appropriate method validation to the measurement of pivotal biomarkers is championed by the FDA who similarly encourage fit-for-purpose (FFP) validation in all other cases, a surrogate for plasma levels and clinical outcomes, represent a way forward and is likely to be the subject of more discussion. At last, an initiative by the FDA, is the use of incurred samples to get a better idea of assay performance under real life conditions has received wide acceptance. This came about as a consequence of comparing spiked data with incurred or real-life samples. The Canadian authorities have always requested such data but had been seen as largely for information purposes only. Many of these initiatives were not even considered some 10 years ago.

What do you think the next decade has in store for the bioanalytical arena?

It is important that the journal understands and embraces everything in the wide of technologies and rationale as to what bioanalysts are doing and why. It is important that now we have a one stop bioanalytical shop that

diversification does taking place as 'technical' interest groups peeling off to do their own thing. This should be addressed to welcoming those involved in new and developing technologies. Some of these currently peripheral areas include cell-based technologies, gene-based therapies and whole range of therapeutics revolving around aspects of nucleic acids, in other words, translation and transcription including small molecules such as antisense drugs.

Neil Spooner (Spooner Bioanalytical Solutions Ltd)

Please introduce yourself & explain how your career in *Bioanalysis* began

My name is Neil Spooner, the Senior Editor of the journal *Bioanalysis* – the Journal. My career in bioanalysis started about 25 years ago at Huntingdon Life Sciences and after 2 years, I moved to SmithKline Beecham, which eventually merged with GlaxoWellcome to form GlaxoSmithKline (GSK). At GSK, I had various roles in the bioanalytical group in Europe and North America until 2.5 years ago, when I left to form my own Company, Spooner Bioanalytical solutions. My journey with the journal began when I was invited at the inception of the journal to join the editorial board.

What role has *Bioanalysis* played in the field since its launch in 2009?

The journal has played a pivotal role in the field of bioanalysis since its launch. It has been a true partnership in helping to develop the science and understanding of bioanalysis. The journal itself has been a fantastic platform for the community to spread ideas and have discussions, whether that be about new technologies, or regulations surrounding bioanalysis. Likewise, the journal has helped publicize those discussions and give opportunity for people to feedback and take part in those discussions, leading to things like Bioanalysis Zone, which has a lot of content highly useful to the bioanalytical community. It has helped bring us together as a community in a way we were unable to before. So, in many ways, *Bioanalysis* has become our house journal and is part of our brand as bioanalysts.

How has the field of bioanalysis evolved over the last 10 years & has the Journal kept up?

The field of bioanalysis has evolved in many ways over the last decade. There has been a lot of changes in regulations and a lot of discussions around these, which *Bioanalysis* has played a part in. There have also been a lot of new technologies, whether it be the move from small molecules and LC–MS to large molecules by ligand-binding assays and LC–MS; to novel forms of therapeutics and therapeutic delivery, which has fundamentally changed the way we do bioanalysis in the last 10 years. *Bioanalysis* has very much been part of this discussion and spreading the word about these technologies, how they are used, and how we should validate and regulate the methods and the data coming out of them.

Compared with when I joined the journal, I would say bioanalysis a very different, much broader and much more interesting science than it was 10 years ago and it continues to develop. I look forward to following the journey through the pages of *Bioanalysis* and Bioanalysis Zone.

What are your thoughts on the partnership between the Journal & Bioanalysis zone?

I think it is a pivotal relationship. *Bioanalysis* represents the more academic, traditional peer-reviewed publications, which are very important to underline the science and prove that we are doing high-quality science and moving the agenda forward. Bioanalysis Zone is an important part of the partnership, which can be a little bit more current, a little bit more personal and a little bit more human than the journal can be. And I do not mean the journal is not cutting edge, but rather the very nature of published work in journals must go through the peer-review process and presented in a precise manner. Whereas Bioanalysis Zone allows a little bit more flexibility and a little bit more of the human face to be brought in. It also incorporates other platforms such as webinars and polls, which allows us to rather than just following the curve (which a manuscript published in the journal will be), allows us to lead the curve and set the agenda. So, I think the two are essential and complementary, providing great platforms for moving forward in bioanalytical science.

What direction would you like to see the journal take in the next few years?

I would like to see the journal helping all its readers stay on top of the inevitable developments that will come in the regulatory and technological arenas. Be that be the analysis of new molecular types, or new analytical technologies or changes in regulations in different parts of the world. I would very much like to see that conversation ongoing through the pages of the journal linking that to what goes on in the Zone.

Disclaimer

H Hill is a previous Senior Editor of *Bioanalysis*. N Spooner is the current Senior Editor of *Bioanalysis*. The opinions expressed in this interview are those of the interviewees and do not necessarily reflect the views of Newlands Press Ltd.

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