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Clinical and Pharmaceutical Solutions through Analysis (CPSA USA 2013): Connecting Patients and Subject Numbers Through Analysis

The 16th Annual Symposium on Clinical and Pharmaceutical Solutions through Analysis (CPSA)
7–10 October 2013, Sheraton Bucks County Hotel, Langhorne, PA, USA.

The 2013 CPSA brought together the various US FDA regulated analytical fields affecting a ‘patient’ for the first time – bioanalysts supporting IND and NDAs, clinical diagnostic and pathology laboratory personnel, and clinical researchers that provide insights into new biomarkers. Although the regulatory requirements are different for each of the above disciplines, the unique analytical perspectives that affect the patient were shared – and the goal of the 2013 CPSA – ‘Connecting Patients and Subject Numbers Through Analysis’ was achieved.

Inaugurated in 1998 as the first industry-led event to focus on the specific needs of industrial researchers, Clinical and Pharmaceutical Solutions through Analysis (CPSA) continuously provides an in-depth review of innovative technology and industry practices, through open discussion of industry-related issues and needs. The cornerstones for all CPSA events are education and specialized training. Over the years, the CPSA annual meeting has retained the same high quality scientific content, open interaction from industry opinion leaders and a collegial environment.

Shane Needham of Alturas Analytics (ID, USA) served as the Program Chair for CPSA USA 2013. Over the course of the week a theme developed in keeping with its title of connecting patients and subject numbers through analysis. In the last 16 years, CPSA has witnessed the progress of the technology from ‘past’ to ‘present’ and started to see the ‘future’. The ‘past’ has always been ‘only about technologies’, whereas the ‘present’ is about understanding the business of our industry and using these technologies more efficiently in bringing products to market. The ‘future’ is connecting these technologies to patient outcomes.

Three short courses were featured at CPSA USA 2013. Shane Needham led a colloquium-style event on LC–MS method development with a focus on fundamentals, new technologies and advanced methods. Another short course was led by Nalini Sadagopan (Agilent Technologies, CA, USA), Gary Valaskovic

(New Objective, MA, USA) and Nathan Yates (University of Pittsburgh, PA, USA), and featured innovations and industry benchmarks on the analysis of peptides and proteins, from sample preparation, to identification and quantitation. Assessment of oral bioavailability in both preclinical species and human, and the impact of physicochemical, biopharmaceutical and physiological factors, was the focus of the course by Ayman El-Kattan (Pfizer, CT, USA). In addition, concurrent workshops were led by Isma Zamora (Molecular Discovery, Perugia, Italy) on biomarkers and metabolite identification, and by Ron Kong (PTC Therapeutics, NJ, USA) and Fangbiao Li (Merck, NJ, USA) on maximizing efficiency from screen hit to bedside medicine.

The executive roundtable session – ‘Where Technology and Solutions Meet Business’ – was led once again by Tim Olah of Bristol-Myers Squibb (NJ, USA). This session featured open discussion on the role of science and business in the industry today. This year, much discussion was focused on assessing the effect of medicinal marijuana on patient care and businesses comprising (and on the periphery of) the pharmaceutical industry. The evening was highlighted by the always fun and spirited reception and sponsors dinner event – the unofficial start of all CPSA USA meetings! The opening remark of the evening ‘Disease is the Enemy’ officially declared by Shane Needham and Mike Lee (Milestone Development Services, PA, USA). The CPSA Charitable Giving, a new event this

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year, was directed by Paul Corcoran of McKinley Scientific (NJ, USA), Emily Ehrenfeld of Mozaic Solutions (MA, USA), Joe Fox of AB SCIEX (CA, USA), Shane Needham, Robyn Rourick of Genentech (CA, USA) and Tony Yeung of Fox Chase Cancer Center (PA, USA). This memorable event was once again hosted by AB SCIEX and featured an update on recent applications of SelexION technology by Yves Leblanc of AB SCIEX (Toronto, Canada) and this year's Distinguished Lecturer, Richard Kibbey of Yale University (CT, USA), on 'Mitochondrial GTB Cycle: A Novel Metabolic Pathway Regulating Glucose Homeostasis'.

Shane Needham formally opened the CPSA USA 2013 meeting on Tuesday with the introduction of the Plenary Lectures, Ola Saad from Genentech (CA, USA) on bioanalytical strategy used for ado-trastuzumab emtansine (T-DM1), and Marjorie Green of Genentech (CA, USA) on clinical development of T-DM1. These two lectures complemented each other very well and set the tone for this year's meeting theme – connecting patients and subject numbers through analysis.

Tuesday's Parallel Sessions provided simultaneous presentations and discussions on the topics of cancer metabolism and a colloquium on rapid turnaround time of bioanalytical data. The cancer metabolism session was led by Roy Vaz of Sanofi (MA, USA) and included a presentation by Renee Deehan-Kenny of Selventa (MA, USA) on 'Stratifying ER and Breast Cancer Patients for Likelihood of Response to Tamoxifen and Identifying Potential Alternative Therapeutic Targets for Likely Non-Responders as Baseline'. The other two presentations in this session included 'Glycolysis: Branch Points and Connections' by Michelle Clasquin of Agios (MA, USA) and 'Readily Accessible Biomarkers from the Fluids of Pancreatic Cancer Resection' by Tony Yeung. The colloquium session had a provocative subtitle, 'No-one pays much attention unless there is a problem', and the session featured some bioanalytical veterans, Bruce Stouffer of Bristol-Myers Squibb (NJ, USA), Eric Woolf of Merck (PA, USA) and Chad Briscoe of PRA international (KS, USA). A variety of bioanalytical issues from sample logistics, to development of reliable assays, to delivery of quality results to clinical teams, were addressed. Hopefully, the bioanalytical motto is changed from 'no news is good news' to 'let's make some noise and get some long over-due recognition'.

Tuesday also featured a lunch and roundtable discussion on 'Accelerating Therapeutic

Antibody and Fusion Protein Development with an Integrated, Automated Sample Prep and Ultra Fast MS Platform' sponsored by Shimadzu Scientific Instruments (MD, USA). The event featured an interactive and scientific mystery 'who done it' and was a great success! Congratulations to the winner – Bingbing Feng of Alliance Pharma (PA, USA).

The CPSA USA 2013 poster session, led by Helene Cardasis of Thermo Fisher (NY, USA), Matthew Szapacs of GlaxoSmith-Kline (PA, USA), Tracie Williams of Centers for Disease Control and Prevention (GA, USA), and Sean Yu of Merck (PA, USA) was one of the highlights of the afternoon. Lively and spirited discussions on the many new technologies and applications were presented.

The afternoon sessions concluded with an open discussion on 'Fit-for-Purpose in the Clinical Laboratory' and a timely roundtable discussion on 'FDA Bioanalytical Method Validation Draft Guidance', which was recently issued and is in the 90-day review period. Excellent presentations were given by Ravinder Singh (Mayo Clinic, MN, USA), Jack Henion (Quintiles, NY, USA), Alan Spitzer (Pediatrix Analytical, PA, USA) and Victor De Jesus (Centers for Disease Control, GA, USA) in the fit-for-purpose session – dubbed the 'Let Them Eat Cake Session' – where the emerging issues in the clinical laboratory was actively portrayed as a bakery with the following elements:

- The baker (clinical chemist);
- Baking equipment seller (MS solution provider);
- Customer/consumer (physician);
- Health inspector (government/public health scientist).

Ravinder provided an overview of quality in laboratory testing in clinical laboratories. Jack compared automated direct elution and LC-MS bioanalysis of DBS using three different approaches. Alan discussed the new testing approaches that will lead to better outcomes for infants and Victor presented the Center for Disease Control's role in assuring quality in newborn screening laboratories worldwide. The roundtable discussion on US FDA draft guidance generated much interest and was led by Chad Briscoe of PRA, Naidong Weng of Janssen (PA, USA), Eric Woolf of Merck and Jim Shen of Bristol-Myers Squibb (NJ, USA). The audiences filled up the entire room and everyone were actively engaged.

Four concurrent workshops were held before dinner on Tuesday. The first workshop, sponsored by AB SCIEX (Toronto, Canada), featured a presentation by Carmen Fernandez-Metzler of PharmaCadence Analytical Services (PA, USA), focusing on 'Peptide Quantitation on the QTRAP Mass Spectrometers with Micro-flow LC: Bridging the Best of Small Molecule and Proteomic Analysis'. In parallel, panelists Ajai Chaudhary of Merck (PA, USA), Tim Garrett (University of Florida, FL, USA), Ken Lewis of OpAns (NC, USA), Shane Needham and Robyn Rourick deliberated the evolving business practices supporting increased patient needs and services. This session was sponsored by McKinley Scientific (NJ, USA). In a session sponsored by Waters (MA, USA), Russell Mortishire-Smith of Waters (Manchester, UK) discussed ion mobility technology that can be used to enhance assay selectivity. A workshop sponsored by PharmaCadence (Hatfield, UK) focused on 'Protein Quantitation', recent experiences with sample preparation, selectivity and precision of analysis was discussed.

The events on Tuesday concluded with concurrent sponsor hospitality and evening workshops. The Food Quality and Safety Summit was sponsored by Agilent Technologies and featured talks by Tom Collins (UC Davis, CA, USA), Steve Lehotay of USDA Agricultural Research Services (PA, USA), Dave Russell of Agilent Technologies and István Pelczar of Princeton University (NJ, USA). The presentations and discussions provided the audience with updated global perspectives on the evolving and important world of food safety.

A second hospitality workshop 'Microsampling' was co-sponsored by McKinley Scientific (NJ, USA) and Drummond Scientific (PA, USA). This session featured several industry opinion leaders in a novel session format. Don Chace (Pediatrix Analytical, FL, USA) shared his views on assuring the quality of the filter paper matrix. Tim Olah discussed design implementation options for DBS in a discovery environment. Wenkui Li (Novartis, NJ, USA) presented DBS sampling in an efficacy study for an anti-malarial drug candidate in monkeys. Perhaps the most exciting part of this session was the panel discussion that followed. The discussion was quite lively, the need for new technology solutions, including microsampling and DBS, was acknowledged by both the session participants and the audience.

The Wednesday morning symposium focused on 'MS in the Operating Room' and was led

by Andy Hoofnagle (University of Washington, WA, USA) and Randy Nelson (University of Arizona, AZ, USA). Three provocative discussions were featured in this morning session. Zoltan Takats (Imperial College, London, UK) began the session with a presentation on 'Real-Time Assays in the Operating Room'. Andy Hoofnagle followed with his perspectives on point-of-care assays with very short turnaround time needs. Finally, Russ Grant (LabCorp, NJ, USA) discussed the extramural workflows with longer turnaround times in a diagnostic laboratory. All three discussions highlighted the increasing role of MS in clinical diagnostics – with three distinct turnaround time needs – and unique analytical perspectives that affect the patient.

The two parallel sessions on Wednesday morning centered on the topics of bridging gaps between technology and patients. The 'Shared Workflows – From a Discovery Laboratory to Hospitals' session was led by Rick King (PharmaCadence, PA, USA) and Petia Shipkova (Bristol-Myers Squibb, NJ, USA). Three speakers discussed their experiences with various aspects of the measurement of biomarkers using LC-MS and other techniques to predict clinical outcomes in three different research environments – pharmaceutical, food and beverage, and clinic. One highlight of the session was the presentation delivered by Justin Cross (Memorial Sloan-Kettering Cancer Center, NY, USA), who discussed the metabolomic workflows in basic and translational research using untargeted profiling and targeted mining of small molecule MS data from clinical samples.

The colloquium session on 'Regulations and Emerging Technology in the Clinical Sciences: The Impact on Research, Patients and Physicians' was led by Ken Lewis and Robert Kennedy (University of Michigan, MI, USA). Three speakers delivered outstanding presentations; 'Implementing New Technologies for the Routine Clinical Laboratory – Challenges and Solutions' by Ken Lewis, 'Development and Applications of Biomarker Assays for Rare Metabolic Disorders' by David Millington of Duke University (NC, USA), and 'Opportunities and Challenges for Education in Clinical Testing' by Tim Garrett.

The Wednesday sponsored lunch and roundtable discussion was sponsored by Thermo Scientific (MA, USA) and featured a unique event on 'Utility of Data-Independent and Data-dependent Acquisition to Increase Coverage of Nefazodone Metabolites from In-Vivo Matrices', presented by Jie Ding of Covance (WI, USA).

Four sponsored workshops were held on Wednesday afternoon. The workshops highlighted 'SWATH for Met ID: Smarter Data Acquisition and Intelligent Data Mining' sponsored by AB SCIEX (Toronto, Canada) and presented by Natasha Penner (Biogen Idec, MA, USA); 'Practical Tips for Success in Biotherapeutics Quantification' sponsored by Waters Corporation (MA, USA) and presented by Erin Chambers of Waters (MA, USA); 'Innovative Workflows for High-performance: Microspray & Nanospray' sponsored by New Objective and presented by Susan Weintraub of University of Texas (TX, USA), Shane Needham and Gary Valaskovic; and 'Next Generation Protein Digestion' sponsored by Perfinity Biosciences (IN, USA) and presented by Kevin Meyer, Nick Herold and Bob Ellis, all from Perfinity.

The Innovator Award session, led by Kevin Bateman (Merck, PA, USA), was held on Wednesday afternoon. Congratulations to all participants and finalists for featuring the most outstanding and innovative technologies, products and services at CPSA.

- First Place: Next Generation Plasma Collection Technology for Clinical and Pharmaceutical Applications – Fred Regnier, Novilytic Laboratories (IN, USA);
- Second Place: NPOI, A Novel Platform for Biomolecular Interaction Analysis and Affinity Capture MS – Keith Waddell, Silicon Kinetics (CA, USA); Perfinity Flash Digest – Kevin Meyer, Perfinity Biosciences;
- Third Place: HPLC-HPIMS – A 2D Separation Tool, Ching Wu, Excellims Corporation (MA, USA); PicoFuze™: The Future of Microflow LC-MS/MS, The Column is the Source, the Source is the Column – Shane Needham; Rodent Plasma Micro-Sampling Evaluation: Outcomes and Next Steps – Joe Siple, Drummond Scientific (PA, USA).

The vendor session featured the famous '5 Minutes of Fame' event, chaired by Mark Hayward of Active Ingredient Technologies (CA, USA), Matt Szapacs of GlaxoSmithKline (PA, USA) and Nicole Donnelly of PharmaCadence (PA, USA). Entertaining presentations (movies and dancing!) of the newest product introductions and services was also captured on video. This unique session allows all CPSA vendors to showcase their products and services - in 5 minutes! A few vendors take their respective '5 Minutes of Fame' to the next level each and every year.

The social hour and keynote dinner lectures continued in conjunction with the North Jersey American Chemical Society Mass Spectrometry Discussion Group and Delaware Valley Drug Metabolism Discussion Group meetings. Eric Yang (GlaxoSmithKline, PA, USA) and Naidong Weng formally announced the annual CPSA Shanghai 2014 meeting. The meeting will be held 16–18 April 2014 in Shanghai, China. Jeff Zhang of Novartis (Shanghai, China) will serve as CPSA Shanghai 2014 Program Chair. The program theme is: "The New Era of Personalized Medicine: Innovative Approaches for Drug Discovery and Development". Visit the CPSA Shanghai meeting website for more information on this unique international event [1].

Paul Corcoran (McKinley Scientific, NJ, USA) formally announced plans for the inaugural CPSA Brazil event. Plans are underway with tentative dates in July 2014 in Sao Paulo, Brazil. More details will be announced soon.

The first keynote dinner lecture on Wednesday evening was delivered by Nathan Yates. Yates presented his vision on 'How Cloud Computing Can Extend the Power and Versatility of MS from the Bench to the Bedside'.

The Wednesday evening event closed with the formal presentation of the Distinguished Scientist Award to Gary Valaskovic. Paul Corcoran and Fred McLafferty (Cornell University, NY, USA) presented the award to Gary, with a wonderful perspective on his career in the sciences and significant contributions to our industry. After humbly and gratefully accepting the award, Gary presented his lecture, 'From Inspiration to Belief, A Journey of Self-Discovery: Thinking Small, Ultra-Low Flow and Ultra-High Throughput MS'. Gary shared his journey of accomplishments in MS and sciences in general, his focus on 'ultra-low flow', and of course, the lifelong friendships he has made over the years through active participation in the sciences.

Thursday, the last day of the conference, opened with a symposium and roundtable session on 'Biomarker and Emerging Technology in the Clinical Sciences: The Impact of Research, Patients and Physicians' led by Jim Shen and Jianing Zeng (Bristol-Myers Squibb, PA, USA). Insightful presentations were given by Binodh DeSilva (Bristol-Myers Squibb, PA, USA), Elizabeth Groeber (Wil Research, OH, USA) and Michael Lassman (Merck, NJ, USA). In her presentation, Binodh shared her insights regarding the FDA draft guidance on bioanalytical method validation, especially

for ligand-binding assays. Elizabeth discussed how to overcome challenges in GxP assay robustness and sensitivity, and used some case studies to illustrate her points. Michael compared LC-MS and immunoassays for clinical biomarker measurements.

Perspectives on tools for data sharing and integration were highlighted in the second of Thursday's symposia and roundtable discussions. Following up his keynote speech on Wednesday, Nathan Yates continued his passionate discussion on CHORUS, which is a community based solution for the storage, analysis and exchange of MS data and information. Loren Olson (AB SCIEX, MA, USA) discussed how to streamline high-throughput ADME by using data sharing, workflow automation and high speed/high resolution analytical MS. John Laycock (Amgen, CA, USA) gave a compelling presentation on why it is important to automate bioanalytical sample analysis through enhanced system integration.

Laura Muirhead (Imperial College, London, UK), a surgeon, led the sponsored lunch and roundtable discussion on MS in the operating theatre. It was one of the most eye-opening presentations of the meeting. Mass spectrometers are being used by surgeon to help diagnose disease and assist the design of operating procedures – a true benchmark of where technology and patients meet.

The final symposia and roundtable of the conference was led by Kevin Bateman and Rick King, and focused on alternative instrumentation. Rick and Kevin initiated an open-discussion event with their vision and perspectives on the importance of non-analytical technologies that will profoundly alter analytical laboratories of the future. The importance of participating in

'scientific design work' was a powerful takehome message from the session.

In summary, the 2013 CPSA brought together the various FDA regulated analytical fields affecting a 'patient' for the first time – bioanalysts supporting IND and NDAs, clinical diagnostics and pathology laboratory personnel that support patient sample analysis, and the clinical researchers that provide insights into new biomarkers. Although the regulatory requirements are different for each of the above disciplines, the unique analytical perspectives that affect the patient were shared – and the goal of the 2013 CPSA – 'Connecting Patients and Subject Numbers Through Analysis' was achieved.

Plans are already underway for next year's annual meeting, the 17th Annual Symposium on Clinical and Pharmaceutical Solutions through Analysis (CPSA USA 2014). The theme of CPSA USA 2014 is 'Defining the Challenges of the Modern Analytical Laboratory: The Risks and Reality of Personalized Healthcare'. CPSA USA 2014 will be held 29 September – 2 October 2014 at the Sheraton Bucks County Hotel in Langhorne, PA, USA. Gary Valaskovic and Paul Corcoran will serve as program co-chairs. More information and details regarding the CPSA USA 2014 meeting can be found online [2].

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Websites

1 CPSA Shanghai meeting website.
www.cpsa-shanghai.com

2 CPSA USA 2014 meeting.
www.cpsa-usa.com