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IVT Validation Week 2016 Meeting Review and Awards Presentations

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OVERVIEW

The 22nd annual IVT Validation Week meeting was held in San Diego, California, October 18-20, 2016. This meeting comprised sessions on regulatory perspective, technical content, and fundamental principles. Awards including IVT Speaker of the Year, Author of the Year for both*Journal of Validation Technology* and*Journal of GXP Compliance,* and the Kenneth G. Chapman Award recognizing significant contributions in validation were also presented. Displays and interactions with validation-related vendors were also available at the meeting.

REGULATORY PERSPECTIVES AND TECHNICAL CONTENT

More than 45 presentations by 30 speakers were provided at this meeting. These discussions include six presentations by current or former FDA and global regulatory agency personnel. Regulatory presentations described the sequence of a simulated regulatory audit, FDA enforcement options, and current top regulatory challenges. FDA focus on data and metrics was discussed. Data integrity issues, a current key inspection issue, was discussed including actual inspection experience. An approach to conduct effective risk assessments was discussed. A “think tank” discussion with authors of “Alternative Methods for Risk-Based Validation” in which opinions on “critical / non-critical” designation were discussed. Aligning validation with FDA quality metrics was discussed.

Numerous discussions on fundamental validation principles on pharmaceutical and medical device applications were presented. These included topics such as Validation Master Plans, protocol development and writing, continued process verification, ICH Guidances, sampling plans, acceptance criteria development, electronic validation, QbD application, cleaning validation, validation management, statistics applications, statistical process control, FAT, SAT, utility systems, computer and software validation, and other topics. Validation of cosmetics, dietary supplements, and tobacco products was also discussed in a “think tank” format.

Several discussions including practical case studies with problem solving were presented. Process validation problems, documentation problems, cleaning validation problems, managing the validation function, data transfer, hand washing methods, and other case studies were presented. A medical device “think tank” discussing device validation problems with senior validation practitioners was held.

AWARDS

Validation Week has also included presentation of awards for many years. These awards include IVT Speaker of the Year, Author of the Year for both *Journal of Validation Technology* and *Journal of GXP Compliance,* and the Kenneth G. Chapman Award recognizing significant contributions in validation were also presented.

IVT Speaker of the Year

The IVT Speaker of the Year award is presented to individuals who receive the highest numerical scores for their presentations from meeting attendees at the various IVT meetings held during the previous year. There are more than 150 speakers eligible for this award. Nominees this year included:

- Gamal Amer, Precision Consultants
- Alan Golden, Abbott Molecular
- Roberta Goode, Goode Compliance International / University of Miami
- Carmen Medina, PAREXEL
- Lizzandra Rivera, Alexion
- Ron Snee, Snee Associates
- Raul Soto, J&J
- David Chesney, Chesney Consulting
- Erik Muegge, Abbott Diagnostics
- Ivan Soto, ValGenesis

Award recipients for 2016 were Roberta Goode and Eric Muegge. Congratulations Roberta and Erik!

Author of the Year Awards

The IVT Authors of the Year awards are presented to authors with outstanding written contributions to the IVT journals during the past year. Authors and papers eligible for this award are identified and selected by the Editorial Advisory Board of the Journals.

Journal of Validation Technology

Nominees for the *Journal of Validation Technology* Author of the Year award were the following:

- *Shelly Asmussen, Ph.D. (AbbVie) with David G. Stroz, M.S., David LeBlond, and Dennis A. Stephens, Ph.D.*

  "Application of a Degree-Hour Approach for the Management of Over-Temperature (OT) Excursions for Investigational Medicinal Products (IMPs) and Non-Investigational Medicinal Products (NIMPs)"

- *Frank Matos with Jennifer Reyes*

  "A Case Study for Qualification of a MALDI-TOF System for use in a Two-Tiered Approach to Microbial Identification"

- *Deirdre O'Keeffe (Health Products Regulatory Authority [HPRA]) with Cliff Campbell and Kevin O'Donnell*

  "A Spectrum of Importance—Challenging the Concept of Critical/Non-Critical in Qualification and Validation Activities"

- *Joseph Wood (Genentech) with Duncan Chadly, Thomas W. Patapoff, Terry Hudson, and Adeyma Arroyo*

  "Exfoliation of EPDM Coupon Surfaces by Bioprocess Soils"

- *Tim Sandle – (Bio Products Laboratory Limited, UK Dept of Health)*

  "Risk Assessment for Intervention Scoring in Relation to Aseptic Processing"

  "Risk-Based Approach to Internal Quality Auditing; Risk Consideration for Aging Pharmaceutical Facilities

  "Microbiological Assessment of Compressed Gases in Pharmaceutical Facilities"

- *Kevin O'Donnell, Ph.D. – Health Products Regulatory Authority (HPRA)*

  QRM in the GMP Environment: Ten Years On—Are Medicines Any Safer Now? A Regulators Perspective

Recipient of the "Author of the Year" award for 2016 was Kevin O'Donnell of HPRA. His paper, "*QRM in the GMP Environment: Ten Years On—Are Medicines Any Safer Now? A Regulators Perspective*" was published in Volume 21, #4 of JVT. Congratulations Kevin!

Journal of GXP Compliance

Nominees for the*Journal of GXP Compliance* Author of the Year award were the following:

- Richard Wedlich (NSF Health Sciences) with Agata E. Libera, Joseph M. Fransen , C. Tellarini, T. Heath, and N. Knight

  "Implementing an Effective GLP Program at the Contract Laboratory"

- Kelly Waldron

  "Integration of Risk Management Principles into the Quality System: Risk-based Impact Assessment"

- Anne O'Meara (Dublin Institute of Technology) with Anne Greene, Paige Kane, and Nuala Calnan, Ph.D.

  "An Investment in Knowledge Pays the Best Interest—Are You Leveraging Your Investment in Your CTDs by Using the Knowledge?"

- Jeanne Moldenhauer (Excellent Pharma Consulting)

  "Data Integrity Issues in Pharmaceutical Companies: Part 2"

- Tim Sandle (Bio Products Laboratory Limited, UK Department of Health)

  "Control of WFI and Clean Steam Systems for Bacterial Endotoxins"

  "Designing Aseptic Process Simulations: The Time and Container Number Conundrum"

"Approaching Microbiological Method Validation"

Recipient of the "Author of the Year" award for 2016 was Tim Sandle. His papers published in 2016 included:

"Control of WFI and Clean Steam Systems for Bacterial Endotoxins" (Vol 20, #4)

"Designing Aseptic Process Simulations: The Time and Container Number Conundrum" (Vol 20, #3(

"Approaching Microbiological Method Validation" (Vol 19, #4)

Congratulations Tim!

Kenneth G. Chapman Award

The Chapman Award recognizes significant contributions in validation. This award is named for the late Kenneth G. Chapman, who was instrumental in developing the guiding principles of many areas of quality assurance, quality systems, and pharmaceutical validation.

The 2016 Chapman Award was presented to Kevin O'Donnell, PhD of the Health Products Regulatory Authority in Dublin, Ireland. Dr. O'Donnell has demonstrated significant leadership in risk management and associated considerations in the recent past. His work has significantly influenced global approaches to risk management in both industry and regulatory agencies. He has continued to be active in research in risk management often in association with the Dublin Institute of Technology.

Kevin is currently is Market Compliance Manager at the HPRA with responsibility for several compliance-related and market-surveillance programs including Quality Defects and Recalls, Post-market Surveillance Testing, and Medicines Advertising in addition to performing site inspections He also represents Ireland at the*Official Medicines Control Laboratory (OMCL)* in Europe. Kevin manages Ireland's OMCL activities and has been elected to a number of advisory groups within this Network over the years. Kevin is also heavily involved in PIC/S and has been the elected Chair of the PIC/S Expert Circle on QRM for the past 4 years. In this role he is involved in providing training to GMP Inspectors and Investigators on how to inspect QRM and risk assessments at an advanced level. He recently (2016) managed an advanced training event at the EMA in London, and chaired similar training events (2015) at US FDA Los Angeles and PMDA in Japan (2014). Dr. O'Donnell's background also includes US pharmaceutical industry experience at Merck and Block Drug in QC, Technical Operations, R&D, and Regulatory Affairs.

Dr. O'Donnell was not able to be in San Diego to accept these awards. However, he sent the following to IVT after the meeting:

"*Hello IVT. I am very sorry to have missed this very special IVT event in San Diego. It is not often that one gets such recognition from one's peers, and I feel truly humbled to receive the Chapman Award as well as the Author of the Year Award.*
Receiving awards like these are only possible because of the many colleagues and friends who helped me along the way, including the many Inspectors and regulators from other agencies I have met over the years, who shared their experiences and wisdom with me.
I am indebted to my colleagues at my own agency, the HPRA, and I am especially grateful to my boss, John Lynch, Director of Compliance. John always allowed me to pursue research and publication activities. I am also indebted to Dr. Anne Greene and her research colleagues at the Dublin Institute of Technology in Dublin. Being part of Anne's research group is an honour for me.
I think being a GMP inspector is truly a great privilege – we get such unprecedented access to the inner workings of manufacturing sites and pharma companies in general. This is an environment in which we can learn and grow, as it allows us to meet many great people, professionals who work every day to make safe and effective medicines for the patients we collectively serve. We also know they just want to get through the inspection and get home to their families at the end of the day! We don't always make it easy for them!

This year has been a very special one, as I got to co-author a paper with my friends Cliff Campbell and Deirdre O'Keeffe. Thank you Cliff and Deirdre.

Finally, I wish to thank my family – my parents, who are still with us, and my four siblings who, I can safely say, have no idea what QRM or pharmaceutical validation are all about. But that is okay. I have a special fondness for my cousins in the US, as well as my in-laws in Japan. I remember writing the final chapter of my PhD thesis in their home, and God knows what they thought of this crazy Irishman, banging away on a laptop the whole time he was there!! Lastly to my wife Mitsuko, my best friend - thank you for allowing me to be part of your life."

Congratulations Kevin!

VENDOR DISPLAYS

Validation Week also included presentations and displays by more than 15 companies with services related to validation, pharmaceutical, and medical device industries. The Validation Week forum enabled numerous opportunities for interactions between attendees and vendors.

ABOUT THE AUTHOR

Paul L. Pluta, PhD, is a pharmaceutical scientist with extensive industrial development, manufacturing, and management experience. He is also editor-in-chief of the*Journal of Validation Technology* and the *Journal of GXP Compliance.* Dr. Pluta is also Associate Professor of Biopharmaceutics at the University of Illinois at Chicago (UIC) College of Pharmacy.

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