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- ValidNMR Workshop in La Jolla (March 8, 2018)
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ValidNMR Workshop March 8, 2018

ValidNMR was formed at PANIC, and the two organizations have been closely linked from the very beginning. The members of the ValidNMR group, while active throughout the year, meet annually at PANIC. This year, the meeting will take place **March 4-8, 2018**, in sunny La Jolla, California! We are very excited to be returning to La Jolla, where the 3rd Annual PANIC Conference was held in February 2015. Join us in March 2018!



The participants of the 2017 NMR Validation Workshop

Agenda 2018

08:00 Coffee is served

08:20 Welcome – Opening Statements

Kim Colson (Bruker) & Torsten Schoenberger (BKA)

08:50 Lightning talk: "Quality Improvement in qNMR Spectroscopy" Elina Zailer (Spectral Service)

09:00 Presentation: "qNMR Method Validation Following the USP 1210 Chapter, Statistical Tools for Procedure Validation" Carlos Amezcua (Baxter International Inc.)

09:20 Workshop Session #1:

(A) ValidNMR Wiki Kristie Adams (Steelyard Analytics)

(B) Required Validation Parameters Stefan Garms (Lonza)

10:20 Workshop debriefing (Session leaders)

10:30 Break

11:00 Lightning talk: "Meeting the requirements of FDA, ISO, GxP" Bernd Diehl (Spectral Service AG)

11:10 Presentation: "Validation Strategy using Lifecycle and Quality Risk Management" Dan Sorensen (Eurofins | Alphora Research Inc.)

11:30 Workshop Session #2:

(C) Data integrity Carlos Amezcua (Baxter International Inc.)

(D) Protocols / Education Elina Zailer (Spectral Service)

12:30 Workshop debriefing (Session leaders)

12:40 Lunch

13:30 Lightning talk: "A new realization of SI for organic chemical measurement: NIST PS1" Michael Nelson (NIST) presented by TBD

13:40 Presentation: "Reference Standards" TBD (TBD)

14:00 Workshop Session #3:

(E) Uncertainty Analysis Michael Maiwald (BAM)

(F) Reference Materials Kevin Millis (CIL)

15:00 Workshop debriefing (Session Leaders)

15:10 Break

15:30 Presentation: "Novel Proficiency Testing Scheme for 1H, 31P and 19F quantitative Nuclear Magnetic Resonance (qNMR)" Markus Obkircher (Merck KGaA)

16:00 Open Forum Kim Colson & Torsten Schoenberger

17:00 Adjourn – Closing Statements Kim Colson & Torsten Schoenberger

New Fellow Elina Zailer

I am the new Fellow (11/2017 - 10/2018). I am currently working on my doctorate with the title "Tagging - Development of alternative qNMR methods" at the University of Würzburg in Würzburg, Germany. I have gained experience in (q)NMR as a study director and project manager at Spectral Service in Cologne, Germany. My mission is to provide education and awareness in NMR Validation through fostering communication and progress in the community. Any great ideas, suggestions or publications? - contact me at elina(at)validnmr.com! I am looking forward to supporting you!



qNMR summit 2018 in Tokyo (by Takako Suematsu - JEOL)

The qNMR Summit 2018 in Tokyo will be held on January 29th and 30th in Tokyo, Japan. This Summit is being hosted by JEOL Ltd and Wako Pure Chemical Industries Ltd. The Summit is supported by the Japanese Ministry of Economy, Trade, and Industry 2017 "Initiative to Promote Strategic International Standardization". The international standardization of qNMR methodology has been selected as one of the projects of this initiative.

The qNMR Summit 2018 in Tokyo will include events that will be open to the public, as outlined below.

qNMR Forum: January 29th, 2018 (afternoon)

USP qNMR Symposium: January 30th, 2018 (morning)

qNMR Symposium: January 30th, 2018 (afternoon)

The qNMR Forum will be a public, open forum and the theme will be "Understanding the NMR standards in the world" as a first step towards international standardization. The planned program will include presentations about the NMR standards in the USA, Europe, China and Japan. The qNMR Symposium will be a public symposium focusing on the pharmaceutical field. The planned presentations will be related to qNMR in the JP and EP, as well as lectures from researchers at pharmaceutical companies in Japan about actual examples of how qNMR is being used. We are planning to close the symposium with a lecture about the future of qNMR. USP qNMR symposium in Tokyo will be held on January 30th in the morning.

For more information:

<https://www.jeol.co.jp/en/news/detail/20171120.2335.html>

qNMR Day in Bari (by Patrick Jonas - Spectral Service)

The last qNMR summit for 2017 took place on November 24 in Bari, Italy.

The qNMR Day was co-organized by the GIDRM (Gruppo Italiano Discussione Risonanze Magnetiche) and the Società Chimica Italiano. The venue was the university "Politecnico di Bari".

The goal of this conference was to highlight the power of NMR, especially to emphasize the growing importance of quantitative NMR spectroscopy worldwide. Scientific results have provided effective ways to check the quality and accuracy of qNMR. The introduction of new and innovative quantitative measurements were part of the conference as well as examples of new NMR application fields. Latest results from round robin tests were discussed to target an objective standard for individual laboratory work.

The conference attendees and speakers represented industrial companies, service providers, governmental and academic institutions from all over the world.

The presentations of this day will be published soon. Please check for more information:
<http://www.gidrm.org/>

A new realization of SI for organic chemical measurement: NIST PS1 (by Michael Nelson - NIST)

As the quantitative NMR (qNMR) technique has grown in favor during recent years, the metrological foundations for accurate and robust practices are currently being established. The first of its kind from NIST, ultra-pure and extensively-characterized NIST PS1 Benzoic Acid Primary Standard for quantitative NMR serves as a definitive, apical reference (calibrant) that establishes direct linkage of the qNMR technique to the International System of Units (SI) base unit mole. A realization of SI explicitly for molecular amount, it has a critical role in promoting accuracy and international comparability across the greater chemical measurement community, supporting clinical diagnostics, food safety and labeling, drug development, and biomedical research. This standard was developed through a Cooperative Research and Development Agreement (CRADA) between the NIST Chemical Sciences Division and Sigma-Aldrich Production GmbH, and in collaboration with the National Research Council (NRC) of Canada. It is being provided by NIST at no cost through Material Transfer Agreements (MTA) to National Metrology Institutes, other government agencies, secondary chemical reference standard producers, chemical and biomanufacturing industries, accredited measurement service providers, and other institutions with directives for high-accuracy traceable qNMR.

<https://www.nist.gov/programs-projects/nist-ps1-primary-standard-quantitative-nmr-benzoic-acid>

Want to be featured in the next ValidNMR newsletter?

The deadline for submissions and contributions to the next newsletter is March 15, 2018.

Please contact us at [committee\(at\)validnmr.com](mailto:committee(at)validnmr.com)!



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