



Bundeskriminalamt

# What's going on in PANIC's NMR Validation Group

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KT12 – Central Analysis Laboratory

Köln, 10.06.2016

5th Annual  
Practical  
Applications of NMR  
in Industry Conference

SONESTA RESORT HILTON HEAD ISLAND • HILTON HEAD ISLAND, SC



- First: 2015 (La Jolla): mainly talks
- Second: 2016 (Houston): mainly „real“ workshops

## **Attendees:**

- Industry, especially Pharma (e.g. Baxter, Pfizer)
- Regulatory (e.g. NIST, FDA, USP, BAM, BKA, Health Canada)
- Vendors (Bruker, Jeol)
- Universities

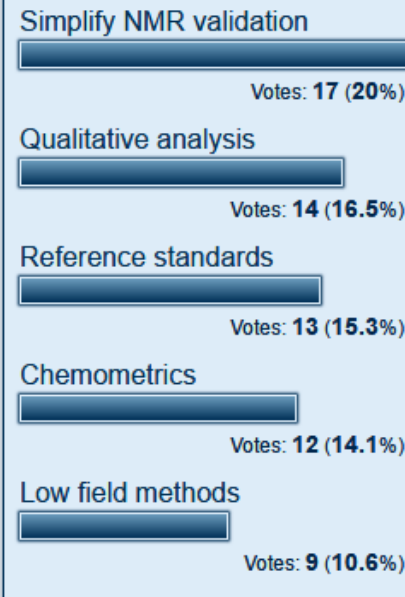
## **Web Page:**

- [www.nmrvalidation.org](http://www.nmrvalidation.org)

- Cracking the NMR Exclusion Nut
- Qualitative Analysis
- Reference Standards
- Chemometrics
- Building a Validation Assistant (expert system)
- Simplify NMR Validation
- Low field methods



Which are your favourite subjects? Please decide on PANIC 2016 workshops. (Please contact us at michael.maiwald {atnospam} bam.de for any other workshop ideas.)



## Identification of ...

- stakeholders
- problems that need to be solved
- possible solutions
- activities

Collected 12 volunteers for “core group activities”

# Small Selection of Identified Problems

- Terminology
- Method review (does method do what says it does)
- misinformation on how “official” organizations work for accepting methods
- Databases - good or bad
- Do we understand how other analytical methods do this?
- Lack of primary (certified) traceable standard
- Methods should be NMR specific
- NMR angst
- ...

# Small Selection of Possible Solutions

- Cooperation with university run validation workshops
- Ring/round robin tests (organizer ?)
- Establish what are critical/non-critical parameters
- Have a standard procedure to validate 2° and 3° reference standards
- Get vendors to do linearity test as part of instrument installation and acceptance
- “recipes” for various methods
- education / “demystify NMR”
- Posters/slides @ conference
- ...

- 1) Publish results of workshop on webpage
- 2) Start cooperation with university
  - organize workshops / education material (youtube...)
  - hosting a Wiki platform
- 3) Find volunteers to collect information about round robin tests / organizers
- 4) Establish **Editorial Boards** for Wiki content  
divided by topics (chemometrics, simplification...)
- 5) Structure finished until next PANIC 2/2017  
→ detailed work on organization / content