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A focus for analytical chemistry in Europe

WG. 2.1.
Technical solutions for validation automation/planning.

Chair

Koit Herodes

20.-21. May 2019, Tartu, Estonia

Technical solutions for validation automation/planning.

- Introduction
  - 17 different institutes
  - 47 participants
  - 19 countries
  - 23 students (universities)
  - 9 regulatory
  - 6 industry
  - 9 other
- How was workshop arranged: Divided into 7 groups, several questions answered online in Google Docs.

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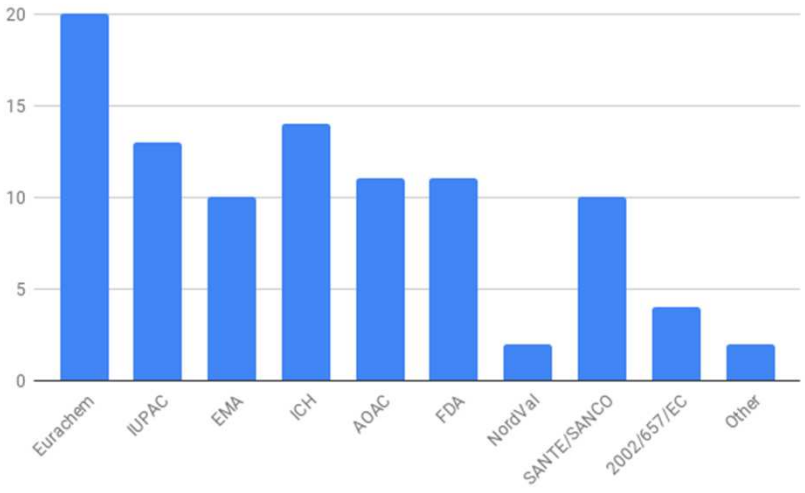
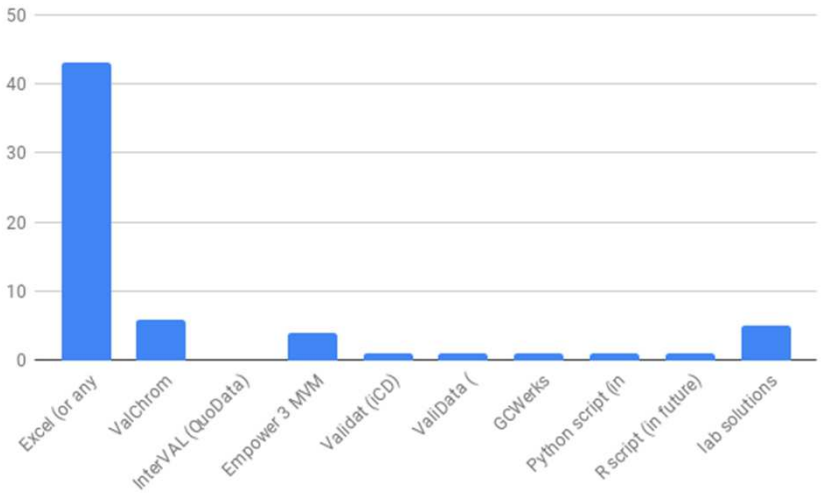
Q1: Most well-known validation guidelines.



Q2: How do we validate?



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Q3: Should validation be taught at universities?

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- All participants answered „Yes“!
  - it is better if you have knowledge before you start working
  - To be aware that is an important as a concept, but not to the specific level
  - It is even helpful if the person already have some laboratory experience
  - Wish I had learned it

Q4: Validation data electronically in separate electronic section of journal

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- Ideas from the working groups:
  - **Advantages**:
  - It will make the published works more reliable.
  - We can do cross checking across the guidelines everytime
  - freedom of knowledge, collaboration, increase comparability, enhance the trustworthiness of data
  - We can always have access to requirements.
  - We can always have access to requirements.
  - **Disadvantages**:
  - Maybe difficult to extract software files with calculation details, may demotivate some persons trying to do new or non targeted analysis
  - Different publishers will design different guidelines, meaning that the problem is still not solved, work intense
  - May be restrictive, would be good as an option. Hard to check calculations

Q5: Official guidelines published as software.

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- Ideas from the working groups:
  - **Advantages**:
  - Yes, so that more students, research institutes, academe and company can benefit with it but with a promise of data protection once our data is inputed in the software.
  - Once validation is relied on software, chemists can work with more complex problems
  - Eurachem validation software is good idea, but…
  - **Disadvantages**:
  - But it can limit our creativity or or interpretation!
  - Eurachem validation software is good idea, but how much would it cost to create
  - Updating the supporting software (MS EXcel, Empower etc.) will need revalidation
  - Eurachem is a nonprofit organization. The problem comes with responsibility. You input all the data and the processing is done by the software. If something goes wrong we may not have a way to check