Method development and validation: where is analytical chemist really needed?

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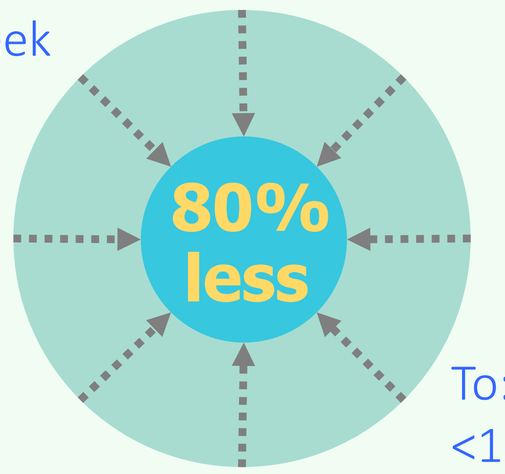
ValChrom

ABSTRACT

The need for optimised and efficient validation[1] is evident for all laboratories that operate in the field of chromatographic analyses.

It has been estimated[2-4] that through automation of the validation process, time spent by analytical chemist on manual labour in spreadsheets and word-processing software could be cut by 60-80%.

From:
>1 week



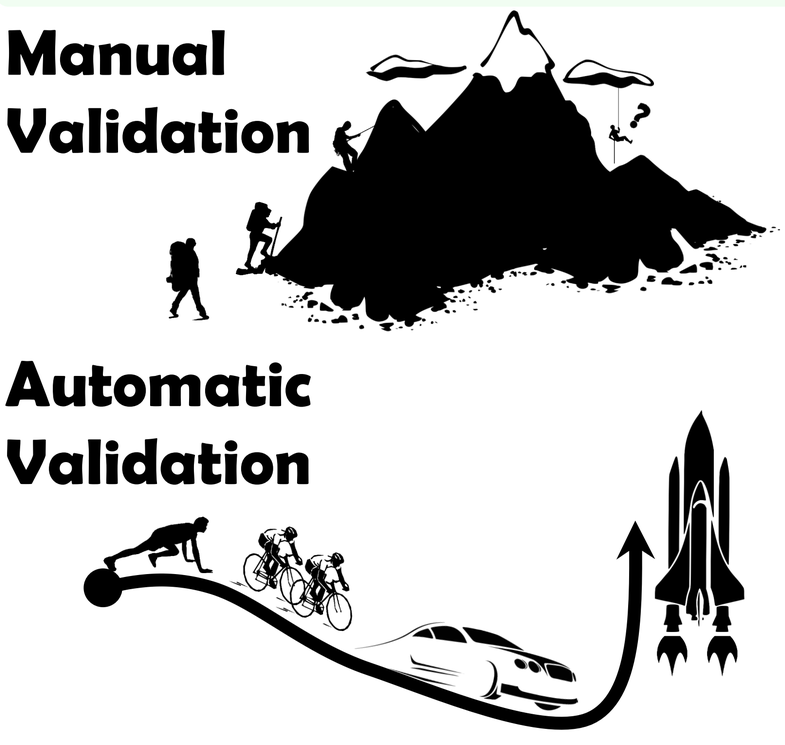
To:
<1 day

OBJECTIVE

Free analytical minds to do more of method development by making validation process more efficient and easier to carry through.

Automated validation:

- Different guidelines
  - ICH
  - Eurachem
  - AOAC
  - EMA
  - FDA
  - etc
- Detailed optimal experiment plans
- Automated calculations
- Automated reporting

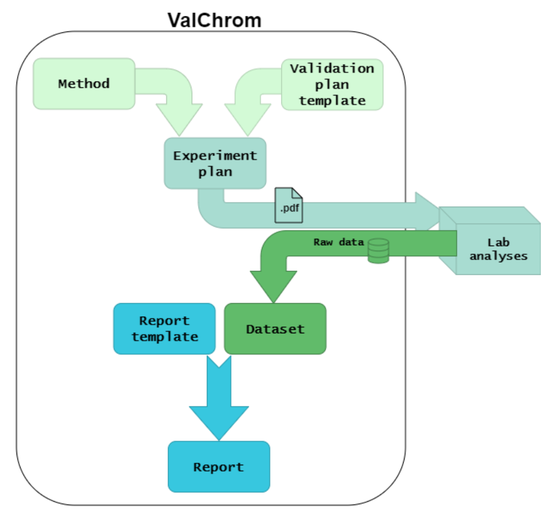


CURRENT STATUS

The results for **ongoing development of free-to-use software ValChrom** can be found at valchrom.ut.ee.

- Currently 3 different guidelines are supported: ICH[5], EMA bioanalytical[6] and Eurachem[7] validation guidelines.
- Simple to use and has a modern user experience.
- New version of guideline. ➞ Centrally updated software as a service.

Tablet area



Parts that can´t be automated	✓ Parts that can be fully automated

Method

- Analyst is needed to provide sufficient description of the method that is to be validated.

Validation plan template

- Analyst decides on guideline, validation parameters and criteria for passing.
- Ready-made or custom templates based on requirements and suggestions of different guidelines are offered by our software.

✓ Experiment plan

- Automatically compiled detailed experiment plan for optimal time use.

Experiments to be carried out

✓ Data treatment

- Fully automated calculations and graph generations.
  - For example CCα and CCβ calculations required in 2002/657/EC
  - Displayed in concise manner
- Some criteria can be automatically tested.
- Analyst is needed to confirm fitness for purpose only.

Overview

✓ Reporting

- Automatic reporting based on premade templates.

References and acknowledgements

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[4] Fusion Analytical Method Validation Analytical Method Validation Software, product information page, http://www.smatrix.com/fusion_lc_method_validation.html
[5] ICH Harmonised tripartite guideline validation of analytical procedures: Text and methodology Q2(R1), Step 4 version, 2005
[6] EMA BA: Guideline on bioanalytical method validation, EMEA/CHMP/EWP/192217/2009, 21 July 2011, Date for coming into effect: 1 February 2012
[7] Eurachem: B. Magnusson and U. Örnemark (eds.) Eurachem Guide: The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics, (2nd ed. 2014). ISBN 978-91-87461-59-0.

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