Introduction: Chromatography, LBA or PK assays?

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Focus Workshop

(*In collaboration with the AAPS and JBF*)

Industry input into ICH M10: Experimental data as the cornerstone for a science driven bioanalytical guideline

The Altis Grand Hotel Lisbon,
Portugal September 24-26, 2017

http://www.europeanbioanalysisforum.eu

Problem statement

Not a real problem, but maybe an opportunity to take a fresh look at our acceptance criteria

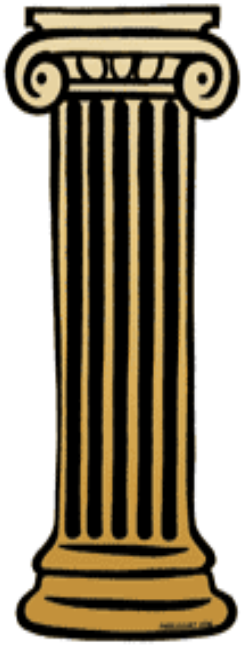
Where does the discussion come from?

EBF – Focus Workshop

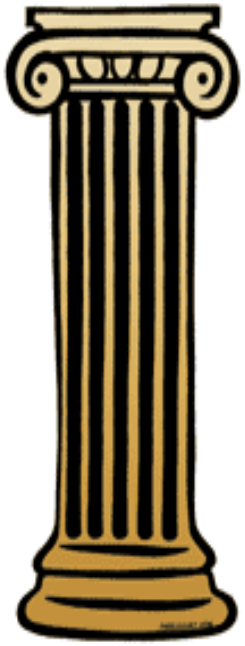
Bioanalytical Strategies for Large Molecules in Modern Drug Development: LBA and LC-MS United

21-22 June 2017, Lisbon, Portugal

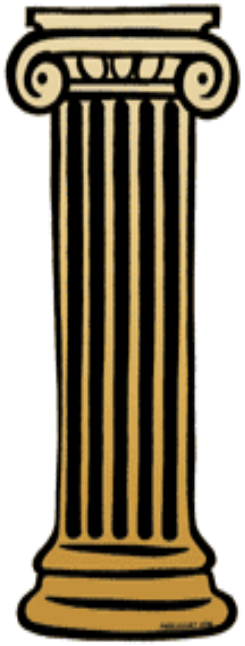
Recently, we defined a 3rd pillar in the BA toolbox?



LBA



HYBRID



CHROM

And we decided to have acceptance criteria ‘à-la-carte’

Of course

There is a school of thought to have the performance of your assay define the acceptance criteria, but

- Wat is the assay really underperforms?

- What is the assay really over performs?

When was the last time we reflected on acceptance criteria?

- CC-II?
  - And although we did discuss it, and decide 4-6-20 is doing the job for Chromatography, they were changed to 4-6-15.
  - A difference between LBQ and Chromatographic assasy was maintained, even though decisions taken with the data war the same

- The ICH M10 discussions may be a good moment to look back and base the criteria on decision made with the data and not on performance of the assay (either a prior defined or as per validation)

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