The Pyramid of Quality

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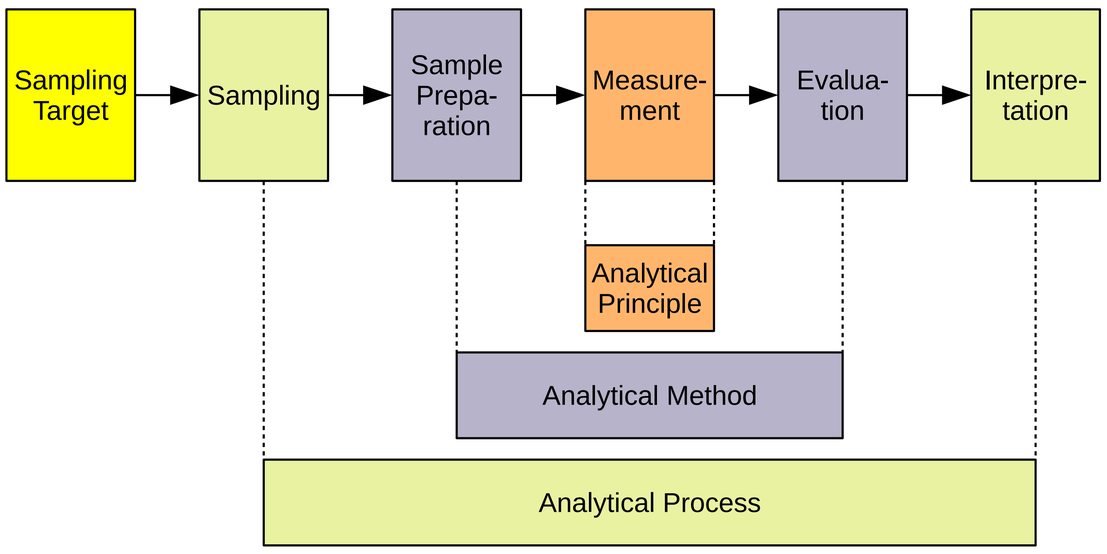
Introduction

The analytical process spans from sampling over sample preparation to the actual measurement process and the evaluation of the data [1]. All steps contribute to the uncertainty of the result.



The aim of an analytical process is to generate valid reportable results that can be further used and interpreted.
For example, the reportable results are

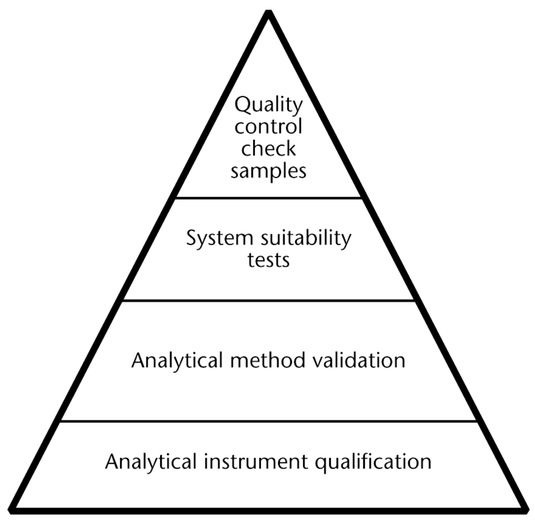
- compared against specifications / limit values according to agreed decision rules,
- used to calculate the value (price) of a good or
- used in scientific studies or in legal cases.

The system behind

In order to achieve a reportable result in the measurement process, various processes are required: Equipment qualification, Method Development and Validation, System Suitability Tests (method internal Quality Assurance, (QA)), Quality Control-(QC)-Sample and Proficiency Tests (PT, external QA), Traceability and Data Integrity.
The description of the interrelationships and their dependencies is important for understanding the analytical process. This can be described very precisely in words. But with such an extensive process, it is difficult to keep track of the interrelationships. These can be captured better graphically.

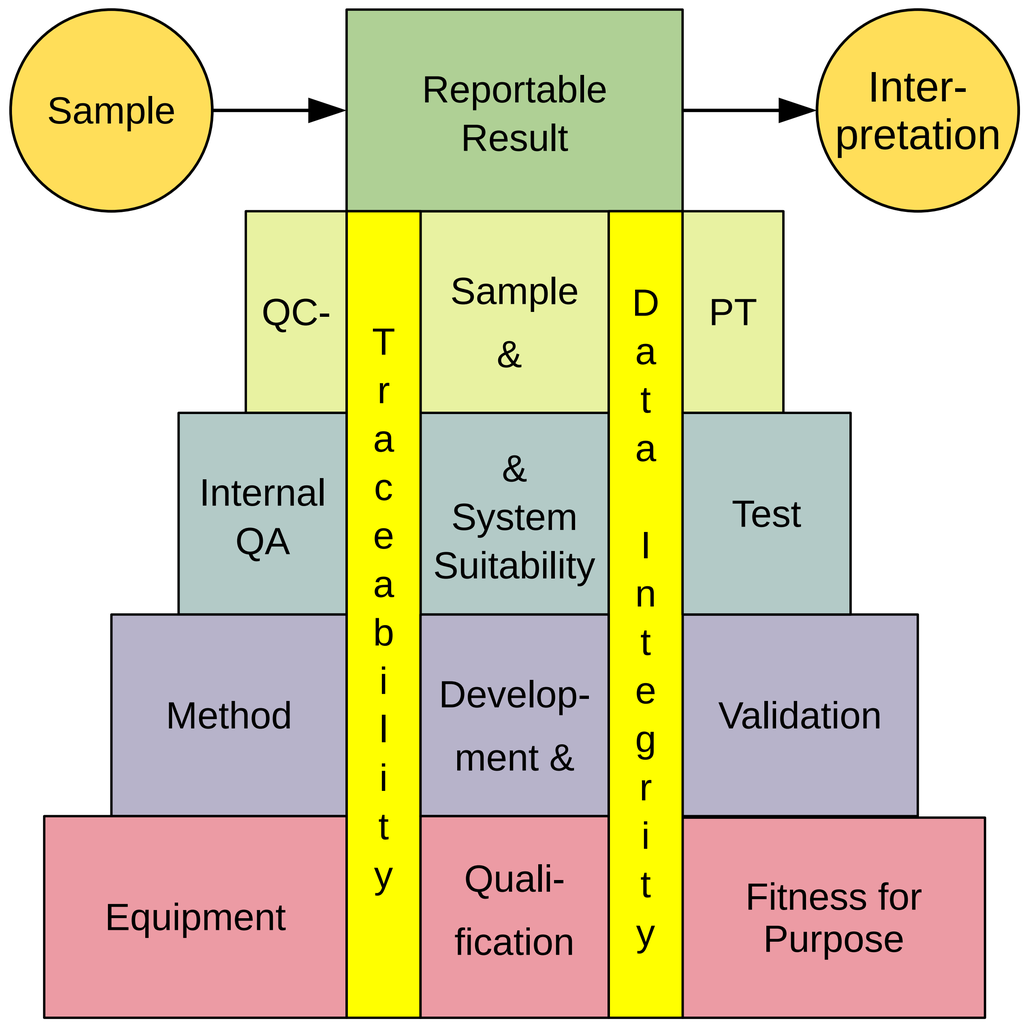
Triangle of Quality [2]

In the general chapter 1058 Analytical Instrument Qualification of the United States Pharmacopeia (USP) the triangle of quality was introduced.



When you look closely at the triangle, you notice that it is actually a pyramid: The method is validated on the qualified equipment. The whole system (equipment, method, reagents and chemicals and the operator is checked in daily use by means of System Suitability Tests (SSTs). QC samples make the result comparable between laboratories and over time.
Some elements are missing, e.g. the traceabilities and the data integrity.
What is the purpose of the quality triangle? The generation of a valid reportable result!
Based on these considerations, the Pyramid of Quality is proposed.

The pyramid of quality



Different measurement objects (samples) and different questions require suitable measuring instruments and analytical equipment. The **analytical equipments** must be fit for their purpose. The influence quantities on the measurement and their variability must be under control (level 1).
The **development and validation of an analytical method** is carried out using the validated equipment (level 2). In order to keep the characteristics of the measurement results comparable to those of the validation or of the transfer of a method, the equipments must be kept in a validated condition.
System suitability tests are performed to verify that the system (equipment, chemicals and reagents, operator, etc.) is performing as it did at the time the method was validated or transfered (level 3).
In order to demonstrate the comparability of results over longer periods of time or between several participating laboratories, QC samples are regularly comparatively analysed and statistically evaluated. Whenever possible, **proficiency tests** (PT) are used to demonstrate the comparability of results from different laboratories and methods (level 4).
Across the four levels, **data integrity** and **traceability** are required. One element of data integrity is the qualification and validation of IT elements. Traceability includes both metrological traceability (idealy with certified reference materials to the SI unit Mole) and process traceability (Who did what with what when and why?).

The pyramid of quality is a visualisation of the analytical method, not of the entire analytical process. In particular, sampling and the associated uncertainty are not part of the pyramid.

References

[1] Georg Schwedt, Taschenatlas der Analytik, Stuttgart, Thieme, 1992
[2] USP 1058 Analytical Instrument Qualification