QUA-THE-040

QUALITY IN ANALYTICAL LABORATORIES
Identification criteria & Validation

• Context

The European decision 2002/657/EC was adopted to harmonize the characterization and validation procedures of analytical methods performances. This decision provides rules on how methods are to be used in the testing of official samples according to Article 15, paragraph 1, second sentence of Council Directive 96/23/EC, as well as common criteria for the interpretation of analytical results of official control laboratories for samples taken according to the same directive. One particular emphasis of this decision is related to the definition of validation guideline(s) for residues and contaminants in biological matrices. Besides, 1881/2006/EC reference document has to be applied in the field of environmental contaminants such as dioxins and PCB, introducing other concepts to be used such as uncertainty, and establishing others rules in terms of method validations.

• General objective(s)

The first objective is to explain the main validation concepts and guideline(s) introduced in the 2002/657/EC decision (i.e. limit of decision CCα, detection capability CCβ, linearity, recovery, stability…) and the second objective is to provide some theoretical and practical basis for understanding the alternative 1881/2006/EC reference document regulating the environmental contaminant area. Mainly focused on mass spectrometry as measurement technique, this module is expected to provide a full overview of European requirements and recommendations in terms of validation of analytical methods and to give all the necessary background to implement this major reference text.

• Main items

2002/657/EC and 1881/2006 decision / validation criteria / analytical limits (CCα & CCβ) / MPRL / uncertainty

• Pedagogical objectives

✓ To know the 6 main analytical parameters to be validated for confirmatory quantitative methods according to the 2002/657/EC decision.
✓ To know 2 different experimental approaches for characterising the limit of decision CCα.
✓ To know the usefulness of including external standard and internal standard compounds in an analytical method.
✓ To know the main procedure for determining measurement uncertainty associated to a result according to the GUM approach.

• Pedagogical tools

✓ PowerPoint slide show (+ paper printout and PDF file copy)
✓ Copy of the 2002/657/EC decision

• Duration

3.5 hours

• Pre-requisite

✓ Principles of Mass Spectrometric acquisition modes (CON-THE-033)
✓ Basics of descriptive statistics: mean, standard deviation, distribution… (cf. SARAF web site)