

QUA-THE-020

QUALITY IN ANALYTICAL LABORATORIES

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.

• General objective(s)

The first objective is to explain the validation concepts and guideline(s) introduced in the 2002/657/EC decision (i.e. limit of decision $CC\alpha$, detection capability $CC\beta$, linearity, recovery, stability...) and the second objective is to provide some practical and fit-for-purpose interpretation rules of these concepts to analysts and Heads of Laboratories. 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 decision / validation criteria / analytical limits ($CC\alpha$ & $CC\beta$) / MPRL

• 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 $CC\alpha$.
- ✓ To know the usefulness of including external standard and internal standard compounds in an analytical method.

• Pedagogical tools

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

• Duration

4 hours

• Pre-requisite

- ✓ Principles of Mass Spectrometric acquisition modes (CON-THE-020)
- ✓ Basics of descriptive statistics: mean, standard deviation, distribution... (cf. SARAF web site)