

QUA-THE-010

QUALITY IN ANALYTICAL LABORATORIES
European Criteria

• **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 illustrate and explain the main validation concepts introduced in the 2002/657/EC decision (i.e. limit of decision $CC\alpha$, detection capability $CC\beta$, linearity,...) through a set of commented and analysed practical real case studies. The second objective is to provide and explain one example of practical ready-to-use guideline (computer file template) for calculating these parameters. Focused on mass spectrometry as measurement technique, this module aims at a proper implementation of this major analytical quality issue in the participating laboratories.

• **Main items**

2002/657/EC decision / MS identification criteria / analytical limits ($CC\alpha$ & $CC\beta$) / MPRL

• **Pedagogical objectives**

- ✓ To know the maximal tolerated values fixed by the 2002/657/EC decision in terms of variability (for retention time, signal, and ion ratio) according to the type of MS technique used.
- ✓ To know the minimal number of identification points required for group A and group B substances.
- ✓ To know the minimal number of diagnostic signals required to identify a group A or a group B substance according to the type of MS technique used.

• **Pedagogical tools**

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

• **Duration**

4 hours

• **Pre-requisite**

- ✓ Principle of SCAN, SIM, SRM and MRM MS acquisition modes (CON-THE-020)
- ✓ Basics of descriptive statistics: mean, standard deviation, distribution... (cf. SARAF web site)