

**QUA-PRA-040**

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**QUALITY IN ANALYTICAL LABORATORIES**  
Validation of analytical methods

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• **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 document. One particular emphasis of this decision is related to the definition of validation guideline(s) for residues and contaminants in biological matrices, which deserves to be confronted to practical and “real life” aspects, constraints and/or possible pitfalls.

• **General objective(s)**

The first objective is to illustrate and explain in practice 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 / validation criteria / analytical limits ( $CC\alpha$  &  $CC\beta$ ) / linearity

• **Pedagogical objectives**

- ✓ To apply correctly the rules of the 2002/657/EC decision in terms of maximal tolerated variability (for retention time, signal, and ion ratio) to a real set of experimental data.
- ✓ To use properly and with autonomy the provided file template to interpret a real set of experimental data.

• **Pedagogical tools**

- ✓ PowerPoint slide show (+ paper printout and PDF file copy) + copy of the 2002/657/EC decision
- ✓ Individual computer for practical exercises on the proposed file template

• **Duration**

1 hour

• **Pre-requisite**

- ✓ Theoretical concepts and rules introduced in the 2002/657/EC decision regarding validation (QUA-THE-040)
- ✓ Basics of PC management (Windows Operating System) and Excel software (cell, formulae...).