Robustness and ruggedness introduction

Definition

- Robustness and ruggedness - the ability of an analytical method to remain unaffected by small variations in method parameters and influential environmental factors and characterize its reliability during normal usage
  - no change of the detected amount of the analyte in a certain sample in spite of the variation of the method parameter
  - no change of the critical performance characteristics (e.g. limit of quantitation) by the variation of the method parameter

Robustness or ruggedness?

- Robustness and ruggedness definitions in the guidelines are very similar
- Both terms – robustness and ruggedness – are in use.
- When used together they are treated as synonyms in most cases
- Robustness – also the feasibility to reproduce the analytical method in different laboratories

Robustness or ruggedness?

- **Ruggedness** should be used as a parameter evaluating constancy of the results when external factors such as analyst, laboratory, instrument, reagents and days are varied

- **Robustness** should be used as a parameter characterizing the stability of the method with respect to variations of the internal factors (parameters) of the method

Robustness/ruggedness

- Sometimes robustness/ruggedness are misinterpreted and actually decision threshold, detection capability or measurement uncertainty is evaluated

- The term **robustness** for expressing the stability of the method against small variations of the intrinsic method parameters

- The term **ruggedness** for expressing the stability of the method against extraneous influencing factors