UE 27 QUALITY CONTROL

5 ECTS

Content

Classes*
  Regulatory environment of quality control - Guidelines
  Sampling: statistical aspects (representativeness, sampling plan) and techniques (preparation
  methods of analytical solutions)
  Content of control monographs
  Formatting results and calculating uncertainty - Specifications - Analysis reports - Result
  compliance
  Validation of analytical methods: general aspects - Validation criteria (specificity,
  answer/response/reply feature)
  Validation criteria (continued) (accuracy, correctness, precision, detection and quantification
  limits)
  Validation of methods: Accuracy profile approach
  Statistical control of process: production monitoring through control charts
  Comparative study of method performances

Tutorials*
  Tutorial organized from one molecule.
    Active raw material analysis (case study)
    Validation of a plasma assay from the critical analysis of a published article
    Dosage of the active substance in the environment (case study)
    Production monitoring

Practical works*
  Dosage of the active substance in the finished product: study of the function
  Dosage of the active substance in the finished product: determination of the validation criteria
  Validation approach through the accuracy profile (in computer room)

* Classes (all students in amphitheater), Tutorials (small groups of students), Practical works (smaller groups of students
 in order to study in adapted practical rooms/laboratories)

Assessment

Final exam about classes and tutorials.
Continuous assessment for the practical works with report writings, oral presentations and/or lectures.
Attendance to practical works needs to be approved.

Contact

Arlette Baillet-Guffroy