Module Title:
Please provide a module title which should have only 30 characters including punctuation and spaces .

Method Validation

Module Code:
Please code according to the code QM-xx-xx, AM-xx-xx or DA-xx-xx

QM0502

Maximum Number of Students:
Please include any limitation on the number of students able to take the module.

30

Total ECTS Credits
This should be the sum of the credits for each of the semesters in which the module is to run.
2

Notional Learning Hours
(a) Contact Time - 15__h
(b) Private Study - 7____ h

Format of Teaching:
Lectures 7__h
Laboratories or Practicals 8___h
Other _____h

Teaching Strategy:
Please show how the contact hours are to be allocated in terms of the type of class involved.
Lectures will cover the theoretical part concerning definitions of validation and validation parameters and the method for calculating and determining them.
Exercises will cover a number of examples of calculating validation parameters. Creation of a validation report as the final conclusion of validation parameters determination will also be covered.

Convener:
The name of the member of permanent staff responsible for the module.
Piotr Konieczka, PhD

University / Department:
The name of the University and Department responsible for the module.

Gdansk University of Technology, Faculty of Chemistry, Department of Analytical Chemistry

Language of Tuition:
Please state whether module is to be taught through the medium of English or another language. If bi-lingual please indicate % of each language

English

Module Description - The Purpose or Aims:
This should specify the purpose of the module where it fits into the programme specification and what it aims to provide. Please list the Aims in numerical order.
The principal aim of this module is to provide students with basic orientation in the field of method validation and determination of validation parameters.
Specifically the following aims should be achieved:

1. Provide insight in to basic theory – definition of validation parameters.
2. Provide skills permitting the effective usage of standard programs for the determination of validation parameters.
3. Provide students with abilities for proper understanding and interpretation of basic statistics for the determination of validation parameters

Specific Learning Outcomes for this module: (contributing to general learning outcomes GLO 1 – GLO 10)
Learning Outcomes should provide statements which articulate what the student has achieved upon completion of the course. What will a student know, understand or be able to do?

1. Getting general orientation in the role and place of method validation in the analytical process.
2. Learning usage of standard programs applied for validation parameters calculations.
3. Learning by examples validation parameter determination.

All these specific outcomes are related to GLO5.

Summary of Course Content:
This should be a summary paragraph of list of the topics to be covered by the module.

Lectures: Basic definition concerning with method validation and validation parameters. Tools used for validation parameters calculation. Basic statistical test. Method for determining selectivity, linearity, limit of detection, limit of quantitation, range, precision, accuracy, uncertainty.
Practical: Usage of standard computer program (MS Excel) for validation parameter calculations.

Transferable Skills Taught:
Please list in numerical order the key skills taught e.g. communication, information technology, interpersonal skills, teaching/study skills. Please relate these to benchmark statements.
Transferable skills will cover chiefly skills related to information technology.

Assessment Methods:
Details of assessment methods should include forms of assessment and the contribution of each to the summative assessment of the module. The relationship to the learning outcomes of the module

should be explicit and the numbers of the various learning outcomes should be attached to the assessment methods listed. Please list in numerical order

Assessment will be done on the basis of the preparation of a validation report on the basis of a set of data measurements. The solution of the latter part may be sent by the students for the evaluation by e-mail after the course.

Assessment Criteria:

Details of assessment methods should include forms of assessment and the contribution of each to the summative assessment of the module. The relationship to the learning outcomes of the module should be explicit and the numbers of the various learning outcomes should be attached to the assessment methods listed. Please list in numerical order.

Treshold:

Correct calculation of 50% of validation parameters and its presentation in the final validation report.

Good:

Correct calculation of 80% of validation parameters and its presentation in the final validation report.

Excellent:

Almost perfect calculation of all validation parameters and excellent preparation of the final validation report.

Resource Implications of Proposal and Proposed Solutions:

Details on any resources required and should be included. Please also list e.g core texts; recommended reading material; equipment; films etc.

Handouts of the lecture presentations will be prepared and sent to the students in advance (2 weeks before the course starts).

Recommended textbooks (in order of preference):

1. L. Huber, "Validation and Qualification in Analytical Laboratories", www.labcompliance.com, 1998.
2. A. Ambrus, "Practical Approach to Validation of Methods for Analysis of Residues", FAO/IAEA Training and Reference Centre for Food and Pesticide Control, Draft 1, http://www.iaea.or.at/programmes/nafa/d5/trcfpc/d5-trcfpc.html, 1999.
3. International Conference on Harmonization (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use: Text on Validation of Analytical Procedures, ICH-Q2A, Geneva 1994.
4. International Conference on Harmonization (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use: Validation of Analitycal Procedures: Metrology, ICH-Q2B, Geneva 1996.
5. United States Pharmacopeial Convention, United States Pharmacopeia 23, US Rockville, 1995.
6. B. W. Wenclawiak, M. Koch, E.Hadjicostas, "Quality Assurance in Analytical Chemistry", Springer Verlag, Berlin Heidenberg 2004.
7. P. Konieczka, J. Namie□nik, "Quality Assurance and Quality Control in the Analytical Chemical Laboratory: A Practical Approach", CRC Press in preparation (will be publish at the end of 2008).

Resources needed:

1. computer laboratory with a number of PCs at least equal to half of the students enlisted.
2. PCs should be supplied with standard programs - MS Excel,
3. multimedia projector for lectures.

Pre-Requisites:

Any module(s) which must have been taken prior to the current module, or any specific background required to take this module.

General orientation and knowledge in basic statistics (definitions, statistical test), and basic knowledge in Excel software is required.