



SUBJECT DATASHEET

Semester:	2011/12/1
Subject:	Fundamentals of quality assurance
Code:	VEMKKAB212M
Responsible department:	Department of Analytical Chemistry
Responsible department code:	MKKA
Responsible lecturer:	dr. Tamás Pap

Educational objectives:

Understanding of the fundamentals of the modern quality assurance.

Detailed content of the subject:

1. Historical summary of the quality assurance. 2. Terms and definitions in the quality control (ISO 8402) 3. Quality management system. General requirements. (ISO 9000) 4. Management responsibility, authority and communication. Management review. (ISO 9001) 5. Resource. Provision of resources. Human resources. Infrastructure. Work environment. (ISO 9001) 6. Planning of product realization. Design and development. Production and service provision. Control of monitoring and measuring equipment. (ISO 9001 - ISO 9003) 7. Measurement, analysis and improvement. Monitoring of measurement. Control of nonconforming product. (ISO 9001 - ISO 9003) 8. Control of measuring instruments in the quality assurance system. (ISO 9004) 9. Conditions of the accreditation of laboratories. 10. Validation of instrumental measurements. 11. Edition of quality assurance manual for analytical laboratories. 12. Round robin tests, international proficiency tests: organisation and evaluation of the results. 13. Using of standard materials. 14. Good manufacturing Practice (GMP), Good laboratory practice (GLP). Computer aided quality assurance (CAQ).

Requirements:

The topics of the lectures

Required and suggested references:

ISO 8402, ISO 9000-9004, ISO 17025 nemzetközi szabványok.