Code: QA851								
Name: Validação de Métodos Analíticos								
Name in English: Validation of Analytical Methods								
Name in Spanish: Validación de Métodos Analíticos								
Subject type: Weekly								
Approval Type: Grade and frequency								
Characteristic: Regular								
Frequency: 75%								
Period Type / Offering period: Semi-annual / Every period								
Requires Final Exam: Yes								
Vectors								
T	L	P	O	PE	OE	SL	WEEKS	CREDITS
2	**0**	**0**	**0**	**0**	**0**	**2**	**15**	**2**
Occurrence on curriculum:								
Pre requirement: QA584 ou QA585								

Summary:

Validation of Analytical Methods.

Program:

Quality warranty: validation, internal quality control, proficiency testing, and accreditation. ISO systems rules. Instrumental and operational qualification. Calibration. Analytical methods validation. Validation parameters: linear range, linearity, matrix effect, selectivity, precision (repeatability and reproducibility), accuracy, robustness, limit of detection and limit of quantification. Statistical data treatment and use of electronic spreadsheets. Variances homogeneity. Anomalous results identification, regression significance tests. Uncertainties. Validation protocols and legislations aspects.

Basic Bibliography

1) MILLER, J.C.; MILLER, J.N. **Statistics for Analytical Chemistry**, 3. Ed. New York: Prentice Hall, 1993. 233 p.

2) INSTITUTO NACIONAL DE METROLOGIA, NORMALIZAÇÃO E QUALIDADE INDUSTRIAL (INMETRO). **Orientações sobre Validação de Métodos de Ensaios Químicos, DOQ-CGCRE-008, 2ª revisão**, 2007.

3) INSTITUTO NACIONAL DE METROLOGIA, NORMALIZAÇÃO E QUALIDADE INDUSTRIAL (INMETRO). **Orientações sobre Validação de Métodos de Ensaios Químicos, DOQ-CGCRE-008, 4ª revisão**, 2011.

Supplementary Bibliography

1) INTERNATIONAL CONFERENCE ON HARMONIZATION (ICH). **Validation of Analytical Procedures: Text and methodology** Q2 (R1), 2005.

2) ANVISA. **Consulta Pública n° 129**, de 12 de fevereiro de 2016.

3) THOMPSON, M.; ELLISON, S.L.R.; WOOD, R. **Pure and Applied Chemistry**, v. 74, p. 835-855, 2002.

4) EURACHEM. **The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics**, 1998.

5) HARRIS, D.C. **Análise Química Quantitativa**. 9. Ed. Rio de Janeiro: LTC, 2017. 774 p.