Module title	**Bioanalytics in a Regulated Environment**
Code	BP7
Degree Program	Master of Science in Life Sciences
Group	Bio / Pharma
Workload	3 ECTS (90 student working hours: 42 lessons contact; 58 h self-study)
Module Coordinator	**Name**: Franka Kalman **Phone**: +41 (0)79 528 25 29 **Email**: franka.kalman@hevs.ch **Address**: HESSO, Valais-Wallis, Sion
Lecturers	• Franka Kalman, HES-SO/VS • Oliver Germershaus, FHNW • Sabina Gerber, ZHAW • Guest Speakers from Industry (currently Lonza Visp)
Entry requirements	• Knows the different physico-chemical principles of liquid chromatography and electrophoresis (including capillary electrophoresis) – see Bibliography • Knows the principles of spectroscopy & refractive index, fluorescence, mass spectroscopy – see Bibliography • Knows the general chemical structure, 3D-structure and properties (e.g. pKa, pI, absorption, fluorescence, molecular weight) of biomolecules (peptides, proteins, glycoproteins, monoclonal antibodies, antibody-drug conjugates, complex carbohydrates (N-glycans) and nucleic acids) – see Bibliography
Learning outcomes and competences	After completing the module, students will be able to: • Know and understand the instrumental (bio)analytical techniques mostly used in current routine (bio)pharmaceutical industry • Knows important quality attributes of (bio)pharmaceuticals & biosimilars, in particular antibodies • Understand the relevance of particles and particle characterization in biological drug products • Identify common challenges related to particles and particle formation in biologics including strategies to circumvent such problems • Describe the basic stability challenges of biologic drugs, especially physical instabilities • Be able to plan an efficient testing monograph for a biopharmaceutical e.g. bioanalytical techniques for the characterization of APIs in the modern (bio)pharmaceutical industry • Understand the difference of a “test” method in relation to an analytical method / technique • Knows specific modern analytical techniques for complex N-glycan analysis, sub-visible particles, AA composition, posttranslational modifications, different digestion strategies for protein APIs, modern aggregation analysis • Knows the basic health authority rules for medicinal products in the regulated pharmaceutical environment

<table>
<tr><td></td><td>

- Understands the basic GMP (Good Manufacturing Praxis) requirements depending on the drug development phase
- Knows the structure of and how to design an analytical SOP and the SST (System Suitability Test) concept
- Knows different ICH guidelines: validation of analytical methods and specification, stability testing

</td></tr>
<tr><td>Module contents</td><td>

- Concept of specification (ICH guideline), User Requirement Specification (URS) = Analytical Target Profile (ATP) and basics of statistical process control (SPC)
- Concept of a test method including structure and criteria of a typical system suitability test (SST), the different development phases of a test method (URS / ATP, feasibility studies, method development inclusive SOP & SST, Validation, QC release, technical method transfer)
- A typical testing monograph for a MAB API / drug product in Pharma QC release analytics
- A typical monograph for a MAB drug put on batch stability testing
- Particle formation and particle characterization in biological drug products
- Typical modern release analytical techniques for content, identity, impurity (product related, process related) *e.g.* aggregate analysis, N-glycan analysis, posttranslational modifications *e.g.* deamination, free and bound sialic acids etc.
- Most important interaction networks / discussion groups *e.g.* PDA (Europe / USA),
- Most important Guideline’s like ICH Method Validation, Stability Testing & Specification, European & US Pharmacopeia & Swissmedic

</td></tr>
<tr><td>Teaching / learning methods</td><td>

- Lectures
- Case studies
- Group work and presentation

</td></tr>
<tr><td>Assessment of learning outcome</td><td>

1. Written final Exam (80%)
2. Presentation of case study(s) prepared by group work (20%)

</td></tr>
<tr><td>Format</td><td>Winter school CW6</td></tr>
<tr><td>Timing of the module</td><td>Block week: structure see following table (Contact teaching: 42 lessons / self-study: 58h)

<table>
<tr><th>Day of the block week</th><th><1</th><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>>5</th></tr>
<tr><td>Contact teaching (lessons)</td><td></td><td>7</td><td>9</td><td>9</td><td>9</td><td>8</td><td></td></tr>
<tr><td>Self-study (hours)</td><td>40</td><td></td><td></td><td></td><td></td><td></td><td>18</td></tr>
</table>
</td></tr>
<tr><td>Venue</td><td>School of Life Sciences – FHNW, Hofackerstrasse 30, 4132 Muttenz</td></tr>
<tr><td>Bibliography</td><td>

Entry level:

- **Entry requirements** (materials for refreshment, knowledge is assumed and a prerequisite to follow the course):
  D.C. Harris “Quantitative Chemical Analysis” 8th edition
  Chapter 3 (Experimental Error)
  Chapter 5 (Quality Assurance and Calibration Methods)

</td></tr>
</table>

	Chapter 22 (Introduction to Analytical Separations) Chapter 24 (High-Performance Liquid Chromatography) Chapter 25 (Chromatographic Methods and Capillary Electrophoresis) • **Entry requirements** (materials for refreshment, knowledge is assumed and a prerequisite to follow the course): F. Lottspeich "Bioanalytics" Chapter 1 (Protein Purification) Chapter 2 (Protein determination) Chapter 5 (Immunological Techniques) Chapter 6 (Chemical Modification of Proteins and Protein Complexes) – for information Chapter 11 (Electrophoretic Techniques) *Questions with respect to the entry requirements will be a substantial part of the final exam!* **Course material:** • ICH guideline (Method Validation, Stability Testing, Specification) • European Pharmacopoeia (Ph. Eur.) 10th edition
	English
Links to other modules	Strong links to central modules Regulatory Affairs (pharma part) (BP6) and Pharmaceutical Sciences Technology (S23)
Comments	
Last Update	08.03.2024