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**: Saša Miladinović **Phone**: +41 (0) 27 207 85 81 **Email**: sasa.miladinovic@hevs.ch **Address**: HESSO, Valais-Wallis, Sion
Lecturers	• Saša Miladinović, HES-SO/VS • Sabina Gerber, ZHAW • Guest Speakers from Industry
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 spectrometry – 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: • Explain the instrumental (bio)analytical techniques mostly used in current routine (bio)pharmaceutical industry • Describe important quality attributes of (bio)pharmaceuticals & biosimilars, in particular antibodies • Describe 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 • Design an efficient testing monograph for a biopharmaceutical e.g. bioanalytical techniques for the characterization of APIs in the modern (bio)pharmaceutical industry • Differentiate between a “test” method and an analytical method / technique • Evaluate specific modern analytical techniques for complex N-glycan analysis, sub-visible particles, amino acid composition, posttranslational modifications, different digestion strategies for protein APIs, modern aggregation analysis • Summarize the basic health authority rules for medicinal products in the regulated pharmaceutical environment • Apply the basic GMP (Good Manufacturing Practice) requirements depending on the drug development phase

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Construct the structure of and how to design an analytical SOP and the SST (System Suitability Test) concept
Interpret different ICH guidelines, including validation of analytical methods, specification, and stability testing

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<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 monoclonal antibody (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. Parenteral Drug Association (PDA Europe/USA),
Most important Guideline’s like ICH Method Validation, Stability Testing & Specification, European & US Pharmacopeia & Swissmedic

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

Lectures
Case studies
Group work and presentation

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<tr><td>Assessment of learning outcome</td><td>
1. Entrance test (20%)
2. Written final Exam (60%)
3. Presentation of case study(s) prepared by group work (20%)
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<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><td>Day of the block week</td><td><1</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>>5</td></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>
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<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)

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	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	08.02.2025