Module title	**Bioanalytics in a Regulated Environment**
Code	BP7
Degree Programme	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** : HES-SO, Valais-Wallis, Sion
Lecturers	• Franka Kalman, HES-SO/VS • Oliver Germershaus, FHNW • Sabina Gerber, ZHAW • Guest Speakers from Industry
Entry requirements	• Knows the different physico-chemical principles of liquid chromatography and electrophoresis (including capillary electrophoresis) • Knows the principles of spectroscopy & refractive index, fluorescence, mass spectroscopy • 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)
Learning outcomes and competences	After completing the module, students will be able to: • Know and understand the instrumental (bio)analytical tools mostly used in current routine (bio)pharmaceutical industry • Knows main quality attributes of bio-pharmaceuticals & biosimilar, in particular antibodies • 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 concept of a “test” method in relation to an analytical method / technique • Know specific modern methods for complex N-glycan analysis, sub-visible particles, AA composition, posttranslational modifications, different digestion strategies for protein APIs, modern aggregation analysis • Know the basic health authority rules for medicinal and drug products in the regulated pharmaceutical environment • Understand the basic GMP requirements depending on the drug development phase • Know the structure of and how to design an analytical SOP / SST concept • Know ICH guidelines: validation of analytical methods and specification, stability testing
Module contents	• Concept of specification (ICH guideline), User Requirement Specification (URS) = Analytical Target Profile (ATP) and basics of statistical process control (SPC)

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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, 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
Typical modern release analytical methods 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), AT Europe, CaSSS
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. Entry Exam on first module day (20%)
2. Written final Exam (60%)
3. Presentation of case study 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><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>
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<tr><td>Venue</td><td>Muttenz</td></tr>
<tr><td>Bibliography</td><td>
Entry level:

D.C. Harris “Quantitative Chemical Analysis” 8th edition
Chapter 3 (Experimental Error)
Chapter 5 (Quality Assurance and Calibration Methods)
Chapter 23 (Introduction to Analytical Separations)
Chapter 25 (High-Performance Liquid Chromatography)
Chapter 26 (Chromatographic Methods and Capillary Electrophoresis)
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

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	Chapter 11 (Electrophoretic Techniques) Course material: • ICH guideline (Method Validation, Stability Testing, Specification) • European Pharmacopoeia (Ph. Eur.) 10th edition
Language	English
Links to other modules	Strong links to central Regulatory Affairs (pharma part) (BP4) and Pharmaceutical Sciences Technology (S23) but no overlap
Comments	
Last Update	08.04.2022