



# Master in Life Sciences

A cooperation between  
BFH, FHNW, HES-SO, ZFH

<b>Module title</b>	<b>Bioanalytics in a Regulated Environment</b>
<b>Code</b>	BP7
<b>Degree Program</b>	Master of Science in Life Sciences
<b>Group</b>	Bio / Pharma
<b>Workload</b>	3 ECTS (90 student working hours: 42 lessons contact; 58 h self-study)
<b>Module Coordinator</b>	<b>Name:</b> Franka Kalman <b>Phone:</b> +41 (0)79 528 25 29 <b>Email :</b> franka.kalman@hevs.ch <b>Address :</b> HESSO, Valais-Wallis, Sion
<b>Lecturers</b>	<ul style="list-style-type: none"> <li>• Franka Kalman, HES-SO/VS</li> <li>• Oliver Germershaus, FHNW</li> <li>• Sabina Gerber, ZHAW</li> <li>• Guest Speakers from Industry</li> </ul>
<b>Entry requirements</b>	<ul style="list-style-type: none"> <li>• Knows the different physico-chemical principles of liquid chromatography and electrophoresis (including capillary electrophoresis)</li> <li>• Knows the principles of spectroscopy &amp; refractive index, fluorescence, mass spectroscopy</li> <li>• 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)</li> </ul>
<b>Learning outcomes and competences</b>	<p>After completing the module, students will be able to:</p> <ul style="list-style-type: none"> <li>• Know and understand the instrumental (bio)analytical tools mostly used in current routine (bio)pharmaceutical industry</li> <li>• Knows main quality attributes of (bio)pharmaceuticals &amp; biosimilars, in particular antibodies</li> <li>• Understand the relevance of particles and particle characterization in biologics drug products</li> <li>• Identify common challenges related to particles and particle formation in biologics including strategies to circumvent such problems</li> <li>• Describe the basic stability challenges of biologic drugs, especially physical instabilities</li> <li>• 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</li> <li>• Understand the concept of a “test” method in relation to an analytical method / technique</li> <li>• 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</li> <li>• Know the basic health authority rules for medicinal and drug products in the regulated pharmaceutical environment</li> </ul>

	<ul style="list-style-type: none"><li>Understand the basic GMP requirements depending on the drug development phase</li><li>Know the structure of and how to design an analytical SOP / SST concept</li><li>Know ICH guidelines: validation of analytical methods and specification, stability testing</li></ul>																								
Module contents	<ul style="list-style-type: none"><li>Concept of specification (ICH guideline), User Requirement Specification (URS) = Analytical Target Profile (ATP) and basics of statistical process control (SPC)</li><li>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)</li><li>A typical testing monograph for a MAB API / drug product in Pharma QC release analytics</li><li>A typical monograph for a MAB drug put on batch stability testing</li><li>Particle formation and particle characterization in biologic drug products</li><li>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.</li><li>Most important interaction networks / discussion groups e.g. PDA (Europe / USA), AT Europe, CaSSS</li><li>Most important Guideline's like ICH Method Validation, Stability Testing &amp; Specification, European &amp; US Pharmacopeia &amp; Swissmedic</li></ul>																								
Teaching / learning methods	<ul style="list-style-type: none"><li>Lectures</li><li>Case studies</li><li>Group work and presentation</li></ul>																								
Assessment of learning outcome	<ol style="list-style-type: none"><li>Written final Exam (80%)</li><li>Presentation of case study prepared by group work (20%)</li></ol>																								
Format	Winter school CW6																								
Timing of the module	<div>Block week: structure see following table (Contact teaching: 42 lessons / self-study: 58h)</div> <table><tr><td>Day of the block week</td><td>&lt;1</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>&gt;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>20</td><td></td><td></td><td></td><td></td><td></td><td>38</td></tr></table>	Day of the block week	<1	1	2	3	4	5	>5	Contact teaching (lessons)		7	9	9	9	8		Self-study (hours)	20						38
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Venue	Muttenz																								
Bibliography	<div>Entry level:</div> <ul style="list-style-type: none"><li>D.C. Harris "Quantitative Chemical Analysis" 8<sup>th</sup> edition<ul style="list-style-type: none"><li>Chapter 3 (Experimental Error)</li><li>Chapter 5 (Quality Assurance and Calibration Methods)</li><li>Chapter 22 (Introduction to Analytical Separations)</li><li>Chapter 24 (High-Performance Liquid Chromatography)</li><li>Chapter 25 (Chromatographic Methods and Capillary Electrophoresis)</li></ul></li></ul>																								

	<ul style="list-style-type: none"> <li>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</li> <li>Chapter 11 (Electrophoretic Techniques)</li> </ul> <p>Course material:</p> <ul style="list-style-type: none"> <li>ICH guideline (Method Validation, Stability Testing, Specification)</li> <li>European Pharmacopoeia (Ph. Eur.) 10th edition</li> </ul>
<b>Language</b>	English
<b>Links to other modules</b>	Strong links to central Regulatory Affairs (pharma part) (BP6) and Pharmaceutical Sciences Technology (S23) but no overlap
<b>Comments</b>	
<b>Last Update</b>	03.03.2023