

Master in Life Sciences

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

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	<p>Name: Franka Kalman Phone: +41 (0)79 528 25 29 Email : franka.kalman@hevs.ch Address : HESSO, Valais-Wallis, Sion</p>
Lecturers	<ul style="list-style-type: none"> • Franka Kalman, HES-SO/VS • Oliver Germershaus, FHNW • Sabina Gerber, ZHAW • Guest Speakers from Industry
Entry requirements	<ul style="list-style-type: none"> • Knows the different physico-chemical principles of liquid chromatography and electrophoresis • Knows the principles of spectroscopy & refractive index, fluorescence, mass spectroscopy • Knows the general chemical structure (including 3D structure) and properties (e.g. pKa, pl, 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	<p>After completing the module, students will be able to:</p> <ul style="list-style-type: none"> • Know and understand the mainly instrumental (bio)analytical tools used in 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 bio pharmaceutical 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 product 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	<ul style="list-style-type: none"> • Concept of specification (ICH guideline), User Requirement Specification (URS) and basics of statistical process control (SPC)

	<ul style="list-style-type: none"> • 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, 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 put to 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) (invite expert from PDA to explain functioning), AT Europe, CaSSS • Most important Guideline's like ICH Method Validation, Stability Testing & Specification, European & US Pharmacopeia & Swissmedic 																								
Teaching / learning methods	<ul style="list-style-type: none"> • Lectures • Case studies • Group work and presentation 																								
Assessment of learning outcome	<ol style="list-style-type: none"> 1. Entry Exam on first module day (20%) 2. Written final Exam (60%) 3. Presentation of case study prepared by group work (20%) 																								
Format	Winter school CW6																								
Timing of the module	<p>Block week: structure see following table (Contact teaching: 42 lessons / self-study: 58h)</p> <table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </table>	Day of the block week	<1	1	2	3	4	5	>5	Contact teaching (lessons)		7	9	9	9	8		Self-study (hours)	40						18
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Venue	Muttenz																								
Bibliography	<p>Entry level:</p> <ul style="list-style-type: none"> • D.C. Harris "Quantitative Chemical Analysis" 9th 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 11 (Electrophoretic Techniques) <p>Course material:</p>																								



	<ul style="list-style-type: none">• 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) (BP6) and Pharmaceutical Sciences Technology (S23) but no overlap
Comments	
Last Update	09.04.2020