

# Master in Life Sciences

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

<b>Module title</b>	<b>Regulatory Affairs</b>
<b>Code</b>	BP4
<b>Degree Programme</b>	Master of Science in Life Sciences
<b>Group</b>	Bio/Pharma
<b>Workload</b>	3 ECTS (90 student working hours: 42 lessons contact = 32 h; 58 h self-study)
<b>Module Coordinator</b>	<p><b>Name:</b> Dr. Marc Pfeifer  <b>Phone:</b> +41 (0)27 606 86 61  <b>Email:</b> <a href="mailto:marc.pfeifer@hevs.ch">marc.pfeifer@hevs.ch</a>  <b>Address:</b> HES-SO, Institute of Life Technologies, Rue du Rawyl 64, 1950 Sitten 2</p>
<b>Lecturers</b>	<ul style="list-style-type: none"> <li>• Dr. Marc Pfeifer, HES-SO</li> <li>• Industry, authority and/or consulting firm representatives</li> </ul>
<b>Entry requirements</b>	B.Sc. in Life Sciences (e.g. Chemistry or Biotechnology); Basic knowledge of Quality Management
<b>Learning outcomes and competences</b>	<p>After completing the module, the student will be able to:</p> <ul style="list-style-type: none"> <li>• understand the role and importance of regulatory affairs within regulated industries (i.e. pharmaceutical, medical device and in vitro diagnostics)</li> <li>• apprehend how product development and manufacturing as well as associated processes and milestones are interlinked with documentation deliverables</li> <li>• appreciate the relevance and high-level conception of clinical and performance evaluations</li> <li>• give support with the preparation and compilation of quality- and regulatory-relevant documents</li> </ul>
<b>Module contents</b>	<ul style="list-style-type: none"> <li>• Role and responsibilities of regulatory affairs professionals within an organization in the healthcare industries</li> <li>• The module will contain two major – related, yet distinct – parts: 1) a drug / biologics, and 2) a medical device / IVD regulatory pathway development (which includes identification of applicable regulations and standards as well as registration sequence for different countries in the world)</li> <li>• Changes in the regulatory landscape in Europe for medical devices and in vitro diagnostics (IVD), i.e. from directives to regulations</li> <li>• Integration of specific requirements in the quality management system (QMS)</li> <li>• Structured communication with Regulatory Bodies and Competent Authorities</li> <li>• Preparation of the technical documentation in preparation for CE mark and US FDA approval (e.g. including preparation of verification and validation activities)</li> </ul>
<b>Teaching / learning methods</b>	Lectures will be given on the principles of Regulatory Affairs referencing guidelines and standards. The seminars will include reviewing real-world case examples also illustrating successful approaches as well as failures, shortcomings and other issues that have occurred in the past. This course requires active participation and individuals / groups are required to develop feasible solutions for potential industry use. The students during interactive exercises are coached by the experts.
<b>Assessment of learning outcome</b>	1. The report of a case study (prepared in groups) has to be handed in latest 3 weeks after the end of the module (100%)
<b>Format</b>	Summer school

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<b>Timing of the module</b>	Spring semester, week 25							
	<b>Day of the block week</b>	<1	1	2	3	4	5	>5
	<b>Contact teaching (lessons)</b>		8	9	9	8	8	
	<b>Self-study (hours)</b>	8	2	2	2	2	2	40
<b>Venue</b>	Sion							
<b>Bibliography</b>	Literature and regulatory guidelines will be provided during the course.							
<b>Language</b>	English							
<b>Links to other modules</b>	Any quality-related, analytical method developments and drug / IVD / med. device development module.							
<b>Comments</b>								
<b>Last Update</b>	25.04.2019							