Module title	**Regulatory Affairs**
Code	BP4
Degree Programme	Master of Science in Life Sciences
Group	Bio/Pharma
Workload	3 ECTS (90 student working hours: 42 lessons contact = 32 h; 58 h self-study)
Module Coordinator	**Name**: Dr. Marc E. Pfeifer **Phone**: +41 (0)58 606 86 61 **Email**: marc.pfeifer@hevs.ch **Address**: HES-SO, Institute of Life Technologies, Rue de l'Industrie 19, 1950 Sion
Lecturers	• Dr. Marc E. Pfeifer, HES-SO • Industry, authority and/or consulting firm representatives
Entry requirements	B.Sc. in Life Sciences (e.g., Chemistry or Biotechnology); Basic knowledge of Quality Management
Learning outcomes and competences	After completing the module, the student will be able to: • understand the role and importance of regulatory affairs within regulated industries (i.e., pharmaceutical, medical device and in vitro diagnostics) • apprehend how product development and manufacturing as well as associated processes and milestones are interlinked with documentation deliverables • appreciate the relevance and high-level conception of clinical and performance evaluations • give support with the preparation and compilation of quality- and regulatory-relevant documents
Module contents	• Role and responsibilities of regulatory affairs professionals within an organization in the healthcare industries • 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) • Changes in the regulatory landscape in Europe for medical devices and in vitro diagnostics (IVD), i.e., from directives to regulations • Integration of specific requirements in the quality management system (QMS) • Structured communication with Regulatory Bodies and Competent Authorities • Preparation of the technical documentation in preparation for CE mark and US FDA approval (e.g., including preparation of verification and validation activities)
Teaching / learning methods	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.
Assessment of learning outcome	1. Written exam (multiple choice and open questions specific to groups' case studies) on the last day of the block week. (100%)
Format	Summer school

<table>
<tr><td>Timing of the module</td><td>Spring semester, week 25
<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>9</td><td>9</td><td>9</td><td>9</td><td>6</td><td></td></tr>
<tr><td>Self-study (hours)</td><td>48</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>0</td></tr>
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<tr><td>Venue</td><td>On-site lectures in Sion</td></tr>
<tr><td>Bibliography</td><td>Literature and regulatory guidelines will be provided during the course.</td></tr>
<tr><td>Language</td><td>English</td></tr>
<tr><td>Links to other modules</td><td>Any quality-related, analytical method developments and drug / IVD / med. device development module.</td></tr>
<tr><td>Comments</td><td></td></tr>
<tr><td>Last Update</td><td>01.09.2023</td></tr>
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