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 Pfeifer **Phone**: +41 (0)58 606 86 61 **Email**: marc.pfeifer@hevs.ch **Address**: HES-SO, Institute of Life Technologies, Rue du Rawyl 64, 1950 Sitten 2
Lecturers	• Dr. Marc 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 with 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. The report of a case study (prepared in groups) has to be handed in latest 3 weeks after the end of the module (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>8</td><td>9</td><td>9</td><td>8</td><td>8</td><td></td></tr>
<tr><td>Self-study (hours)</td><td>8</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>40</td></tr>
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<tr><td>Venue</td><td>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>08.09.2020</td></tr>
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