Module	**Quality Management & Regulatory Affairs**
Code	MLS_S10 (including BP4)
Degree Program	Master of Science in Life Sciences (MSLS)
Cluster	Bio/Pharma
Specialization	Applied Biosciences
ECTS Credits	1 + 3
Workload	120 h: Contact 56 lessons = 42 h; Self-study 78 h
Module Coordinator	**Name** Prof. Dr. Marc Pfeifer **Phone** +41 27 606 86 61 **Email** marc.pfeifer@hevs.ch **Address** HES-SO Valais / Wallis, Institute of Life Technologies, Route du Rawyl 47, CH-1950 Sion 2
Lecturers	• Prof. Dr. Marc Pfeifer, HES-SO Valais / Wallis • Industry, authority and/or consulting representatives
Entry Requirements	B.Sc. in Life Sciences (e.g. Chemistry or Biotechnology); Basic knowledge of Quality Management
Learning Outcomes and Competences	Quality management (1 ECTS) Upon completion, the students shall have an understanding of Quality and QMS principles, implementation, certification and QM improvement possibilities for instance in an industry or hospital context. They shall be able to assume an active role during execution of a risk analysis. The students shall understand the process of regulatory inspections. Their competences include the ability to identify requirements specifications, especially in the context of process control and validation. Regulatory Affairs (3 ECTS = BP4) • 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 Content	Quality management (1 ECTS) • QMS implementation, certification and QM improvement approaches • Risk management (e.g. failure mode and effects analysis, FMEA) • Regulatory inspection (e.g. Swissmedic). • Specifications and in-process control (IPC), analytical methods, validation approaches, properties of a SOP. Regulatory Affairs (3 ECTS = BP4) • 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 Quality management and 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	The report of a case study (prepared in groups) has to be submitted latest 3 weeks after the end of module BP4 (100%). Thus, module MLS_S10 is directly linked to module BP4.
Bibliography	Literature and quality / regulatory guidelines will be provided the course.
Language	English
Comments	Traveling costs associated with organized site / industry visits will have to be covered by the students.
Last Updates	16.03.2017 / Marc Pfeifer 18.04.2018 / Marc Pfeifer 12.06.2020 / Marc Pfeifer