<table>
<thead>
<tr>
<th>Module</th>
<th>Quality Management &amp; Regulatory Affairs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>MLS_S10 (including BP4)</td>
</tr>
<tr>
<td>Degree Program</td>
<td>Master of Science in Life Sciences (MSLS)</td>
</tr>
<tr>
<td>Cluster</td>
<td>Bio/Pharma</td>
</tr>
<tr>
<td>Specialization</td>
<td>Applied Biosciences</td>
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<tr>
<td>ECTS Credits</td>
<td>1 + 3</td>
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<tr>
<td>Workload</td>
<td>120 h: Contact 56 lessons = 42 h; Self-study 78 h</td>
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</tbody>
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### Module Coordinator
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- **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 contains 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