

Industry Based Learning Guidelines for the Study program MAS in Medical Device Regulatory Affairs and Quality Assurance



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**UNIVERSITÄT
BERN**

1. Objectives of the IBL program

Objectives	The objective of Industry-Based Learning is to provide students with the opportunity to integrate theoretical knowledge with the practical applications and experiences in a regulatory environment. It also aims to provide students with opportunities for personal growth and the development of interpersonal skills. and to allow them to develop a professional network.
Benefits to the student	<p>The program aims to provide the following benefits to students:</p> <ul style="list-style-type: none">• Opportunity to consolidate theoretical learning through practical implementation• Opportunity to experience particular areas of the medical device regulatory profession prior to graduation allowing them to make more informed career decisions• Opportunity to gain professional experience and thus improve employment opportunities• Opportunity to learn from the knowledge and experience of industry specialists• Opportunity to establish a professional network and an understanding of the medical device industry• Opportunity to earn an income during the program

2. General Description

Official Requirements	Industry based learning is offered to students of the MAS in Medical Device Regulatory Affairs and Quality assurance to allow them to gain practical industry experience during their studies. It is not however, required for graduation of the MAS in Medical Device Regulatory affairs and Quality Management and is therefore not a compulsory component of the program.
Prerequisites	Industry based learning program does not have any official prerequisites. It is however, highly recommended that students have fundamental knowledge in the European medical device regulations, risk management and quality assurance prior to commencement. It is thus recommended that the IBL placement commences after the completion of the first year of study (30 ECTS). Placements can, however, commence at any time during study with mutual agreement of the student, host institution and the study coordinator.

Duration and Timing	It is recommended that the placement be undertaken for a duration of 6 - 12 months. However, a placement of any length can be undertaken with mutual agreement of the student, host institution and the study coordinator. The placement must commence after enrolment of the student at the University of Bern and must be completed before graduation from the study program. Any employment of the student preceding or exceeding the students enrolment in the study program, will be done so without the involvement or responsibility of the University of Bern. For placements beginning at the start of the second year of study (September), placement applications will take place during the preceding spring semester.
Workload	It is recommended that students commit 100% of their work time to the completion of the IBL placement and the program studies. The students course workload will not exceed 20 hours per week and will depend on the timing of the placement and the selected elective studies. Study workload is reduced in the second year of study to allow students to dedicate more time to their IBL placements.
Renumeration	It is recommended that host institutions offer payment to the students during the placement to eliminate the need for additional employment. Any renumeration must be agreed upon by the host institution and the student.
MAS Thesis	On agreement between the student, host institution and study coordinator it is possible for the student to complete their MAS thesis during the IBL placement at the host institution. The MAS thesis must be conducted according the thesis regulations.

3. Responsibilities

Responsibilities of the Host Institution	The host institution is responsible for selecting a candidate and for negotiating the terms of the placement with the student. It is recommended that during the placement, the student be assigned a mentor within the host institution who takes responsibility for the development of the students day to day program and their learning, in collaboration with the study coordinator and who acts as a contact for communication between the student, host institution and the University. It is recommended that students undertake standard tasks of a junior regulatory office or quality manager during the placement but that they are also exposed, when possible, to a wide variety of situations and tasks to maximize their learning experience. Representatives of the host institution will be invited to attend non-compulsory information sessions at the sitem Center relating to the IBL program of to the MAS study program.
Responsibilities of the student	The student is responsible for expressing their intention and commitment to undertake an IBL by February of Year 1.

The student is responsible for applying for IBL positions advertised through the study program or for finding their own alternative placement. The student is responsible for negotiating the terms of the placement contract with the host institution. The student is responsible for managing their studies during the IBL program and for informing the host institution of ongoing study requirements during the program. Students have the right to apply for, accept, or reject any proposed IBL placement. Students have a maximum of two opportunities to get their IBL placement through the University network. Students are responsible for completing the IBL registration form and seeking approval from the programme team prior to commencement of the placement.

Responsibilities of the University	The University of Bern is responsible for advising and supporting the host institution and the student during the IBL Placement. The University shall advertise proposed IBL placements to students and meet with students and host institutions regarding possible placements. However, the University is not responsible for finding placements for students nor for selecting candidates for placements nor for negotiating terms of placement contracts. The programme team will organise to meet with the student and the host mentor on commencement of the placement and at least once every 6 months thereafter. The University will be responsible for approving and monitoring Master thesis projects, undertaken within the host institution.
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Other terms and conditions	<p>While students may indicate their host institution preferences, the University can't guarantee their placements. Placements depend on the needs of the host institutions and the suitability of the candidates (the students).</p> <p>The contract, salary, start, and finish date are to be arranged between the student and the host institution. The University does not take part in this process.</p>
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