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| **Modulbezeichnung** | **Introduction to the approval process of medical devices** |
| Englischer Titel | **Introduction to the approval process of medical devices** |
| Modulniveau nach DQR |  |
| Modulnummer |  |
| Untertitel |  |
| Lehrveranstaltungen |  |
| empfohlenes Studiensemester |  |
| Häufigkeit des Angebots/ Angebotsturnus | Every winter semester |
| Modulverantwortliche:r | Prof. Dr. rer. biol hum Heike Walles |
| Dozent:in |  |
| Sprache | englisch |
| Zuordnung zum Studiengang/ Curriculum / Verwendbarkeit des Moduls | Master program |
| Lehrform und SWS | Lecture, Tutorial OR Lecture, Seminar ??Time of attendance: 2 SWS Lecture, 1 SWS Tutorial (??)Autonomous work: follow-up lecture and exercises - elaboration of term paper |
| Arbeitsaufwand |  |
| Dauer des Moduls | One semester |
| Credit Points (CP) | 5 CP = 150 h (45 h time of attendance + 105 h autonomous work) |
| Voraussetzung für die Vergabe von CP |  |
| Teilnahmevoraussetzungen | Attending the module Basics for Medical Device Approval of MT Bachelor (OvGU) is an advantage |
| Empfehlungen für die Teilnahme | none |
| Modulziele / angestrebte Lernergebnisse / Learning Outcomes | In contrast to pharmaceuticals, no worldwide uniform legally requirements are available for the approval and CE certification of medical devices. Every manufacturer is responsible to set up the process and documentation of his medical devices to get it approved according to defines OECD Guidelines and ISO norms. The regulatory affair offers an unexpectedly exciting and diverse range of tasks for all students, especially in small and medium-sized companies. As part of the elective module, we want to arouse students’ interest in these regulatory affairs topics in the modules including active participation of representatives of the medical device industry. We want to teach the essential basics for an activity in the regulatory environment. In the first semester, we will address the process as whole as well as regulatory and structural requirements. |
| Inhalt | The content is based on the specifications for the European CE approval and relevant DIN ISO specification. It includes the following topics:* Introduction to the process of market approval
* GxPractice and alternative

We will build groups of two students to perform a Term work. Content of work are selected examples to illuminate the approval procedures for different medical device classes and to address particular regulatory issues. These Term work are presented and discussed in a short lecture to all students. The homework is 50% of the examination performance. In addition, an exam is written at the end of the course, which also accounts for 50% of the total grade. |
| Studien- / Prüfungsleistungen / Prüfungsformen | Term paper and its presentationWritten examination ?? min (Term paper and exam each 50% of the final grade) |
| Literatur | Will be made available digitally at the beginning of the course |
| Sonstige Informationen |  |
| Freigabe / Version |  |