HAW HAMBURG

Faculty of Life Sciences

Module compendium

Master degree program
European Master of Medical Technology and Healthcare Business (EMMaH)

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Module compendium

Master degree program

European Master of Medical Technology and Healthcare Business (EMMaH)

Faculty of Life Sciences
Department of Biomedical Engineering

March 2017

approved by the Faculty Council of the Faculty of Life Sciences on 23.03.2017

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Aims of the study program

These module description is valid for the master programme: Medical Technology and Healthcare Business (EMMaH). This Master Programme runs jointly with three institutions:

- Hamburg University of Applied Sciences (HAW Hamburg)
- Escola Superior de Saúde do Politécnico do Porto (ESS)
- Université de Lille II – Faculté Ingénierie et Management de la Santé (ILIS)

They regulate the organization, execution of the studies and the examinations and are supplemented by the subject-related regulations for the specific master's programme at each institution.

Giving due regard to changes and requirements in the working world, the aim of the Master's Programme in EMMaH is to impart to students holding a relevant bachelor's degree the particular knowledge, skills and methods required in the medical technology and management field in a way that enables them to conduct scientific work, to critically assess and integrate scientific findings and knowledge, and to act responsibly. In order to achieve these objectives, the Master's programme in EMMaH strives to link research and instruction very closely with one another, inter alia through intensive lab courses conducted in collaboration with the three faculties Hamburg, Lille and Porto.

Master degree programs are advanced courses and lead to a further and higher academic and vocational qualification. This module compendium describes the course of studies "European Master of Medical Technology and Healthcare Business (EMMaH)" of the Hamburg University of Applied Sciences (HAW).

The full time study is designed for 4 semesters (2 years). The graduate-level courses in Hamburg part cover scientific and engineering knowledge focused on the field of biomedical engineering with emphasis on the processing, control and imaging of biomedical signals and physiological control loops including virtual reality applications. The course is completed by regulatory and technology assessment aspects. Most lectures are complemented by associated practical courses with up-todate software tools and hardware, e.g. in our research labs or at the hospital sites of our collaboration partners. In a mandatory scientific project the students are engaged in autonomous scientific studies in small groups with one person of each country. Enhanced soft skills are acquired in the seminars and during the lectures by intense discussions and small projects like preparation of presentations, posters and papers. In the master thesis later, the students will demonstrate their ability for autonomous scientific work at graduate level. The courses are held in English language.

After completing the study program, degree holders will have adopted competences in the following learning aims:

I) Knowledge and Comprehension

II) Analysis objectives and tasks

III) Finding and use of knowledge in new situations

IV) Problem solving, research and decision making

V) Self-system

VI) Reflection and Communication

These competences enable degree holders to successfully apply in the following work fields at health care institutions, industry and academia:

I) Innovation Management

II) Implementation, maintenance and service

III) Project Management

IV) Marketing and Distribution

V) Controlling

Graduates have the ability to independently acquire new fields of knowledge and to solve complex problems, even above the current state of knowledge, using scientific methods. Graduates are capable to isolate problems in a new area of expertise or such an area in development and to encircle the most probable solution approach. They have the continuing ability of composing new technical solutions and new process strategies in the field of biomedical engineering and to transfer these solutions into clinical use or in industrial production. Although the course is designed for students interested in designing biomedical applications, graduates can not only work in research & development, but also in a company's production division or in technical functions in a hospital or research institutes. Graduates are qualified to join a doctorate program subsequently.

The Study and Examination Regulation for this course (Studiengangsspezifische Prüfungs- und Studienordnung des Masterstudiengangs "European Master of Medical Technology and Healthcare Business (EMMaH)" an der Hochschule für Angewandte Wissenschaften Hamburg) as well as the General Study and Examination Regulation for Bachelor- and Master Courses of Studies in Engineering, Natural and Health Science as well as Informatics of the Hamburg University of Applied Sciences (HAW) (Allgemeine Prüfungs- und Studienordnung für Bachelor- und Masterstudiengänge der Ingenieur-, Natur- und Gesundheitswissenschaften sowie der Informatik an der Hochschule für Angewandte Wissenschaften Hamburg (APSO-INGI)) are important applicable documents, too. These and more applicable regulations and further information are accessible at the HAW websites, in particular at the sites of the Faculty of Life Sciences, Department of Biomedical Engineering.

The study courses are organized in modules based on their topics. Generally, modules are completed by a module exam. The total number of credit points (CP) is 120. One CP is equivalent to 30 work hours (1 hour = 60 minutes). On the following pages all modules are described in detail with information on e.g. course titles, learning content and aims, kind of exam etc.. The table below contains a matrix of learning goals organizing the modules according to the learning aims and work fields mentioned above.

Master thesis

The Master thesis represents the written composition of a theoretical, empirical and/or experimental study. With the Master thesis students prove their capability to express a sound scientific study hypothesis, explore its relevant bibliographic background, select, adapt or develop appropriate scientific study methods to collect and analyze gathered data and discuss the results in relation to the study aims and relevant literature conclusively. The time-limit for delivery of the master thesis is six months. It is credited by 30 credit points.

Target Matrix

1	2	General learning aims						Work fields				
Nr	**Modul**	**Knowledge and Comprehension**	**Analysis objetctives and tasks**	**Finding and unse of new knowledge in new situations**	**Problem solving, research and decision making**	**Self-System**	**Reflection and Communication**	**Innovation management**	**Implementation, maintenance and service**	**Project Management**	**Marketing and Distribution**	**Controlling**
1	Project Seminar in Engineering		x	x	x		x	x		x	x	x
2	Data Acquisition and Processing	x		x	x	x			x			
3	Advanced Biosignal Processing	x							x			
4	Modelling Medical Systems	x		x	x	x		x				
5	Simulation and Virtual Reality in Med	x		x	x	x		x				
6	HTA/Regulatory Affairs		x		x				x	x	x	x
7	Master Thesis		x	x	x		x	x		x		x

Module and course structure

1. Semester: Modules at Hamburg University of Applied Sciences

Nr.	Module	CP	Semester*	Course	Course type	SHW	Achievment type	Exam type	Group size
1	Project Seminar in Engineering	5	W	Project Seminar in Engineering	PJ	4	PL	K, H, R, M	15
2	Data Acquisition and Processing	5	W	Data Acquisition	SeU	2	PL	K, H, R; M	20
			W	Data Acquisition, **Practical Work**	SeU	2			20
3	Advanced Biosignal Processing	5	W	Biosignal Processing	SeU	2	PL	K, H, R, M	20
			W	Advanced Filtering Techniques for Biosignals	SeU	2			
4	Modelling Medical Systems	5	W	Modelling Methods	SeU	2	PL	K, H, R, M	20
			W	Modelling Tools, **Practical Work**	SeU	2			
5	Simulation and Virtual Reality in Medicine	5	W	Simulation and Virtual Reality in Medicine	SeU	2	PL	H, K, R, M	20
			W	Simulation and Virtual Reality in Medicine, **Practical Work** (SimLab)	SeU	2			20
6	HTA /Regulatory Affairs	5	W	Regulatory Affairs	SeU	2	PL	H, K, R, M	20
			W	HTA	SeU	2			20
	Total	**30**				**24**			

2. Semester: Modules at Escola Superior de Tecnologia da Saúde do Porto

Nr.	Module	CP	Semester*	Course	Course type	SHW	Achievment type	Exam type	Group size
1	Project Seminar in Health	5	S	Project Seminar in Health	PJ	4	PL	K, H, R, M	15
2	Medical Imaging Technologies and Devices	5	S	Medical Imaging Technologies and Devices	SeU	4	PL	K, H, R; M	20
3	Medical Measurement Techniques	5	S	Medical Measurement Techniques	SeU	4	PL	K, H, R, M	20
4	Applied Clinical Imaging	5	S	Applied Clinical Imaging	SeU	4	PL	K, H, R, M	20
5	Applied Clinical Signals	5	S	Applied Clinical Signals	SeU	4	PL	H, K, R, M	20
6	Human-Technology Interaction on Clinical Environment	5	S	Human-Technology Interaction on Clinical Environment	SeU	4	PL	H, K, R, M	20
	Total	**30**				**24**			

3. Semester: Modules at Université de Lille II - Faculté Ingénierie et Management de la Santé, Lille

Nr.	Module	CP	Semester*	Course	Course type	SHW	Achievment type	Exam type	Group size
1	Project Seminar in Healthcare Business	5	W	Project Seminar in Healthcare Business	PJ	4	PL	K, H, R, M	15
2	Principles of Marketing in the Healthcare Business	5	W	Principles of Marketing in the Healthcare Business	SeU	4	PL	K, H, R; M	20
3	International Healthcare Marketing and Business	5	W	International Healthcare Marketing and Business	SeU	4	PL	K, H, R, M	20
4	Marketing for Innovative Medical Technology	5	W	Marketing for Innovative Medical Technology	SeU	4	PL	K, H, R, M	20
5	Legal and regulatory considerations in the HealthCare Industry	5	W	Legal and regulatory considerations in the HealthCare Industry	SeU	4	PL	H, K, R, M	20
6	Industrial Purchasing, Outsourcing in the Healthcare Industry	5	W	Industrial Purchasing, Outsourcing in the Healthcare Industry	SeU	4	PL	H, K, R, M	20
	Total	**30**				**24**			

4. Semester: Modules at Hamburg University of Applied Sciences

Nr.	Module	CP	Semester*	Course	Course type	SHW	Achievment type	Exam type	Group size
	Masterarbeit	30	S	Masterarbeit			PL	MT	
	Total	**30**							

Legend:
SHW = Presence hours per week during semester
Course type: ST = seminaristic teaching, PJ. = Project, Sem. = Seminar (>80% presence obligatory)
Achievement type: SL = Test (not graded), PL = Exam (graded)
Exam type: K = written exam, M = oral exam / presentation, R = seminar paper, H = homework, P = Project documentation/poster

Module descriptions

Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 01	**Project Seminar in Engineering**
Module coordination/ Resposible person	Prof. Dr. Friedrich Ueberle; Prof. Dr. Bernd Flick
Associated courses	• Project Seminar in Engineering
Lecturer	All university lecturers of the department MT, Prof. Dr. Ueberle
Semester / Period / Offer of this turnus	1st semester / one semester / winter semester
ECTS Credits/Presence hours per week	5 CP / 4 SHW
Workload	150 h, laboratory work, private study, includes 32 h seminar
Status	Obligatory module
Preconditions / Required skills	Appropriate knowledge from previous academic studies in a professionally associated field, bachelor degree The projects must be individually supervised by a professor of the biomedical department (Department Medizintechnik / Fakultät LS). The project regulations of the Department Medizintechnik apply.
Teaching language	English
General learning aims and work fields	• Analysis objectives and tasks; Finding and use of new knowledge in new situations; Problem solving, research and decision making • Innovation management; Project Management; Marketing and Distribution; Controlling

Acquired competences / educational objectives

The students are able to develop a biomedical component, device, software or study.

Therefore, they ...

- approach and handle complex problems, tasks and projects in the biomedical field.
- understand and apply complex laboratory and biomedical equipment to solve the project tasks.
- find and understand appropriate literature, assess and understand complex informations and apply them to the project (E.g. literature data bases, specialized publications).
- autonomously design, develop and implement laboratory experiments / software / hardware.
- autonomously design, keep records and interpret measurements using appropriate mathematical and scientific methods.
- provide and track a project plan.
- understand and define project goals and negotiate them with the project sponsors.
- present the results to peers and sponsors.

The students are able to...

- handle projects responsible, with awareness to cost, risk and safety.
- autonomously organize project groups, organize meetings and communication among the project participants and identify and solve all problems typical to scientific projects.
- get in contact to experts, where necessary, discuss project and test plans with co-workers and project sponsors and defend their plans and results against critical objections.

Learning matter

project skills in practice

the scientific matters depend on the projects, which must be supervised / approved by a professor of the biomedical department

the projects should address scientific level problems from any aspect of biomedical engineering and biomedical sciences

Teaching methods/ methods generally / types of media	Typically: experimental laboratory work / hardware and software engineering / literature work / seminar / presentations / project meetings / project documentation / web based cooperation
Course- and examination achievements	Regular form for the module examination: written project report with oral presentation The type of examination will be announced by the lecturer at the beginning of the course. The participation in at least 80% of the project seminar meetings is obligatory, presentations (1..2, not graded), writing of 1..2 seminar minutes and project poster required.
Literature and learning aids	Scientific literature, depending on the project

Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 02	**Data Acquisition and Processing**
Module coordination/ responsible person	Prof. Dr. Kay Förger
Associated courses	• Data Acquisition • Data Acquisition, Practical Work
Lecturer	Prof. Dr. Kay Förger
Semester / Period / Offer of this turnus	1st semester / one semester / winter semester
ECTS Credits/Presence hours per week	5 CP / 4 SHW • Data Acquisition (2 SHW) • Data Acquisition, Practical Work (2 SHW)
Workload	150 h: 64h presence, 86 h private studies
Status	Obligatory module
Preconditions / Required skills	None / Basic skills in programming and mathematics (e.g. acquired in a bachelor degree program)
Teaching language	English
General learning aims and work fields	• Knowledge and Comprehension; Finding and use of new knowledge in new situations; Problem solving, research and decision making; Self-System • Implementation, maintenance and service

Acquired competences / educational objectives

Expertise and methodological competences The students are able to use the computer as universal tool to solve practical problems:

- on the one hand complex simulations can be performed by LabVIEW with little effort and
- on the other hand data can be acquired and processed with a computer easily.

Data and signals are simulated to make the theoretical relations understandable and better applicable.

The students are able …

- to apply statistical methods and
- to test the developed evaluation methods by simulation to get more reliable programs.
- Especially by such an approach subtle programming errors become obvious, which otherwise could be found hardly but distort the results much. That sensitizes students especially to such errors.
- Additionally the students are enabled by computer simulations to analyze measurement and processing techniques (signal sampling, averaging, statistical tests etc.) if some restrictive mathematical prerequisites (e.g. sampling theorem, normal distribution of random variables) are not exactly met in practical problems. Methods which provide reliable results in such cases are highlighted as robust procedures.
- The students are able to look for robust procedures / techniques.

In practical applications the parallel acquisition and processing of measurands and the simultaneous reaction on user input is an essential requirement, which is difficult to understand and implement in text based programming languages. On the contrary the graphical programming environment of LabVIEW enables the students to

- design programs with parallel execution and synchronization which are easy to implement and understand.

acquire and process data from real experiments correctly and scientifically founded.

Personal and interpersonal skills

The students are able to …

- keep one's distance to their results and especially to their own programs.
- recognize the must of software tests using simulations with results which are known in advance to assess the extent of tests for methods and procedures more precisely.
- develop solutions for a given data acquisition project using the methods presented.

Learning matter

- Introduction to LabVIEW programming,
- statistical evaluation of measured data
  - basic statistical quantities (mean, variance and standard error, median etc.)
  - hypothesis tests
  - parameter estimation
- acquisition and processing
  - Fourier Transform und series: basics, examples and discretization

- Sampling Theorem: Aliasing, smoothing Windows etc. - Digital Filters: linear filters (FIR and IIR)	
Teaching methods / methods generally / types of media	The course is split into a lecture part and a practical part which last approximately the same amount of time. Lecture part: Mainly presented in form of a seminaristic lectures, i.e. with student interaction to discuss and present different solutions, results and programming approaches by demonstrating the usage of software tools directly. Additional exercises are to be solved by the students to improve their comprehension. Lab (practical) part: Solution of prepared exercises during the attendance. To difficulties and misunderstood issues is responded by mentoring individually. Selected solutions were presented to the study group.
Course- and examination achievements	Regular form for the module examination: written exam Further possible examinations: oral examination, presentation, homework reports The type of examination will be announced by the lecturer at the beginning of the course.
Literature / working materials	Press, W. H. et al (1998). Numerical recipes in C. New York: Cambridge University Press. Bronstein, I.N., Semendyayev, K.A. et al. (2004). Handbook of Mathematics, 4th Ed. Berlin Heidelberg: Springer. Jamal, R., Pichlik, H. (1998). LabVIEW Applications. München: Prentice Hall. LabView User Manual, National Instruments, January 1998 Hamming, R.W. (1983). Digital Filters. New Jersey: Englewood Cliffs.

Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 03	**Advanced Biosignal Processing**
Module coordination/ responsible person	Prof. Dr. Friedrich Ueberle
Associated courses	• Biosignal Processing • Advanced Filtering Techniques for Biosignals
Lecturer	HAW professors and assistant lecturers with background in science, hospital or industry
Semester / Period / Offer of this turnus	1st semester / one semester / winter semester
ECTS Credits/Presence hours per week	5 CP / 4 SHW • Biosignal Processing (2 SHW) • Advanced Filtering Techniques for Biosignals (2 SHW)
Workload	150 h: 64 h presence, 86 h private study
Status	Obligatory module
Preconditions / Required skills	None / Appropriate knowledge from previous academic studies in a professionally associated field, bachelor degree: mathematics, informatics, electronics, physics, mechanics, signals and systems, human biology
Teaching language	English
General learning aims and work fields	• Knowledge and Comprehension • Implementation, maintenance and service

Acquired competences / educational objectives

Expertise and methodological competences

Biosignal Processing

The students…

- are able to solve demanding scientific and engineering problems.
- know and apply advanced concepts of biomedical signals and systems and the processing of biomedical signals (e.g. EEG, ECG, phonocardiogram, EMG, EOG).
- know and apply advanced mathematical methods in technology, e.g. linear systems analysis and synthesis of medical sound fields, application of finite element methods for biomedical problems etc.
- know and apply advanced algorithms for the extraction of functional parameters from biomedical signals, (e.g independent component analysis – ICA, statistical parameter mapping – SPM).

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- understand relevant literature and implement the knowledge in biomedical problems solving.
- are able to critically read, understand and review original articles and working documents.
- are able to present and discuss their concepts in a peer group and with experts
- are able to develop solutions for biomedical signals processing tasks.

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Learning matter (examples, subjects are chosen by the lecturers)

Biosignal Processing Methods -1:

- Signal analysis in phonocardiography
- ECG signal processing
- EEG signal processing

Biosignal Processing Methods -2:

- z-Transformation, FIR and IIR Filter design, adaptive filters
- ICA, fourier methods, wavelets
- Linear systems approach for field mapping (e.g. Ultrasound: Field-II, Dream)
- Finite element methods

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<tr><td>(Teaching methods / methods generally / types of media)</td><td>Seminaristic lectures, labs, expert puzzle, teamwork, distance learning elements, web-based cooperation, autonomous studies / Power Point, blackboard, overhead projection, multimedia, software</td></tr>
<tr><td>Course- and examination achievements</td><td>Regular form for the module examination: written exam

Further possible examinations: oral examination, presentation, homework reports

The type of examination will be announced by the lecturer at the beginning of the course.</td></tr>
<tr><td>Literature / working materials</td><td>To be advised by the lecturers</td></tr>
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Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 04	**Modelling Medical Systems**
Module coordination/ responsible person	Prof. Dr. Nicholas Bishop
Associated courses	• Modelling Methods • Modelling Tools, Practical Work
Lecturer	Prof. Dr. Nicholas Bishop, Prof. Dr. Jürgen Lorenz
Period / Semester/ Offer of this turnus	1st Semester/one semester/winter semester
ECTS Credits/Presence hours per week	5 CP / 4 SHW • Modelling Methods (2 SHW) • Modelling Tools, Practical Work (2 SHW)
Workload	150 h: 64 h presence, 86 h private study
Status	Obligatory module
Preconditions / Required skills	None / Students should have knowledge in electronics, biomedical engineering, computer science (especially programming) and human biology.
Teaching language	English
General learning aims and work fields	• Knowledge and Comprehension; Finding and use of new knowledge in new situations; Problem solving, research and decision making; Self-System • Innovation management

Acquired competences / educational objectives

Expertise and methodological competences

The courses of this module enable the student to...

- understand model-based simulation methods
- model dynamical systems o structured, by first principles (white box) o unstructured, from measurement data (black box)
    - semi-structured, by adapting model parameters (gray box)
- model continuum mechanics problems o discretisation of continuum problems o solution by numerical methods
- use simulation tools, e.g. MATLAB / Simulink to... o build a model from physical differential-algebraic equations (white box) o identify parameters from measurement data (black box / gray box) o validate a model
    - simulate dynamic behavior
- use finite element analysis software o model mechanical structures
- design and conduct experiments with biosignal recording
- use Matlab-based analysis software for biological signals (e.g. Kubios-HRV)

Personal and interpersonal skills

The students are able to ...

- discuss modelling concepts in a team.
- decide which concepts are applicable.
- guide the parameter identification process.
- understand basics of engineering tools.
- describe biological feed-back systems (e.g. heart rate variability) using mathematical analysis in time- and frequency domain and using non-linear methods
- describe biological system interactions by appropriate methods
- critically read, understand and review original articles and working documents.
- present and discuss their concepts in a peer group.

Learning matter

Numerical Modelling of Structures

- Methods: Finite element analysis will be used to approximate solutions to distributed parameter models, described by partial differential equations. Discretisation of a problem into simpler elements allows efficient analysis of complex problems using numerical techniques. Particular attention will be paid to modelling elastic structures. A solid model must be generated, with appropriate boundary conditions, discretised, solved and assessed. Errors Involved in such modelling methods will be discussed.
- Practical Work: Finite element software will be used to design a structure. Models will be developed based on verifiable steps. Accuracy of solutions will be achieved according to convergence analysis. Solution efficiency will be addressed by simulating symmetry planes using boundary conditions.

Teaching methods / methods generally / types of media	Seminaristic lectures, practical courses, expert-puzzle, team-work PowerPoint-presentation, tutorials, private study blackboard, projector, software-demonstration e-Learning
Course- and examination achievements	Regular form for the module examination: written exams (one per course) Further possible examinations: oral examination, presentation, homework reports The type of examination will be announced by the lecturer at the beginning of the course.
Literature / working materials	Lee, H (2015) Finite Element Simulations with ANSYS Workbench 16: Theory, Applications, Case Studies. SDC Publishers. Chen, X & Liu Y (2014). Finite Element Modeling and Simulation with ANSYS Workbench. CRC Press. Bathe, K. (2007). Finite Element Procedures. New Jersey: Prentice Hall. Scientific Journals and papers depending on the project

Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 05	**Simulation and Virtual Reality in Medicine**
Module coordination/ Resposible person	Prof. Dr. Boris Tolg
Associated courses	• Simulation and Virtual Reality in Medicine • Simulation and Virtual Reality in Medicine, Practical work (SimLab)
Lecturer	Prof. Dr. Boris Tolg, Prof. Dr. Jürgen Lorenz
Semester / Period / Offer of this turnus	1st semester / one semester / winter semester
ECTS Credits/Presence hours per week	5 CP / 4 SHW • Simulation and Virtual Reality in Medicine (2 SHW) • Simulation and Virtual Reality in Medicine, Practical work (SimLab) (2 SHW)
Workload	150 h: 64 h presence, 86 h private study
Status	Obligatory module
Preconditions / Required skills	
Teaching language	English
General learning aims and work fields	• Knowledge and Comprehension; Finding and use of new knowledge in new situations; Problem solving, research and decision making; Self-System • Innovation management

Acquired competences / educational objectives Expertise

and methodological competences

The courses of this module enables the students to…

- decide based on a given scenario which simulation technique fits best.
- develop training scenarios for given situations.
- evaluate and analyze training results.

Personal and interpersonal skills

The students are able to…

- critically read, understand and review original articles and working documents.
- present and discuss their concepts in a peer group.
- develop solutions for simulation tasks.

Learning matter

- 3D Simulation
    - Mathematical Background
        - Transformation matrices
        - Quaternions
        - Kinematics
        - Propagation Models
        - …
    - Computer Graphics Background
        - Lighting
        - Data Structures
        - …
    - Simulation Background
        - Main Loop
        - Events
        - Storing results with MySQL
        - …
- Other Simulation methods
    - Simulation Patients
    - Mass Casualty Incidents (MCI)
    - CAVE
    - 3D-Visual systems
- Evaluation
    - Mathematical Background
        - Statistics
        - …
    - Methodical Background
        - Questionnaires
        - Physiological data
    - Psychological Background

Teaching methods/ methods generally / types of media	Typically: experimental laboratory work / hardware and software engineering / literature work / seminar / presentations / project meetings / project documentation / web based cooperation
Course- and examination achievements	Regular form for the module examination: written project report Further possible examinations: written exam, oral examination, oral presentation, homework reports The type of examination will be announced by the lecturer at the beginning of the course. The participation in at least 80% of the project seminar meetings is obligatory, presentations (1..2, not graded) required.
Literature and learning aids	Scientific literature, depending on the project

Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 06	**HTA/Regulatory Affairs**
Module coordination/ responsible person	Prof. Dr. Marc Schütte
Associated courses	• Regulatory Affairs • Health Technology Assessment (HTA)
Lecturer	Prof. Dr. Marc Schütte
Semester / Period / Offer of this turnus	1st semester / one semester / winter semester
ECTS Credits/Presence hours per week	5 CP / 4 SHW
Workload	150 h: 64h presence, 86 h private study
Status	Obligatory module
Preconditions / Required skills	Appropriate knowledge from previous academic studies in a professionally associated field, bachelor degree
Teaching language	English
General learning aims and work fields	• Analysis objectives and tasks; Problem solving, research and decision making; Self-System; Reflection and Communication • Implementation, maintenance and service; Project Management; Marketing and Distribution; Controlling

Acquired competences/educational objectives

Expertise and methodological competences

This course enables the student to …

- describe the basic strategy and procedures of Health Technology Assessment (HTA) based on the general concept of evidence-based medicine.
- identify quality criteria of scientific publications (ethics, study design, statistical methods, outcome measures, publication bias, journal impact etc.).
- apply HTA both as a prospective and retrospective tool of quality assurance in the development and evaluation of medical technologies.
- retrieve and evaluate relevant information using internet-based data bases (PubMed, Medline, Cochrane library etc.).
- apply economical evaluation methods (cost/benefit-analysis) to healthy technologies.

Personal and interpersonal skills

The students will be able to …

- critically read and review original articles.
- present and discuss their critique on a paper in a group (“journal club presentation”).
- write a “peer review”-like evaluation report of a published paper.
- write and revise an own text contribution (“workpackage”) to a review paper prepared by the group

Learning matter

Health Technology Assessment:

- basis and methodologies of evidence based medicine
- National and international health technology assessment organizations Process of peer-reviewed scientific publication

Regulatory Affairs:

- Principal routes to marketing medical devices: premarket approval, investigational device exemption, product development protocol, premarket notification (FDA process)
- Medical device regulation in Europe
- Role of the biomedical engineer in premarket reviews and postmarket controls of medical devices

Teaching methods / methods generally / types of media	• Powerpoint presentations • Group work (internet retrieval, discussions) • Excursions (“expert interviews”)
Course- and examination achievements	Regular form for the module examination: oral presentation Further possible examinations: oral examination, presentation, homework reports The type of examination will be announced by the lecturer at the beginning of the course.
Literature / working materials	Introduction to health technology assessment. CS Goodmann. HTA 101, 2004. Sterne JA, Egger M, Smith GD. Systematic reviews in health care: investigating and dealing with publication and other biases in metaanalysis. BMJ. 2001; 323:101-5. Steinberg EP. Cost-effectiveness analyses. N Engl J Med. 1995; 332:123. Oxman AD, Sackett DL, Guyatt GH. Users' guides to the medical literature. I. How to get started. JAMA. 1993; 270(17): 2093-5. Guyatt GH, Haynes RB, Jaeschke RZ, et al. Users’ guide to the medical literature, XXV: Evidence-based medicine: principles for applying the users’ guides to patient care. Evidence-Based Medicine Working Group. JAMA. 2000; 284:1290-6.

Master degree program European Master of Medical Technology and Healthcare Business	
Module code digit: 07	**Masterthesis (Masterarbeit)**
Module coordination/ Responsible person	Prof. Dr. Bernd Flick
Associated courses	
Lecturer	All university lecturers
Semester / Period/ Offer of this turnus	4th semester / one Semester / summer semester
ECTS Credits	30 CP
Workload	900 h (Autonomous private study)
Status	Obligatory module
Preconditions / Required skills	At least 210 CP from the previous academic studies in relevant scientific fields/ relevant knowledge in electronics, biomedical engineering, informatics, human biology Before the official start of the assignment the subject-matter and the supervisors must be approved by the board of examiners of the Department Medizintechnik / Fakultät Life Sciences. The first examiner must be a professor of the Department Medizintechnik / Fakultät Life Sciences.
Teaching language	English, German language if agreed by the examiners
General learning aims and work fields	• Analysis objectives and tasks; Finding and use of new knowledge in new situations; Problem solving, research and decision making; Reflection and Communication • Innovation management; Project Management; Controlling

Acquired competences / educational objectives

Expertise and methodological competences

The students …

- can solve challenging engineering specific and natural scientific problems.
- are familiar with the concepts of scientific work in the medical engineering and use them conducive.
- use mathematical / physical and technical methods on problems in the bioengineering.
- have a scientific method-knowledge and are able to evaluate critical results from the literature and to express and transact them in their own words.
- have knowledges and abilities in project- and time management that allow them to work out large scientific results in the given period.

Personal and interpersonal skills

The students …

- are able to talk in trade public about correlative job definitions and methods.
- are able to deal unaffiliated with technical and medical working materials.
- can describe and overbring theoretical contexts in the bio medicine.
- are specially invoked to present and protect their results in form of scientific publications and / or public presentations.

Learning matter

- See attachment: catalog of criteria for master thesis

Requirements

- Master Thesis: in written form
- poster or pdf file for a poster
- the results are to be presented and protected in form of a presentation with following discussion in a specific forum which is named by the adviser (e.g. seminar, Hamburger Studententagung, expert conference, etc.)

Teaching methods / methods generally / types of media	Active work, discussion, seminar, presentation, elaboration and publication
Course- and examination achievements	Regular form for the module examination: written composition, presentation, poster, colloquium Further possible examinations: written exam, oral examination, oral presentation, homework reports, colloquium, practical exams The type of examination will be announced by the lecturer at the beginning of the course.
Literature and learning aids	Scientific literature

Lecturers

Professors

Name	Expertise
Prof. Dr. Bernd Flick	Electronics, Electro-, Measurement- and RF-Engineering
Prof. Dr. Boris Tolg	Mathematik und Informatik
Prof. Dr. Friedrich Ueberle	Medizinische Mess- und Gerätetechnik
Prof. Dr. Gerwald Lichtenberg	Physics & Control Systems
Prof. Dr. Jürgen Lorenz	Humanbiologie
Prof. Dr. Kay Förger	Datenverarbeitung
Prof. Dr. Marc Schütte	Psychologie
Prof. Dr. Nicholas Bishop	Biomechanik
Prof. Dr. Petra Margaritoff	Medizinische Datensysteme

Academic personal

Dipl. Ing. Jan-Claas Böhmke
Dipl. Ing. Jens Martens
Dipl. Ing. Peter Krüß
Dipl. Ing. Sakher Abdo
Dipl. Ing. Stefan Schmücker
Dipl. Ing. Sylvia Haase
Dr. Dagmar Rokita

External lecturers

Prof. Dr. Andreas Brensing
PD Dr. Fehlauer
Michal Huflejt (M.Sc.)
Dr. Ulrich Katscher
Dr. Wolfgang Wöllmer
Dr. Lothar Spies

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