UNIVERSITÄT BONN

Module Handbook

Master of **„Drug Regulatory Affairs“**

Faculty of Mathematics and Natural Science
of the Rhenish Friedrich Wilhelm University of Bonn

September 2023

September 2023

Module Title: Definition and Scope of Drug Regulatory Affairs and Good Regulatory Practice

Module ID/Code: 1

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Introduction to the scope of "Drug Regulatory Affairs", in particular to convey the definitions and classifications of medicinal products and the relevant approval procedures of medicinal products with a focus on the EU.
Learning outcomes	Learn the subject-specific terminology and definitions as well as their application. The aim is to obtain a good overview of the tasks and responsibilities of the "Drug Regulatory Affairs" department in the pharmaceutical industry as well as in the agency (national and international).

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Definition and Scope of Drug Regulatory Affairs and Good Regulatory Practice	Eng./Ger.		40	150

3. Prerequisites for the module

compulsory	None
recommended	Basic knowledge in the field of drug regulatory affairs

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	1.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	5
Assessment (incl. weighting) and examination language	Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.) (Eng.)	

7. Frequency				8. Workload	9. Duration
Winter semester	☒	Winter and summer semester	☐	150 h per semester: 40 h presence 110 h self-study	1 semester
Summer semester	☐				

Module coordination

Teacher	Dr. Jan Heun, N.N.
Module coordinator	Dr. Jan Heun
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	Links to the pages of the European Commission and EMA: https://health.ec.europa.eu/index_en https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation

Module Title: Pharmaceutical Law

Module ID/Code: 2

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Fundamental and in-depth knowledge of German and European pharmaceutical law. In particular, the participants critically examine the approval of generics, clinical trials and the distribution of medicinal products, the law on advertising of medicinal products and the demarcation of medicinal products from food and cosmetics.
Learning outcomes	Borderline and problem cases from the fields will be discussed, enabling participants to apply the legal principles they have learned and to develop concepts to classify products.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Pharmaceutical Law	Eng./Ger.		40	180

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	1.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	6
Assessment (incl. weighting) and examination language	Study paper and written examination or study paper and oral examination* (Eng./Ger. to the selection) Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.), written examination (Processing time: 20-40 min), oral examination (Duration: 10-20 min).	

7. Frequency				8. Workload	9. Duration
Winter semester	☒	Winter and summer semester	☐	180 h per semester: 40 h presence 140 h self-study	1 semester
Summer semester	☐				

Module coordination

Teacher	N.N.
Module coordinator	N.N.
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	Pharma Codex Volumes 1 to 6 of the German Pharmaceutical Industry Association; Notice to Applicants 2 A Chapter 1

* the forms of examination in modules 2, 3, 5, 8, 9 and 10 alternate - as indicated - every two years. The examination board shall announce the form of examination applicable for the respective semester in good time before the beginning of the semester in accordance with § 9 Para. 7 of the Examination Regulations of 18 July 2018.

Module Title: International Registration Procedures

Module ID/Code: 3

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Awareness and understanding of the legal and regulatory requirements for approval procedures, especially in Europe, the USA and selected countries such as Japan, China, India.
Learning outcomes	The competence is developed to independently design approval strategies, taking into account the relevant legal bases and regulatory requirements in a global context, to represent them professionally and to name alternatives.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	International Registration Procedures	Eng./Ger.		60	210

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	1.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	7
Assessment (incl. weighting) and examination language	Study paper and written examination or study paper and oral examination* (Eng./Ger. to the selection) Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.), written examination (Processing time: 20-40 min), oral examination (Duration: 10-20 min).	

7. Frequency				8. Workload	9. Duration
Winter semester	☒	Winter and summer semester	☐	210 h per semester: 60 h presence 150 h self-study	1 semester
Summer semester	☐				

Module coordination

Teacher	Dr. Ekkehard Baader, N.N.
Module coordinator	Dr. Ekkehard Baader
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	https://www.ema.europa.eu/en https://www.fda.gov/ https://www.pmda.go.jp/english/ http://english.nmpa.gov.cn/

* the forms of examination in modules 2, 3, 5, 8, 9 and 10 alternate - as indicated - every two years. The examination board shall announce the form of examination applicable for the respective semester in good time before the beginning of the semester in accordance with § 9 Para. 7 of the Examination Regulations of 18 July 2018.

September 2023

Module Title: General Aspects of Module 1 (CTD), Registration of Special Medicinal Products Module ID/Code: 4	UNIVERSITÄT BONN

1. Content and intended learning outcomes	
Content	Identification and implementation of registration requirements as per Module 1 of the Common Technical Document (CTD). Overview on legal and regulatory requirements for special medicinal products, e.g., phytopharmaceuticals, veterinary medicinal products, blood products, vaccines, and advanced therapies. Detailed knowledge about the product information and its management.
Learning outcomes	Students are knowledgeable about Module 1 of the CTD, in particular about the application form and product information, and are able to apply this knowledge in their work environment. Case studies enable students to practice their new regulatory knowledge in special medicinal products and develop concepts and classify medicinal products. Students will be able to critically examine regulatory aspects of special medicinal products and develop regulatory strategies

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	General Aspects of Module 1 (CTD), Registration of Special Medicinal Products	Eng./Ger.		40	150

3. Prerequisites for the module	
compulsory	None
recommended	Basic knowledge of medicinal product registration in the European Union. Basic knowledge in immunology, hematology and cell/molecular biology.

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	1.

5. Requirements for the award of credits (ECTS)		**6. Credits**
Required achievements	Presentation in form of a group work	5
Assessment (incl. weighting) and examination language	Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.) (Eng./Ger. to the selection)	

7. Frequency				**8. Workload**	**9. Duration**
Winter semester	☒	Winter and summer semester	☐	150 h per semester: 40 h presence 110 h self-study	1 semester
Summer semester	☐				

Module coordination	
Teacher	Dr. Niels Krebsfänger, N.N.
Module coordinator	Dr. Niels Krebsfänger
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information	
(Reading lists, information links etc.)	None

Module Title: Maintenance of Marketing Authorisations/Pharmacovigilance

Module ID/Code: 5

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Maintenance of marketing authorisations: In-depth insight into the formal aspects of maintaining a marketing authorisation, such as notifications of variations, extension of marketing authorisations, expiry of marketing authorisations, OTC switch and supply shortages (national/European). Pharmacovigilance: Summary of the basic legal and regulatory requirements for pharmacovigilance with regard to the reporting, recording and assessment of post-authorisation adverse reactions and the establishment of company-specific pharmacovigilance systems. In-depth knowledge of European pharmacovigilance procedures / the German graduated plan, management of safety signals and the adverse reaction reporting procedure (national/European).
Learning outcomes	Maintenance of marketing authorisations: Acquire an in-depth basic understanding of the complex legal requirements for maintaining marketing authorisations and be able to apply them strategically. Pharmacovigilance: Understanding and planning a pharmacovigilance system, product-specific risk management plans and the procedures for managing signals.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Maintenance of Marketing Authorisations / Pharmacovigilance	Eng./Ger.		40	180

3. Prerequisites for the module

compulsory	None
recommended	Maintenance of marketing authorisations: • Basic regulatory knowledge, e.g. from module 1, is desirable • Knowledge of the initial authorisation of medicinal products

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	1.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	6
Assessment (incl. weighting) and examination language	Study paper and written examination or study paper and oral examination* (Eng./Ger. to the selection) Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.), written examination (Processing time: 20-40 min), oral examination (Duration: 10-20 min).	

7. Frequency				8. Workload	9. Duration
Winter semester	☒	Winter and summer semester	☐	180 h per semester: 40 h presence 140 h self-study	1 semester
Summer semester	☐				

Module coordination

Teacher	Dr. Michael Horn / Prof. Dr. Barbara Sickmüller, N.N.
Module coordinator	Dr. Michael Horn / Prof. Dr. Barbara Sickmüller
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs
Further information	
(Reading lists, information links etc.)	Maintenance of marketing authorisations: • AMG • DIRECTIVE 2001/83/EU • VO 726/2004 • Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products • Procedural Guidance of the CMDh (https://www.hma.eu/27.html) Pharmacovigilance: • AMG, Dir. 2001/83/EC, Reg. (EC) 726/2004 • Implementing Regulation (EU) 520/2012 Guidelines on good pharmacovigilance practices (GVP) – Modules

* the forms of examination in modules 2, 3, 5, 8, 9 and 10 alternate - as indicated - every two years. The examination board shall announce the form of examination applicable for the respective semester in good time before the beginning of the semester in accordance with § 9 Para. 7 of the Examination Regulations of 18 July 2018.

Module Title: Information Management, e-CTD (electronic Common Technical Document)

Module ID/Code: 6

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Participants will learn about different document management systems and the basics of document management in the regulatory authority (including regulatory documentation, file formats, different standards for Regulatory activities, e.g., eCTD requirements) as well as the pharmaceutical industry (e.g., implementations, electronic submission). In addition, scientific databases and relevant information systems are introduced and their use is practiced. Here the participant deals in depth with the learned basics.
Learning outcomes	Acquisition of an in-depth basic understanding of procedures and processes in the compilation and administration as well as their use in the approval of product data for pharmaceutical products. For this purpose, solutions are jointly developed in theory and with practical examples. To this end, product data systems and methods of research will be presented, and various document management systems and their benefits will be discussed. There will be a critical examination and evaluation of the application of these systems. All topics are offered with presentations, including practical training in their application. Participants will be able to develop their own strategies in regulatory processes and projects and to make and present decisions analytically and comprehensibly.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S, Ü	Information Management, Standardisation in Regulatory Affairs	Eng./Ger.		30	90

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	1.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	3
Assessment (incl. weighting) and examination language	Project work (Processing time: 3 h) (Eng./Ger. to the selection)	

7. Frequency				8. Workload	9. Duration
Winter semester	☒	Winter and summer semester	☐	90 h per semester: 30 h presence 60 h self-study	1 semester
Summer semester	☐				

Module coordination

Teacher	Wolfgang Witzel, N.N.
Module coordinator	Wolfgang Witzel
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	1. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) https://www.ich.org

	2. BfArM Anforderungen eSubmissions https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/e-Submission/eSubmission.html 3. Das **Electronic Common Technical Document (eCTD)** ist eine Schnittstellendefinition für die elektronische Übertragung von Informationen eines Arzneimittelherstellers an zuständige Behörden zum Zwecke der Arzneimittelzulassung. Inhaltlich basiert der Standard auf den Definitionen des Common Technical Document (CTD). https://de.wikipedia.org/wiki/ECTD 4. The European Medicines Agency (EMA) is implementing the ISO IDMP standards for the identification of medicinal products in a phased programme, based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (SPOR) data https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/substance-product-organisation-referential-spor-master-data

Module Title: Quality Management/Medical Devices

Module ID/Code: 7

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Quality Management: Defining the term quality and its relevance in pharmaceutical industry. The objectives and different roles of quality management (QM), quality assurance (QA) and quality control (QC) are presented. Further, the national and international regulatory frameworks of Good Manufacturing Practice are introduced. The most relevant quality control systems are described, in pharmaceutical companies and as well as in health authorities. Also, measures against counterfeits of medicinal products are introduced. Medical Devices: Demarcation of medical devices from pharmaceuticals (definition for both product groups and explanation of their modes of action) as well as knowledge transfer of the basics and systematics of medical device law. Additional key topics are the basic safety and performance requirements with a focus on standards and specifications, notified bodies and conformity assessment procedures, clinical evaluation and investigations, the european databank Eudamed, medical device vigilance and quality management systems. In addition, the module provides an excursus of the regulatory requirements of in vitro diagnostics.
Learning outcomes	Quality Management: The participants of this course are encouraged to understand, to critically comment and to evaluate the relevance of pharmaceutical quality management and key elements (such as change control, GMP compliance, internal audits/inspections, and risk management). Medical Devices The participants should get a good overview of the subject matter of medical device law. Particular attention is paid to the safe analysis and demarcation of pharmaceuticals from substance based (drug-related) medical devices and the classification of material medical devices into the appropriate risk class.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Quality Management/ Medical Devices	Eng./Ger.		40	150

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	2.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	5
Assessment (incl. weighting) and examination language	Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.) (Eng./Ger. to the selection)	

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☐	150 h per semester: 40 h presence 110 h self-study	1 semester
Summer semester	☒				

Module coordination

Teacher	Prof. Dr. Werner Knöss / Dr. Angela Graf, N.N.

Module coordinator	Prof. Dr. Werner Knöss / Dr. Angela Graf
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs
Further information	
(Reading lists, information links etc.)	Medical Devices: Regulation (EU) 2017/145 on Medical Devices); Medizinproduktedurchführungsgesetz (MDCG)

Module Title: Chemical Pharmaceutical Documentation

Module ID/Code: 8

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	This module provides an overview of the regulatory requirements with respect to the chemical pharmaceutical documentation "body of data" of the registration dossier for human medicinal products in the European Union including biotechnological drug substance and drug product. The main focus is set on the manufacture of starting materials, development and manufacture of medicinal products, validation of analytical procedures, specifications as well as stability of starting materials and drug products, reference substances / standards and immediate packaging materials. Furthermore, biopharmacy as well as the European Pharmacopeia is introduced. Frequent deficiencies observed by assessors are finally summarized covering all areas of chemical pharmaceutical documentation.
Learning outcomes	Participants will gain knowledge on how the chemical pharmaceutical documentation impacts the registration dossier and are encouraged to critically assess the dossier compilation.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Chemical Pharmaceutical Documentation	Eng./Ger.		40	180

3. Prerequisites for the module

compulsory	None
recommended	Previous pharmaceutical knowledge and scientific studies are an advantage.

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	2.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	6
Assessment (incl. weighting) and examination language	Study paper and oral examination or study paper and written examination * (Eng./Ger. to the selection) Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.), written examination (Processing time: 20-40 min), oral examination (Duration: 10-20 min).	

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☐	180 h per semester: 40 h presence 140 h self-study	1 semester
Summer semester	☒				

Module coordination

Teacher	N.N.
Module coordinator	N.N.
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	1) ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Quality Guidelines and Multidisciplinary Guidelines: https://www.ich.org/page/quality-guidelines, https://www.ich.org/page/multidisciplinary-guidelines. 2) EMA (European Medicines Agency) Quality Guidelines: https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/quality-guidelines. 3) Pharmacopeia Europaea & Certification of Suitability to Monographs of the Ph.Eur. Technical Guide for the elaboration of monographs. 4) EudraLex Vol.2 – Pharmaceutical legislation on notice to applicants and regulatory guidelines for medicinal products for human use: https://ec.europa.eu/health/documents/eudralex/vol-2_en. 5) Announcement on the authorisation of medicinal products by BfArM (Federal Institute for Drugs and Medical Devices/Bundesinstitut für Arzneimittel und Medizinprodukte. 6) Container Closure System • Guideline on Plastic Immediate Packaging Materials (CPMP/QWP/4359/03) • FDA Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics • European Pharmacopoeia o 3.1. Materials used for the manufacture of containers o 3.2. Containers • Japanese Pharmacopoeia - General Tests, Processes and Apparatus: o 7. Test for Containers and Packaging Materials ▪ 7.01 Test for Glass Containers for Injections ▪ 7.02 Test Methods for Plastic Containers ▪ 7.03 Test for Rubber Closure for Aqueous Infusions • United States Pharmacopeia – General Chapters o <381> Elastomeric closures for injections o <660> Containers – Glass o <661> Plastic Packaging Systems and Their Materials of Construction incl. subsections 661.1 and .2 o <671> Containers – Performance Testing o <1207> Package Integrity Evaluation - Sterile Products incl. subsection 1207.1 to .3 o <1661> Evaluation of plastic packaging systems and their materials of construction with respect to their user safety impact o <1663> Assessment of extractables associated with pharmaceutical packaging/delivery systems o <1664> Assessment of drug product leachables associated with pharmaceutical packaging/delivery systems 7) Biopharmazie • Guideline on the Investigation of Bioequivalence • Questions & Answers on the Bioavailability and Bioequivalence Guideline • Product-specific recommendations for generics: (https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance) • Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms • US-FDA Guidance for Industry “Waiver of in vivo bio-equivalence studies for immediate release solid oral dosage forms containing certain active moieties/active ingredients based on a Biopharmaceutics Classification System.

	• WHO Technical Report Series No. 937, Review 2014, Annex 7, annex 8 • ICH M9 Biopharmaceutics Classification System-based Biowaivers

* the forms of examination in modules 2, 3, 5, 8, 9 and 10 alternate - as indicated - every two years. The examination board shall announce the form of examination applicable for the respective semester in good time before the beginning of the semester in accordance with § 9 Para. 7 of the Examination Regulations of 18 July 2018.

Module Title: Pharmacology and Toxicology Documentation

Module ID/Code: 9

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	The participants will learn about the international legal and regulatory requirements for the pharmacology and toxicology documentation with respect to the current obligations (German Medicinal Products Act, guidelines, etc.). The principles of pharmacology and toxicology studies will be explained, the timing of these investigations will be compared with the clinical development plan, and the options for the extrapolation of the results of the animal studies to the human situation will be discussed. Along with the risk-benefit analysis, a particular focus will be placed on the consideration of ethical aspects and animal protection.
Learning outcomes	The competence for responsible and legally compliant decision-making will be taught. The international outlook and multidisciplinary cooperation will be especially emphasized.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Pharmacology and Toxicology Documentation	Eng./Ger.		40	180

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	2.

5. Requirements for the award of credits (ECTS) / 6. Credits

Required achievements	Presentation in form of a group work	6
Assessment (incl. weighting) and examination language	Study paper and oral examination or study paper and written examination * (Eng./Ger. to the selection) Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.), written examination (Processing time: 20-40 min), oral examination (Duration: 10-20 min).	

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☐	180 h per semester: 40 h presence 140 h self-study	1 semester
Summer semester	☒				

Module coordination

Teacher	Prof. Dr. Gerd Bode, N.N.
Module coordinator	Prof. Dr. Gerd Bode
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	

* the forms of examination in modules 2, 3, 5, 8, 9 and 10 alternate - as indicated - every two years. The examination board shall announce the form of examination applicable for the respective semester in good time before the beginning of the semester in accordance with § 9 Para. 7 of the Examination Regulations of 18 July 2018.

Module Title: Clinical Documentation

Module ID/Code: 10

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Basic knowledge about clinical development strategies and methodology is provided: from Target-Product-Profile to clinical trials Phase 1 to 4, respective trial objectives and designs and the relevance of trial results for the development of the SmPC. The organisation of clinical trials is explained with focus on the clinical trial responsibilities of the sponsor including ethical and quality requirements according to Good Clinical Practice. The regulatory environment for clinical trials created by the Directives 2001/20/EC and 2005/28/EC and their translation into the national German legislation AMG as well as the transition conditions into Regulation (EU) 536/2014 get delineated. Especially the application for clinical trial authorisation, the compilation of the application dossier, the reporting of trial results and the translation of the trial results into the label are subject to exercises. Additionally, collection, assessment and reporting of safety data and core aspects of paediatric clinical development are explained.
Learning outcomes	The students get prepared for the strategic regulatory contributions to the clinical development plan to be contributed by Regulatory Affairs. They learn the technical processes of clinical trial authorisation and result reporting. They are made knowledgeable about the required quality level of clinical data presented in the marketing authorisation application dossier.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Clinical Documentation	Eng./Ger.		40	180

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	2.

5. Requirements for the award of credits (ECTS) / 6. Credits

Required achievements	Presentation in form of a group work	6
Assessment (incl. weighting) and examination language	Study paper and oral examination or study paper and written examination * (Eng./Ger. to the selection) Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.), written examination (Processing time: 20-40 min), oral examination (Duration: 10-20 min).	

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☐	180 h per semester: 40 h presence 140 h self-study	
Summer semester	☒				

Module coordination

Teacher	Dr. Ingrid Klingmann, N.N.

Module coordinator	Dr. Ingrid Klingmann
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs
Further information	
(Reading lists, information links etc.)	

* the forms of examination in modules 2, 3, 5, 8, 9 and 10 alternate - as indicated - every two years. The examination board shall announce the form of examination applicable for the respective semester in good time before the beginning of the semester in accordance with § 9 Para. 7 of the Examination Regulations of 18 July 2018.

Module Title: Benefit, Efficiency, Reimbursement

Module ID/Code: 11

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Introduction to the function of health care organisations and their tasks (e.g. Joint Self-Government of Physicians and Health Insurance Funds, Joint Federal Committee, Institute for Quality and Efficiency in Health Care, GKV-Spitzenverband). In-depth insight into the legal and methodological basis of market access according to AMNOG (Arzneimittelmarktneuordnungsgesetz).
Learning outcomes	Political, social, epidemiological and ethical evaluation criteria of benefit and cost-benefit assessment are presented and critically examined using examples.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Benefit, Efficiency, Reimbursement	Eng./Ger.		30	90

3. Prerequisites for the module

compulsory	None
recommended	None

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	2.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	3
Assessment (incl. weighting) and examination language	Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.) (Eng./Ger. to the selection)	

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☐	90 h per semester: 30 h presence 60 h self-study	1 semester
Summer semester	☒				

Module coordination

Teacher	Prof. Dr. Eva Susanne Dietrich, N.N.
Module coordinator	Prof. Dr. Eva Susanne Dietrich
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)

1. IQWIG: Allgemeine Methoden
2. www.g-ba.de
3. Marthe R. Gold, Joanna E. Siegel, Louise B. Russell, Milton C. Weinstein. Cost-Effectiveness in Health and Medicine. Oxford University Press, 1996. ISBN: 0195108248

Module Title: Regulatory Management/Decision Making

Module ID/Code: 12

UNIVERSITÄT BONN

1. Content and intended learning outcomes

Content	Learning and application of the most important management tools and procedures; learning and application of strategies to successfully implement these methods in the regulatory environment (e.g. presentations, role playing). The methodology of decision analysis is applied in the processing of scientific and economic tasks of "Drug Regulatory Affairs".
Learning outcomes	Participants are thus able to develop their own strategies in regulatory processes and projects and to make decisions analytically based and comprehensive.

2. Teaching and learning methods

	Type of instruction	Topic	Language of instruction	Group size	contact time [h]	Workload [h]
	V, S	Regulatory Management/ Decision Making	Eng./Ger.		20	60

3. Prerequisites for the module

compulsory	None
recommended	Basic knowledge in Regulatory Affairs

4. Degree program allocation

	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	2.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Presentation in form of a group work	2
Assessment (incl. weighting) and examination language	Study paper (Processing time: four weeks. Length: 4-15 DIN-A4 pages.) (Eng.)	

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☐	60 h per semester: 20 h presence 40 h self-study	1 semester
Summer semester	☒				

Module coordination

Teacher	Dr. Josef Hofer, Herbert Jopp
Module coordinator	Dr. Josef Hofer
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information

(Reading lists, information links etc.)	Current case studies from regulatory tasks

Module Title: Internship

Module ID/Code: 13

UNIVERSITÄT BONN

1. Content and intended learning outcomes	
Content	Application of the acquired theoretical knowledge in a relevant professional environment (field of "Drug Regulatory Affairs"). Practical experience as well as implementation and deepening of knowledge.
Learning outcomes	With the help of the contents learned and the skills acquired during the studies the participants are able to draw the right conclusions and to put their knowledge into practice of the respective internship. Skills from the studies are implemented in and linked to professional experience.

2. Teaching and learning methods						
	Type of instruction	Topic	Language of instruction	Group size	contact time	Workload [h]
	P	Internship	Eng./Ger.			900

3. Prerequisites for the module	
compulsory	Participation in six out of twelve modules and completion of the associated study paper
recommended	none

4. Degree program allocation			
	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	3.(or) 4.

5. Requirements for the award of credits (ECTS)		6. Credits
Required achievements	Written internship report	30
Assessment (incl. weighting) and examination language		

7. Frequency				8. Workload	9. Duration
Winter semester	☐	Winter and summer semester	☒	900 h	Six months full-time / part-time accordingly longer
Summer semester	☐				

Module coordination	
Teacher	Examination Board, Study programme management „Drug Regulatory Affairs“
Module coordinator	
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information	
(Reading lists, information links etc.)	

Module Title: Master's Thesis

Module ID/Code: 14

UNIVERSITÄT BONN

1. Content and intended learning outcomes	
Content	Independently work on a problem from a special field being subject of the degree programme, using scientific methods.
Learning outcomes	Ability to collect, process, analyse information from different sources and critically interpret data in order to develop solutions to specific problems within a given period of time.

2. Teaching and learning methods						
	Type of instruction	Topic	Language of instruction	Group size	contact time	Workload [h]
		Master's Thesis	Eng./Ger.			900

3. Prerequisites for the module	
compulsory	Participation in six out of twelve modules and completion of the associated study paper
recommended	Knowledge of literature research and modes of citation

4. Degree program allocation			
	Study program	compulsory/ elective	Semester
	Drug Regulatory Affairs, M. D. R. A.	compulsory	3.(or) 4.

5. Requirements for the award of credits (ECTS)		**6. Credits**
Required achievements		30
Assessment (incl. weighting) and examination language	Master's Thesis (Eng./Ger. to the selection)	

7. Frequency				**8. Workload**	**9. Duration**
Winter semester	☐	Winter and summer semester	☒	900 h	6 months
Summer semester	☐				

Module coordination	
Teacher	N.N.
Module coordinator	N.N.
Institute/Department	Faculty of Mathematics and Natural Sciences/Pharmacy Section/Department of Drug Regulatory Affairs

Further information	
(Reading lists, information links etc.)	• Guideline Master's Thesis (Student Advisory Service) • Leaflets for the correct use of scientific citation (Student Advisory Service)