UNIVERSITÄT BONN

Master‘s degree programme for continuing education

„Drug Regulatory Affairs“

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In cooperation with

DGRA
DEUTSCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS


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The Master's degree programme

International and interdisciplinary, combining the fields of **pharmacy, law and medicine**, and including specific, **practice-oriented** postgraduate training.

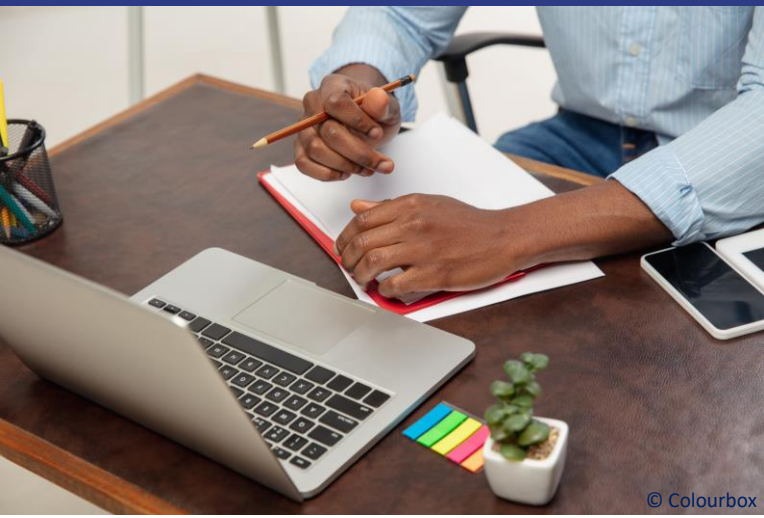
You will meet representatives from authorities, pharmaceutical companies and the university, enabling you to build up a **network** for your professional future during your studies.

You will be provided with **up-to-date knowledge** from the various subject areas of regulatory affairs for effective and successful work. A wide range of topics from the life cycle of medicinal products and medical devices, quality and document management, reimbursement and regulatory-strategic planning will give you a comprehensive overview.

You can expect a **dedicated team of over 100 lecturers** made up of experts from the fields of pharmacy, toxicology, medicine and law.

You receive the **academic degree** *Master of Drug Regulatory Affairs* **(M.D.R.A.)**.

www.pharma.uni-bonn.de/drug-regulatory-affairs/en/mdra



Certificate courses and single modules

Suitable for **further education in specific topics** to build up individual competences. Can be freely selected and combined, provided that compulsory modules are included in the certificate course. They offer relevant knowledge, **from the basics to in-depth specialised knowledge**, **practical examples**, in-depth understanding of legal regulations, acquisition of competences (analysis/critical assessment/strategic planning/etc.).
You receive a **training certificate** upon successful completion.

Professional fields

MDRA students and graduates work in various professional fields. They work in the **pharmaceutical industry**, in national and international **authorities** involved in approval procedures or drug monitoring and in higher federal authorities within the remit of the Federal Ministry of Health.

Other possible professional activities can be found in **centers for clinical studies**, **contract research institutes** and **consulting companies**. **Law firms**, **ethics committees**, **professional associations** and **specialist societies** also fall within the professional fields of regulatory affairs managers. **Universities** and research institutions also offer jobs in research and teaching.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Online and on site

In 12 modules, **online and on site in Bonn (50%/50%)**, the course offers further qualification for professional life and enables participants to understand, analyse and critically evaluate current topics and changes in the field of regulatory affairs. There will be sufficient time to **network with students and our lecturers**, experts from all relevant fields of Regulatory Affairs.

Admission requirements

The postgraduate Master's degree program "Drug Regulatory Affairs" is aimed at applicants who

1. have a first relevant professionally **qualifying university degree** (at least 180 LP) in pharmacy, medicine, life sciences or similar (not mandatory for certificate courses/single modules) and

2. at least **one year of relevant professional experience** at the start of the program as well as

3. language skills in **English (B2)**.

Tuition fees

- Master‘s degree programme: 8.000 €
- Certificate course/single module: according to the module assignment

Study programme plan (example)

1. Academic Year

Modules 1-12	ECTS
1 Definition and Scope of Drug Regulatory Affairs and Good Regulatory Practice	5
2 Pharmaceutical Law	6
3 International Registration Procedures	7
4 General Aspects of Module 1 (CTD), Registration of Special Medicinal Products	5
5 Maintenance of Marketing Authorisations/Pharmacovigilance	6
6 Information Management, e-CTD (electronic Common Technical Document)	3
7 Quality Management/Medical Devices	5
8 Chemical Pharmaceutical Documentation	6
9 Pharmacology and Toxicology Documentation	6
10 Clinical Documentation	6
11 Benefit, Efficiency, Reimbursement	3
12 Regulatory Management/Decision Making	2
Total	**60**

2. Academic Year

	ECTS
Internship	30
Master's thesis	30
Total	**60**

Master's degree programme	ECTS
Modules 1-12	60
Internship/Master's thesis	60
Total	**120**

Contact and study counselling

Study programme manager

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www.pharma.uni-bonn.de/drug-regulatory-affairs/en/mdra

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www.dgra.de

Cooperation partners

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