UNIVERSITÄT BONN

Master‘s degree programme for continuing education

„Drug Regulatory Affairs“

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In cooperation with

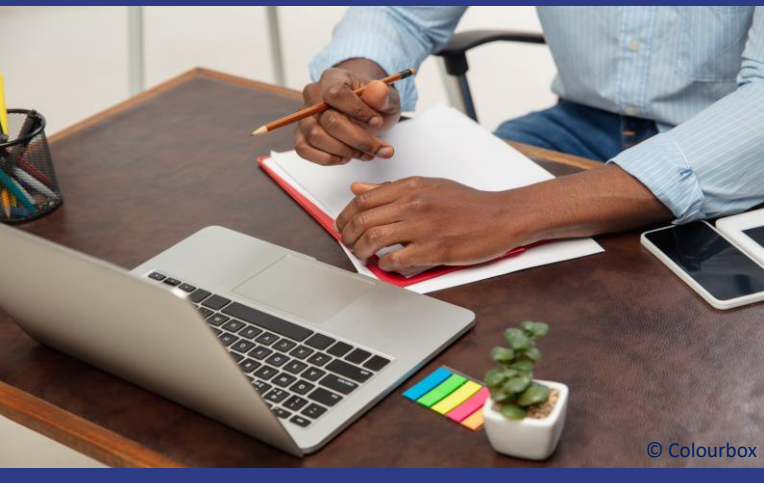
DGRA
DEUTSCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS

"Drug Regulatory Affairs"
Master's degree programme

International and interdisciplinary education, combining the fields of **pharmacy, law and medicine**, focused on **practice-oriented** postgraduate training and provides you with **up-to-date knowledge** in regulatory affairs: Medicinal products/medical devices/life cycle/quality-safety-efficacy/document management/market access/ decision making/etc.

- **Connect** with more than 100 passionate senior experts from health authorities, pharmaceutical companies, industry associations, academia, and expand your professional network.
- **Get trained** on a comprehensive range of regulatory science and healthcare topics.
- **Learn** how science and regulatory competence can create additional value for patients, healthcare systems, and society.
- **Expand** your expertise and **accelerate** your professional development with excellent teaching from our dedicated team of experts.
- Receive the **academic degree** *Master of Drug Regulatory Affairs* **(M.D.R.A.)**.

Ready to take your career to the next level?
Study at one of Germany's Universities of Excellence!
----The University of Bonn----



Certificate courses and single modules

Suitable for **continued education in specific topics** to build up individual competences.

- **Certificate courses** can be **freely selected and combined**, at least one compulsory module must be included. Relevant knowledge, **from the basics to in-depth specialised up-to-date knowledge**, **practical examples**, in-depth understanding of legal regulations, acquisition of competences (analysis/critical assessment/strategic planning/etc.). You receive a **certificate** upon successful completion.
- **Single modules** can be freely selected. You receive a **specific certificate** depending on attendence and/or successful completion.
- Later **‚upgrade'** to Master's degree programme possible.

Professional fields

MDRA students and graduates work in various professional fields, including the **pharmaceutical industry** and national and international **authorities.**

They also find job opportunities in **centers for clinical studies**, **contract research institutes** and **consulting companies,** in **law firms**, **ethics committees**, **professional associations** and **specialist societies.** Furthermore, **universities** and research institutions also offer job opportunities in research and teaching.

Online and on site

In 12 modules, **online and on site in Bonn (80%/20%)**, 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 for **networking with students and lecturers**, experts from all relevant areas of regulatory affairs.

Admission requirements

Master's degree programme "Drug Regulatory Affairs“

- first relevant professionally **qualifying university degree** (at least 180 LP) in pharmacy, medicine, life sciences or similar
- at least **one year of professional experience**
- **English (B2).**

Certificate Course

- at least **one year of relevant professional experience**
- **English (B2).**

Single module

- **English (B2) recommended.**

Tuition fees

- Master‘s degree programme: €9,900
- Certificate course/single module: according to the module assignment (Please visit our website)

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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Visit us and APPLY NOW!

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

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www.dgra.de

Cooperation partners

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