Master's degree programme "Drug Regulatory Affairs"
Study plan: MDRA-27
Academic year 2025/2026

(subject to change, 23 Jan 2024), xx = online/on site to be determined

Module 1 Definition and Scope of Drug Regulatory Affairs and Good Regulatory Practice

Part 1: Friday 19 September 2025 from 8:30 to 18:30
Saturday 20 September 2025 from 8:00 to 16:00

Part 2: Friday 26 September 2025 from 8:30 to 18:30
Saturday 27 September 2025 from 8:00 to 16:30

Part 1 Uniclub, Part 2 Uniclub — Submission of study paper: 27/Oct/2025

Module 2 Pharmaceutical Law

Part 1: Friday 10 October 2025 from 8:30 to 18:30
Saturday 11 October 2025 from 8:00 to 16:00

Part 2: Friday 24 October 2025 from 8:30 to 18:30
Saturday 25 October 2025 from 8:00 to 16:00

Part 1 xx, Part 2 xx — Submission of study paper: 24/Nov/2025

Module 3 International Registration Procedures

Part 1: Friday 07 November 2025 from 8:30 to 18:30
Saturday 08 November 2025 from 8:00 to 16:00

Part 2: Friday 21 November 2025 from 8:30 to 18:30
Saturday 22 November 2025 from 8:00 to 16:00

Part 3: Friday 05 December 2025 from 8:30 to 18:30
Saturday 06 December 2025 from 8:00 to 16:00

Part 1 xx, Part 2 xx, Part 3 xx — Submission of study paper: 03/Jan//2026

Module 4 General Aspects of Module 1 (CTD), Registration of Special Medicinal Products

Part 1: Friday 09 January 2026 from 8:30 to 18:30
Saturday 10 January 2026 from 8:00 to 16:00

Part 2: Friday 23 January 2026 from 8:30 to 18:30
Saturday 24 January 2026 from 8:00 to 16:00

Part 1 xx, Part 2 xx — Submission of study paper: 23/Feb/2026

Module 5 Maintenance of Marketing Authorisations / Pharmacovigilance

Part 1: Friday _PV 06 February 2026 from 8:30 to 18:30
Saturday _PV 07 February 2026 from 8:00 to 16:00

Part 2: Friday _MMA 20 February 2026 from 8:30 to 18:30
Saturday _MMA 21 February 2026 from 8:00 to 16:00

Part 1 xx, Part 2 xx — Submission of study paper: 23/Mar/2026

Module 6 Information Management, e-CTD

Part 1: Friday 06 March 2026 from 8:30 to 18:00
Saturday 07 March 2026 from 8:30 to 18:00

Part 2: Friday 20 March 2026 from 8:30 to 18:30
Saturday 21 March 2026 from 8:30 to 14:00 (project work)

Part 1 xx, Part 2 xx

Written examination (Module 2 / 3 / 5), Thursday 16 April 2026, 13 o'clock
lecture hall X / University of Bonn

Module 7 Quality Management / Medical Devices

Part 1: Friday _QM 17 April 2026 from 8:30 to 18:30
Saturday _MD 18 April 2026 from 8:00 to 16:00

Part 2: Friday _MD 24 April 2026 from 8:30 to 18:30
Saturday _QM 25 April 2026 from 8:00 to 16:00

Part 1 xx, Part 2 xx Submission of study paper: 26/May/2026 (Tuesday!)

Module 8 Chemical Pharmaceutical Documentation

Part 1: Friday 08 May 2026 from 8:30 to 18:30
Saturday 09 May 2026 from 8:00 to 16:00

Part 2: Friday 15 May 2026 from 8:30 to 18:30
Saturday 16 May 2026 from 8:00 to 16:00

Part 1 xx, Part 2 xx Submission of study paper: 15/Jun/2026

Module 9 Pharmacology and Toxicology Documentation

Part 1: Friday 29 May 2026 from 8:30 to 18:30
Saturday 30 May 2026 from 8:00 to 16:00

Part 2: Friday 12 June 2026 from 8:30 to 18:30
Saturday 13 June 2026 from 8:00 to 16:00

Part 1 xx, Part 2 xx Submission of study paper: 13/Jul/2026

Module 10 Clinical Documentation

Part 1: Friday 26 June 2026 from 8:30 to 18:30
Saturday 27 June 2026 from 8:00 to 18:00

Part 2: Friday 10 July 2026 from 8:30 to 18:30
Saturday 11 July 2026 from 8:00 to 16:00

Part 1 xx, Part 2 xx Submission of study paper: 10/Aug/2026

Module 11 Benefit, Efficiency, Reimbursement

Thursday 23 July 2026 from 14:00 to 18:45
Friday 24 July 2026 from 08:30 to 18:30
Saturday 25 July 2026 from 08:00 to 16:00

xx Submission of study paper: 24 August 2026

Module 12 Regulatory Management / Decision Making

Friday 07 August 2026 from 8:30 to 18:30
Saturday 08 August 2026 from 8:00 to 16:00

Uniclub Submission of study paper: 07/Sept/2026

Oral examination (Module 8 / 9 / 10): Time period: September – November 2026