

Master's degree programme "Drug Regulatory Affairs"

Study plan: **MDRA-28**

Academic year 2026/2027

(subject to change, 13 May 2026)

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

Wednesday	16 September 2026 from 12:00 to 18:30
Thursday	17 September 2026 from 8:00 to 18:30
Friday	18 September 2026 from 8:00 to 18:30
Saturday	19 September 2026 from 8:00 to 16:00

On site (Bonn): Pharmaceutical Institute, Bonn-Endenich

Submission of study paper: 19/Oct/2026

Module 2 Pharmaceutical Law

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

Part 2: Friday	16 October 2026 from 8:30 to 18:30
Saturday	17 October 2026 from 8:00 to 16:00

Part 1 Online, Part 2 Online

Module 3 International Registration Procedures

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

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

Part 3: Friday	04 December 2026 from 8:30 to 18:30
Saturday	05 December 2026 from 8:00 to 16:00

Part 1 Online, Part 2 Online, Part 3 Online

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

Part 1: Friday	15 January 2027 from 8:30 to 18:30
Saturday	16 January 2027 from 8:00 to 16:00

Part 2: Friday	29 January 2027 from 8:30 to 18:30
Saturday	30 January 2027 from 8:00 to 16:00

Part 1 Online, Part 2 Online

Submission of study paper: 01/March/2027

Module 5 Maintenance of Marketing Authorisations / Pharmacovigilance

Part 1: Friday_PV	12 February 2027 from 8:30 to 18:30
Saturday_PV	13 February 2027 from 8:00 to 16:00

Part 2: Friday_MMA	26 February 2027 from 8:30 to 18:30
Saturday_MMA	27 February 2027 from 8:00 to 16:00

Part 1 Online, Part 2 Online

Module 6 Information Management, e-CTD

Part 1: Friday	12 March 2027 from 8:30 to 18:00
Saturday	13 March 2027 from 8:30 to 18:00

Part 2: Friday	19 March 2027 from 8:30 to 18:30
Saturday	20 March 2027 from 8:30 to 14:00 (project work)

Part 1 Online, Part 2 On site (Bonn): Pharmaceutical Institute, Bonn-Endenich

Written examination (Module 2 / 3 / 5), Thursday 08 April 2027, 13 o'clock
lecture hall X / University of Bonn

Module 7 Quality Management / Medical Devices

Part 1: Friday_QM 09 April 2027 from 13:00 to 18:30
Saturday_MD 10 April 2027 from 8:00 to 16:00

Part 2: Friday_MD 23 April 2027 from 8:30 to 18:30
Saturday_QM 24 April 2027 from 8:00 to 16:00

Part 1 On site (Bonn): Uniclub, Part 2 Online Submission of study paper: 24/May/2027

Module 8 Chemical Pharmaceutical Documentation

Part 1: Friday 07 May 2027 from 8:30 to 18:30
Saturday 08 May 2027 from 8:00 to 16:00

Part 2: Friday 21 May 2027 from 8:30 to 18:30
Saturday 22 May 2027 from 8:00 to 16:00

Part 1 Online, Part 2 Online

Module 9 Pharmacology and Toxicology Documentation

Part 1: Friday 04 June 2027 from 8:30 to 18:30
Saturday 05 June 2027 from 8:00 to 16:00

Part 2: Friday 18 June 2027 from 8:30 to 18:30
Saturday 19 June 2027 from 8:00 to 16:00

Part 1 Online, Part 2 Online

Module 10 Clinical Documentation

Part 1: Friday 02 July 2027 from 8:30 to 18:00
Saturday 03 July 2027 from 8:30 to 18:00

Part 2: Friday 16 July 2027 from 8:30 to 18:00
Saturday 17 July 2027 from 8:30 to 16:15

Part 1 Online, Part 2 Online

Module 11 Benefit, Efficiency, Reimbursement

Thursday 29 July 2027 from 14:00 to 18:45
Friday 30 July 2027 from 08:30 to 18:30
Saturday 31 July 2027 from 08:00 to 16:00

Online

Submission of study paper: 30/Aug/2027

Module 12 Regulatory Management / Decision Making

Friday 06 August 2027 from 8:30 to 18:30
Saturday 07 August 2027 from 8:00 to 16:00

On site (Bonn): Uniclub

Submission of study paper: 13/Sept/2027

Oral examination (Module 8 / 9 / 10): Time period: September – November 2027