

Master's degree programme "Drug Regulatory Affairs"

Study plan: **MDRA-27**

Academic year 2025/2026

(subject to change, 09 Jan 2026)

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

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| Wednesday | 17 September 2025 from 12:00 to 18:30 |
| Thursday | 18 September 2025 from 8:00 to 18:30 |
| Friday | 19 September 2025 from 8:00 to 18:30 |
| Saturday | 20 September 2025 from 8:00 to 16:00 |

Pharmaceutical Institute, Bonn-Endenich

Submission of study paper: 20/Oct/2025

Module 2 Pharmaceutical Law

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

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

Part 1 Online, Part 2 Online

Module 3 International Registration Procedures

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

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

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| Part 3: Friday | 12 December 2025 from 8:30 to 18:30 |
| Saturday | 13 December 2025 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

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

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

Part 1 Online, Part 2 Online

Submission of study paper: 23/Feb/2026

Module 5 Maintenance of Marketing Authorisations / Pharmacovigilance

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| Part 1: Friday_PV | 06 February 2026 from 8:30 to 18:30 |
| Saturday_PV | 07 February 2026 from 8:00 to 16:00 |

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| 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 Online, Part 2 Online

Module 6 Information Management, e-CTD

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

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| 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 Online, Part 2 Pharmaceutical Institute, Bonn-Endenich

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

Module 7 Quality Management / Medical Devices

Part 1: Friday_QM 17 April 2026 from 13:00 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 Uniclub
Part 2 Online

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 Online, Part 2 Online

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 Online, Part 2 Online

Module 10 Clinical Documentation

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

Part 2: Friday 10 July 2026 from 8:30 to 18:00
Saturday 11 July 2026 from 8:30 to 16:15

Part 1 Online, Part 2 Online

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

Online

Submission of study paper: 24/Aug/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