

**Study plan of the postgraduate master's course
"Drug Regulatory Affairs"**

**MDRA-26
WS 2024/2025 - SS 2025**

(subject to change, 13/Feb/2024)

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

Part 1: Friday 13 September 2024 from 8:30 to 18:30
Saturday 14 September 2024 from 8:00 to 16:00

Part 2: Friday 27 September 2024 from 8:30 to 18:30
Saturday 28 September 2024 from 8:00 to 16:30

Part 1 Uniclub, Part 2 Uniclub

Submission of study paper: 28/10/2024

Module 2 Pharmaceutical Law

Part 1: Friday 11 October 2024 from 8:30 to 18:30
Saturday 12 October 2024 from 8:00 to 16:00

Part 2: Friday 25 October 2024 from 8:30 to 18:30
Saturday 26 October 2024 from 8:00 to 16:00

Part 1 Online, Part 2 Uniclub

Submission of study paper: 25/11/2024

Module 3 International Registration Procedures

Part 1: Friday 08 November 2024 from 8:30 to 18:30
Saturday 09 November 2024 from 8:00 to 16:00

Part 2: Friday 22 November 2024 from 8:30 to 18:30
Saturday 23 November 2024 from 8:00 to 16:00

Part 3: Friday 06 December 2024 from 8:30 to 18:30
Saturday 07 December 2024 from 8:00 to 16:00

Part 1 Uniclub, Part 2 and 3 Uniclub

Submission of study paper: 06/01/2025

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

Part 1: Friday 17 January 2025 from 8:30 to 18:30
Saturday 18 January 2025 from 8:00 to 16:00

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

Part 1 Uniclub, Part 2 Online

Submission of study paper: 24/02/2025

**Module 5 Maintenance of Marketing Authorisations /
Pharmacovigilance**

Part 1: Friday_PV 07 February 2025 from 8:30 to 18:30
Saturday_PV 08 February 2025 from 8:00 to 16:00

Part 2: Friday_MMA 21 February 2025 from 8:30 to 18:30
Saturday_MMA 22 February 2025 from 8:00 to 16:00

Part 1 Online, Part 2 Uniclub

Submission of study paper: 24/03/2025

Module 6 Information Management, e-CTD

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

Part 2: Friday 14 March 2025 from 8:30 to 18:30
Saturday 15 March 2025 from 8:30 to 14:00 (project work)

Part 1 Online, Part 2 Pharmaceutical Institute, Bonn-Endenich

Oral examination (Module 2 / 3 / 5), Time period: March - June 2025

Module 7 Quality Management / Medical Devices

Part 1: Friday_QM 28 March 2025 from 8:30 to 18:30
Saturday_MD 29 March 2025 from 8:00 to 16:00

Part 2: Friday_MD 04 April 2025 from 8:30 to 18:30
Saturday_QM 05 April 2025 from 8:00 to 16:00

Part 1 Online, Part 2 Uniclub

Submission of study paper: 05/05/2025

Module 8 Chemical Pharmaceutical Documentation

Part 1: Friday 02 May 2025 from 8:30 to 18:30
Saturday 03 May 2025 from 8:00 to 16:00

Part 2: Friday 16 May 2025 from 8:30 to 18:30
Saturday 17 May 2025 from 8:00 to 16:00

Part 1 Online, Part 2 Uniclub

Submission of study paper: 16/06/2025

Module 9 Pharmacology and Toxicology Documentation

Part 1: Friday 30 May 2025 from 8:30 to 18:30
Saturday 31 May 2025 from 8:00 to 16:00

Part 2: Friday 13 June 2025 from 8:30 to 18:30
Saturday 14 June 2025 from 8:00 to 16:00

Part 1 Online, Part 2 Uniclub

Submission of study paper: 14/07/2025

Module 10 Clinical Documentation

Part 1: Friday 27 June 2025 from 8:30 to 18:30
Saturday 28 June 2025 from 8:00 to 18:00

Part 2: Friday 11 July 2025 from 8:30 to 18:30
Saturday 12 July 2025 from 8:00 to 16:00

Part 1 Online, Part 2 Uniclub

Submission of study paper: 11/08/2025

Module 11 Benefit, Efficiency, Reimbursement

Thursday 24 July 2025 from 14:00 to 18:45
Friday 25 July 2025 from 08:30 to 18:30
Saturday 26 July 2025 from 08:00 to 16:00

Wissenschaftszentrum

Submission of study paper: 25/08/2025

Module 12 Regulatory Management / Decision Making

Friday 08 August 2025 from 8:30 to 18:30
Saturday 09 August 2025 from 8:00 to 16:00

Wissenschaftszentrum

Submission of study paper: 08/09/2025

Written examination (Module 8 / 9 / 10): Thursday, 07 August 2025, 13 o'clock, lecture hall X / University of Bonn