

# Master's degree programme "Drug Regulatory Affairs"

Study plan: **MDRA-27**

**Academic year 2025/2026**

(subject to change, 31 Mar 2025)

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

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**

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

<b>Part 2:</b>	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

Submission of study paper: 24/Nov/2025

## **Module 3      International Registration Procedures**

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

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

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

Part 1 Online, Part 2 Online, Part 3 Online

Submission of study paper: 03/Jan//2026

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

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

<b>Part 2:</b>	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**

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

<b>Part 2:</b>	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

Submission of study paper: 23/Mar/2026

## **Module 6      Information Management, e-CTD**

<b>Part 1:</b>	Friday	06 March 2026 from 8:30 to 18:00
	Saturday	07 March 2026 from 8:30 to 18:00

<b>Part 2:</b>	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, 13 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 Pharmaceutical Institute, Bonn-Endenich

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

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 Online, Part 2 Online

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 Online, Part 2 Online

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

Online

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

Pharmaceutical Institute, Bonn-Endenich

Submission of study paper: 07/Sept/2026

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