7FHH2006: The Regulatory Environment in the Middle East and North Africa

27/01/2026 - 29/01/2026

LOCATION: TOPRA THIRD FLOOR, CITY REACH, 5 GREENWICH VIEW PLACE, LONDON E14 9NN, UK

Module Leader(s): Natasha Bankowski and Eva Kopecna

Day 1: Tuesday, 27 January 2026

Time	Activity	Speaker
12:00 – 12:30	**Registration**	
12:30 – 12:45	**Welcome & Introduction to the Module**	**Natasha Bankowski**
12:45 – 14:15	Lecture 1: Navigating the Regulatory MENA Landscape • Regulatory complexities • Cultural Differences • Market analysis • Compliance challenges in the MENA region • Emerging Trends and Future Trends	**TBC**
14:15 – 14:30	**Refreshment break**	
14:30 – 16:00	Lecture 2: General Regulatory requirements for the MENA region • Life cycle management – including variations, renewals and post-approval commitments • Import and Export Regulations and Documentation for MENA • Digital Transformation	TBC
16:00 – 17:00	**Lecture 3: Clinical Trial requirements in the MENA region** • **Clinical Trial regulatory framework in MENA** • **Approval process of Clinical trial applications** • **Ethics considerations** • **Technological advances transforming clinical trial operations in MENA**	**TBC**

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Day 2: Wednesday, 28 January 2026

Time	Activity	Speaker
9:00 – 10:00	**Lecture 4: GCC Centralised Registration Procedure** • **Reliance Pathways** • **Streamlined Technical Requirements** • **Joint Inspection Initiatives**	**TBC**
10:00 – 11.00	Lecture 5: An intro to Saudi Arabia • Regulatory system • Regulatory Pathways for different categories of products (medicines, MD, FS) • Regulatory Pathway for Innovative Products	TBC
11:00 – 11:15	**Morning Break**	
11:15 – 12:15	Lecture 6: An Intro to UAE • Regulatory System • Regulatory Pathways for different categories of products (medicines, MD, FS) • Regulatory Pathway for Innovative Products	TBC
12:15 – 13:15	**Lunch**	
13:15 – 15:15	Case Study	TBC
15:15 – 15:30	**Afternoon Break**	
15:30 – 16:30	Lecture 7: An intro to Egypt • Regulatory system • Regulatory Pathways for different categories of products (medicines, MD, FS) • Regulatory Pathway for Innovative Products	TBC

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Day 3: Thursday, 29 January 2026

Time	Activity	Speaker
9:00 – 10:00	**Lecture 8: Convergence and Harmonisation in Africa** • **Africa Harmonisation Initiative** • **Africa Continental Reliance Framework** • **AMA continental pilot**	**TBC**
10:00 – 11:00	Lecture 9: Regulatory submissions in MENA sing Traditional Registration Dossiers, CTC or eCTD • Format Used by Different MENA Countries (Traditional Registration Dossiers, CTC or eCTD) • Similarities and Differences Between CTD Requirements in the MENA Region, USA & EU	TBC
11:00 – 11:15	**Morning Break**	
11:15 – 12:15	Lecture 10: Pharmacovigilance framework in MENA • Regulatory requirements for PV in MENA • PV inspections and audits	TBC
12.15 – 13:15	**Lecture 11: Pricing and Reimbursement Mechanism in MENA** • **Pharmaceutical pricing policies in the MENA region and related issues** • **Coverage and reimbursement policies and procurement in the MENA region** • **Local industrial policies** • **Impact of pricing, reimbursement and procurement policies in the MENA region** • **Future policy options**	**TBC**
13:15 – 13:30	Conclusion & Close	