

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 Kopečna

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 <ul style="list-style-type: none">• Regulatory complexities• Cultural Differences• Market analysis• Compliance challenges in the MENA region• Emerging Trends and Future Trends	Joelle Blokissa Arcera LifeSciences
14:15 – 14:30	Refreshment break	
14:30 – 16:00	Lecture 2: General Regulatory requirements for the MENA region <ul style="list-style-type: none">• Life cycle management – including variations, renewals and post-approval commitments• Import and Export Regulations and Documentation for MENA• Digital Transformation	Artee Patel ICON UK
16:00 – 17:00	Lecture 3: Clinical Trial requirements in the MENA region <ul style="list-style-type: none">• Clinical Trial regulatory framework in MENA• Approval process of Clinical trial applications• Ethics considerations• Technological advances transforming clinical trial operations in MENA	David Odhiambo African Pharmaceutical Network

Day 2: Wednesday, 28 January 2026

Time	Activity	Speaker
9:00 – 10:00	Lecture 4: GCC Centralised Registration Procedure <ul style="list-style-type: none">• Reliance Pathways• Streamlined Technical Requirements• Joint Inspection Initiatives	TBC
10:00 – 11:00	Lecture 5: An intro to Saudi Arabia <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Regulatory System• Regulatory Pathways for different categories of products (medicines, MD, FS)• Regulatory Pathway for Innovative Products	Ariana Mina Product Life Group
12:15 – 13:15	Lunch	
13:15 – 15:15	Case Study	Natasha Bankowski Eva Kopecna
15:15 – 15:30	Afternoon Break	
15:30 – 16:30	Lecture 7: An intro to Egypt <ul style="list-style-type: none">• Regulatory system• Regulatory Pathways for different categories of products (medicines, MD, FS)• Regulatory Pathway for Innovative Products	TBC

Day 3: Thursday, 29 January 2026

Time	Activity	Speaker
9:00 – 10:00	Lecture 8: Convergence and Harmonisation in Africa <ul style="list-style-type: none">• Africa Harmonisation Initiative• Africa Continental Reliance Framework• AMA continental pilot	David Odhiambo African Pharmaceutical Network
10:00 – 11:00	Lecture 9: Regulatory submissions in MENA using Traditional Registration Dossiers, CTC or eCTD <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Regulatory requirements for PV in MENA• PV inspections and audits	Mareez William Arcera lifesciences
12.15 – 13:15	Lecture 11: Pricing and Reimbursement Mechanism in MENA <ul style="list-style-type: none">• 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	
