

AGENDA

DAY 1 | 21 MARCH 2022



8:00 - 9:00

Breakfast Registration
Meet Up in the Lobby

9:00 - 9:15

Inauguration and Keynote Presentation

Dr. Mona Al Moussli
Co-Founder and Managing Director
PRA Consultancy

H. E. Dr. Amin Hussain Al Amiri
UAE Assistant Undersecretary of
Public Health Policy and Licensing Sector
Ministry of Health and Prevention (MOHAP), UAE

9:15 - 10:00

Session 1: Pharma Regulatory Updates in GCC
Moderated by: Dalia Fouad, Sanofi

UAE Regulations MOHAP
Dr. Mona Ali Alhammadi
Head of Registrations,
Ministry of Health and Prevention UAE

Oman Regulations
Ph. Nisreen Mohammad Nassr
Director of Drug Control,
Oman MoH

Q&A UAE, Oman

10:00 - 10:45

Session 2: Pharma Regulatory Updates in GCC
Moderated by: Dr. Dina Fathy, MSD

Bahrain Regulations,
Dr. Mariam Al Jalahma
CEO,
National Health Regulatory Authority (NHRA)
Bahrain

Q&A Bahrain

10:45 - 11:15

Coffee and Networking Break

11:15 - 12:15

Session 3: Value based Pricing in GCC
Chaired by: Dr. Jeffery Kemprecos,
Government Affairs & Public Policy Executive, GSK

Dr. Sattam Alghodyr
Director, Regulatory Affairs
SPIMACO

Qutaiba Al Manaseer
Government Affairs Director
AstraZeneca

Speaker's Panel Discussion

12:15 - 13:00

Session 4:
Lifecycle Management leveraging Regulatory Reliance
Moderator by: Dr. Shaimaa Elmeligy

Dr Ibrahim Nasser
RA Director
ABBVIE

Dr Yousra Farid
Head of Regulatory Affairs & CDQA
EPD-Gulf & Emerging Markets Scientific
Office Manager UAE, ABBOTT

Speaker's Panel Discussion

13:00 - 14:00

Lunch and Networking Break

14:00 - 14:30

Session 5: Combination Products Regulations
Moderated by: Omkolthoom Mahmoud Weisy

Dr. Samah Ragab Ibrahim
Regulatory Affairs and PV Director, Middle East
Organon

14:30 - 15:00

**Session 6: Biosimilars & Interchangeable Biologics:
More Treatment Choices**

Moderated by: Dr. Enas Hasan, General Manager, PRU

Dr. Neeraj Pant
Co Founder and Regulatory Affairs Director,
DDReg

15:00 - 15:45

Session 7: Value added Medicine
Moderated by: Dr Rabab Tayyem ACDIMA

Dr. Safa' H. Abu Gharbiah
Regulatory Affairs Director MENA
HIKMA Pharmaceuticals

Dr. Eman Awamleh
Regulatory Affairs
JFDA

Q&A

15:45 - 16:15

**Session 8: Regulatory Compliance
in Mergers & Acquisition**
Moderated by: Doa' Wassif, Viatrix

Dr. Marielouise Abi Hanna
Managing Director
The Reg.Cloud

16:15 - 16:45

**Session 9: Access to innovative medicines timelines in GCC/MEA
- IQVIA study outcome.**

Chaired by: Jeffery Kemprecos,
Government Affairs & Public Policy Executive, GSK

Simge Sasmaz
Principal, IQVIA

Dr. Inas Chehimi
Regulatory Affairs Head Middle East
Novartis

16:45 - 17:15

Coffee and Networking Break

17:15 - 18:00

Round Table discussions with Authorities

Table 1:
UAE Regulations MOHAP
Eslam Abdo Mohamed Selim Salem
Drug Registration Officer
Ministry of Health and Prevention UAE

Table 2:
Oman Regulations
Ph. Nisreen Mohammad Nassr
Director of Drug Control,
Oman MoH

Table 3:
Bahrain Regulations,
Dr. Mariam Al Jalahma
CEO,
Bahrain National Health Regulatory
Authority (NHRA)

**Pharma Industry:
Mergers & Acquisitions**

23 March 2022
10:00GST - 16:00GST

NEW

AGENDA

DAY 2 | 22 MARCH 2022



8:00 - 9:00

Breakfast Registration
Meet Up in the Lobby

9:00 - 9:10

Morning Welcome and Honorary Mentions
Dr. Rabab Tayyem, CEO/Executive Director, ACCIMA BioCenter

9:10- 10:00

Session 1: Track and Trace GCC
Moderated by: Dr. Lyna Slimani, Gilead

Ali Juma AlAjme
Director of Digital Health Department at Ministry of Health and Prevention - UAE

Rami Habbal
Chief Executive Officer
Gs1

Baha AbuSalem
Program Director - Tatmeen
EVOTEQ

Dr. Lamis Yousef
Senior Regulatory Affairs Manager
Pfizer

9:45 - 10:45

Session 2: e-Labeling - ePI
Moderated by: Amani Mansour, Pfizer

World Wide -industry vision of ePI landscape
Amani Mansour,
Head of Regulatory Affairs Middle East
Pfizer, MERN

Implementation of e-Labeling from Global Perspective: Michael Ritter

implementation of e-labelling at Takeda Japan
Dr. Nawel Boukhatem,
Head of Regulatory Affairs Middle East
Takeda

Panel: Dr. Hala Abu Ghazalah, Pfizer,
Dr. Ahmed Mohamed Hussein Babiker, Qatar MoH

10:45 - 11:15

Coffee and Networking Break

11:15 - 12:15

Session 3: Improve regulatory compliance
Moderated by: Zeeshan Ahmed Cosmotrace

Varun S. Singh
Head of Regulatory Affairs Middle East
Honeywell

12:15 - 12:45

Session 4: Introduction to Quality 4.0- Reshaping Business Culture Operating Model
Chaired by: Eman Abdulrahim
Regulatory Affairs Manager at Viatrix

Dr. Mazen Boughanem,
Quality Director-MENA at Bausch Health

12:45 - 13:15

GCC Pharma Regulatory Award 2022 Announcement
and Event Group Photo



13:15 - 14:15

Lunch and Networking Break

14:15 - 15:00

Session 5: Clinical Trials Regulation GCC
Moderated by Dr. Samar Osama, J&J

Rana Malkawi
Head of clinical studies department
Regulatory Consultant
JFDA

Dr. Ruba Jabar
Senior Clinical Research Manager
Hikma Pharmaceuticals

Dr. David Olafsson
Global Head of Clinical Research and Head of R&D; MENA
Hikma Pharmaceuticals

15:00 - 15:30

Session 6: RAFED
Moderated by: Puneet Kumar, Supply Chain & Logistics Lead, Roche

RAFED Introduction
Dr. Ahmed Al Bastaki
Director of Strategy
RAFED

15:30 - 16:30

Session 7: Regulatory Affairs Invited Governments
Chaired by: Dr. Safa' H. Abu Gharbiah

JFDA Regulatory Affairs, Dr. Bayan Hiasat
Director of Pharmacy and Medicine
Jordan

Tunisia Regulatory Affairs, Dr Myriam Khrouf
Director of Pharmacy and Medicine
MoH, Tunisia

Ethiopia Regulatory Affairs, Mr. Nathan Seyoum
External Medicine Dossier Assessor
EFDA, Ethiopian Food & Drug Authority

Kurdistan, Dr. Salam Waiss
Head of registration department
KMCA

16:30 - 17:00

Coffee and Networking Break

17:00 - 17:45

Round Table discussions with Authorities

Table 1:
JFDA Regulatory Affairs
Dr. Bayan Hiasat
Director of Pharmacy and Medicine
Jordan

Table 2:
Tunisia Regulatory Affairs,
Dr Myriam Khrouf
Director of Pharmacy and Medicine
MoH, Tunisia

Table 3:
Ethiopia Regulatory Affairs,
Mr. Nathan Seyoum
External Medicine Dossier Assessor
EFDA, Ethiopian Food & Drug Authority

Table 4:
Kurdistan
Dr. Salam Waiss
Head of registration department
KMCA