AGENDA

DAY 1 | 22 APRIL 2024

GCCRA REGULATORY AFFAIRS PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

8:00 - 9:00

Breakfast & Registration
Meet Up in the Lobby

9:00 - 9:15

Morning Welcome

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

Principal Sponsor Opening

Dr. Hossam Abo Ouf
Country Head KSA & UAE
Sanofi CHC

9:30 - 9:50

Session 1: Under The Patronage Of NHRA Pharma Regulatory Authorities Update

Moderated by:
Dr. Haidy Saad
Head of Regulatory Affairs GDD
Novartis Pharmaceuticals
Gulf Region

NHRA Pharma Regulatory Updates
Dr. Shima Altaher
Pharmacist & Regulatory Affairs Specialist
National Health Regulatory Authority
Bahrain

Q&A Panel Discussion

AGENDA

DAY 1 | 22 APRIL 2024

GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

9:50 - 10:30 **Session 2: Pharma Manufacturing in the GCC**

Moderated by:
Dr. Abobakr Abasaeed
Regulatory Affairs Manager
ADCAN Pharma
UAE

Manufacturing Localization & Opportunities
Dr. Rasha Darweish
Corporate Research & Development Manager
Tabuk Pharmaceutical Company

Pharmaceutical Glocalization... Where Do We Stand?
Dr. Rawya Kredly
Medical and Regulatory Affairs Director
Gulf Pharmaceutical Industries
(Julphar)

Q&A Panel Discussion

10:30 - 11:00 **Session 3: KSA updates**

Industry Overview Of The Pharma Regulations In Saudi
Dr. Sara Chaito
Regulatory & PV Manager
MENA region
Biologix

Q&A

11:00 - 11:30 **Networking and Coffee Break**

AGENDA

DAY 1 | 22 APRIL 2024

GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

11:30 - 13:15 **Session 4: Regulatory Digitization: Track and Trace Serialization**

Moderated by:
Ms. Supriya Shetty
GRS Led, GEM Cluster & Africa
Bristol Myers Squibb

Track And Trace - An Overview Of The Region
Mr. Jihad Tayara
CEO
EVOTEQ

Supply Chain Security & Real-Time Visibility to Prevent Counterfeit & Diversions
Mr. Shine Vijayan
Chief Technology Officer
ACG Inspection Systems Pvt Ltd

Distributor's Implementation & Management of Tatmeen & How to Track Unregistered Items
Mr. Zeeshan Ahmed
Founder & CEO
CosmoTrace

Aseptic Carton Serialization
Mr. Görkem Aydin
International Marketing Manager
VISIOTT Traceability Solutions

Panel Discussion

Mr. Mohammad Rabi
IT Supervisor
Jordan Food & Drug Administration
(JFDA)

13:15 - 13:30 **Conference Photo Group Shot**

13:30 -14:30 **Lunch and Networking Break**

AGENDA

DAY 1 | 22 APRIL 2024

GCCRA REGULATORY AFFAIRS PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

14:30 - 15:00 **Session 5: Impact of Post Approval Changes (PAC) Guidelines Differences on Commercial Supplies of Biosimilars**

Moderated by:
Dr. Khaled Rozza
Regulatory Affairs Lead Gulf
Acino

Overview Of Biosimilars In Mena
Safa' Abu Gharbiah, Phd
Senior Director - Regulatory Affairs
MENA
Hikma Pharmaceuticals

Comparative Assessment Of Biosimilars Pac Guidelines In Mena
Dr. Farah Arar
Regulatory Affairs Senior Manager
Hikma Pharmaceuticals

Q&A

15:00 - 15:45 **Session 6: Access to Orphan Drugs: A Review of Regulations & Policies**

Moderated by:
Dr. Hind Mahreche
Head of Corporate Affairs, Patient Advocacy, Communications & Crisis Management UMEA (Ukraine, Middle East & Africa)
Takeda

Overview of Orphan Drugs in Emerging Markets
Ms. Helene Sou
Director, Regulatory Policy and Innovation
Growth & Emerging Markets
Takeda Pharmaceuticals

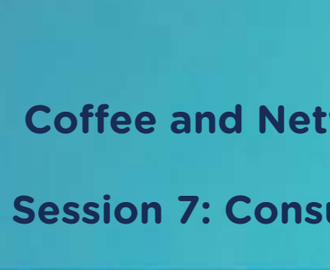
Regulatory Policies of Orphan Drugs in GCC Countries
Dr. Nawel Boukhatem
Head of Regulatory Affairs Ukraine
Middle East & Africa
Takeda Pharmaceuticals

Q&A Panel Discussion

Oman
Ph. Muna Al Saidi
Section Head (Registration Section of Human Medicine)
Ministry of Health
Oman

15:45 - 16:15 **Coffee and Networking Break**

16:15 - 17:00 **Session 7: Consumer Access to OTC Drugs**



Moderated by:
Dr. Samar Abdalhalim
Director of Regulatory Affairs Middle East & Africa
Procter & Gamble Health

Public Affairs & Policy Head, Africa Middle East & Türkiye
Dr. Mohamed Larbi Jelassi
Head of AMET Public Affairs
Sanofi CHC

NRA panel

Qatar
Dr. Ahmed M. Hussein Babiker
Head, Registration and Pricing Section
Pharmacy & Drug Control Department
Ministry of Public Health
Qatar

AGENDA

DAY 1 | 22 APRIL 2024

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

17:15 - 18:00 **Round Table Discussions with Authorities**

Oman MoH
Ph. Muna Al Saidi
Section Head (Registration Section of Human Medicine)
Ministry of Health
Oman

Qatar MoH
Dr. Ahmed M. Hussein Babiker
Head, Registration and Pricing Section, Pharmacy & Drug Control Department - Ministry of Public Health
Qatar

NHRA, Bahrain
Dr. Shima Altaher
Pharmacist & Regulatory Affairs Specialist
National Health Regulatory Authority
Bahrain

NHRA, Bahrain
Dr. Aisha Mohamed
Regulatory Affairs Specialist
Pharmacy and Pharmaceutical Product Regulation Department
National Health Regulatory Authority
Bahrain

AGENDA

DAY 2 | 23 APRIL 2024

GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

8:00 - 9:00 **Breakfast & Registration**
Meet Up in the Lobby

9:00 - 9:45 **Session 1: GCC National Regulatory Authority Updates**

Moderated by:
Dr. Fatima Zaid Abu Zanat
Regional Director of Regulatory Affairs & Scientific Office Middle East
Turkey & Africa
Ipsen Pharma

Oman Regulatory Updates
Ph. Muna Al Saidi
Section Head (Registration Section
of Human Medicine)
Ministry of Health
Oman

Qatar Regulatory Updates
Dr. Ahmed M. Hussein Babiker
Head, Registration and Pricing Section
Pharmacy & Drug Control Department
Ministry of Public Health
Qatar

Q&A Panel Discussion

9:45 - 10:30 **Session 2: (PAC) - Regulatory Reliance**

Moderated by:
Dr. Amal Fathy
Amal fathy title
Regulatory and Medical Head (Africa - Middle East - Turkey)
Sanofi CHC

Industry Overview Presentation: Reliance Best Practices for Post Approval Variations

Dr. Fatima Zaid Abu Zanat
Regional Director of Regulatory Affairs & Scientific Office
Middle East Turkey & Africa
Ipsen Pharma

Q&A Panel Discussion

Dr. Yousra Farid
Regulatory Affairs
Quality Assurance
Director & Strategic Project Lead
Gulf & Emerging Markets
Abbott

Egypt Drug Authority
Dr. Eman Hussein Awad
Regulatory Administration Director
Central Administration of Pharmaceutical Affairs
Egyptian Drug Authority
(EDA)

10:30 - 11:00 **Network and Coffee Break**

AGENDA

DAY 2 | 23 APRIL 2024

GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

11:00 - 12:00 **Session 3: Regulatory Digitization: EPI**

Moderated by:
Dr. Lamis Youssef
Senior Regulatory Affairs Manager
Gulf Cluster
Pfizer

e-Labelling & Digital Transformation in Healthcare
Ms. Shatha Safi
Labelling Supervisor
Regulatory Affairs Department
Hikma Pharmaceuticals

Practical Solutions for Labeling Challenges
Ms. Katarina Kresankova
Senior Account Executive
Schlafender Hase

Panel Discussion Regional EPI

Mr. Mohammad Rabi
IT Supervisor
Jordan Food & Drug Administration
(JFDA)

12:00 - 13:00 **Session 4: Regulatory Digitization - Influence of Ai**

Moderated by:
Ms. Dolcinea Chirazi
Business Development Director
The Applied AI Company
(AAICO)

Regulatory Innovation with Ai: Balancing Progress and Compliance
Mr. Fabrizio Maniglio
Industry and Business Development Director
Honeywell

The impact of Ai in Data management
Eng. Nusaibah Aljaloudi
CEO of Pi Pharma Intelligence

Q&A Panel Discussion

Mr. Benjamin Ping
Head of Business Operations &
Portfolio Management for UMEA
(Ukraine, Middle East and Africa)
Takeda Pharmaceuticals

Mr. Rafael Rozenblum
Head of Data, Digital and Technology
UMEA (Ukraine, Middle East and Africa)
Takeda Pharmaceuticals

13:00 - 13:30 **GCC Regulatory Affairs Awards Announcement**

13:30 - 14:30 **Lunch and Networking Break**

AGENDA

DAY 2 23 APRIL 2024

GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

14:30 - 15:30 **Session 5: Digital Transformation and Data Governance**

Moderated by:
Ms. Samah Ragab, Mpp
Regulatory Affairs and Pharmacovigilance Director
Middle East
Organon

At the Pulse of Your Data: Introducing RIMS to Harmonize Digital Heartbeats

Mr. Michael Faust
RCC Business Consultant
EXTEDO

GxP Data Integrity: Harnessing Trust for Informed Decision-Making Across Medical Product Lifecyle

Mr. Mazen Boughanem
GxP Compliance Expert
Formerly Global Quality Director
Strategic Compliance

Q&A Panel Discussion

AGENDA

DAY 2 | 23 APRIL 2024

GCCRA REGULATORY AFFAIRS PHARMA SUMMIT

"Navigate Pharma Regulations with Ease & Amplify Commercial Success"

15:30 - 16:45 **Session 6: Invited National Regulatory Authorities**

Moderated by:
Safa' Abu Gharbiah, Phd
Senior Director - Regulatory Affairs
MENA
Hikma Pharmaceuticals

Jordan FDA
Dr. Rana Malkawi
Drug Directorate Director
Regulatory Affairs Consultant
Jordan Food and Drug Administration
(JFDA)

Egyptian Drug Authority
Dr. Eman Hussein Awad
Regulatory Administration Director
Central Administration of Pharmaceutical Affairs
Egyptian Drug Authority
(EDA)

ANPP
Ms. Naoual Assam
Sub-Director of Technical and Regulatory
Control of Pharmaceutical Products
The National Agency for Pharmaceutical
Products
(ANPP)

Iraq MoH
Dr. Areej Jawad
Prime Pharmacist
Manager of Pharmacy Department
Iraq Ministry of Health

Q&A Panel Discussion

17:05 - 17:30 **Round Table discussions with Authorities**

Egyptian Drug Authority
Dr. Eman Hussein Awad
Regulatory Administration Director
Central Administration of Pharmaceutical Affairs
Egyptian Drug Authority
(EDA)

Jordan FDA
Dr. Rana Malkawi
Drug Directorate Director
Regulatory Affairs Consultant
Jordan Food and Drug Administration
(JFDA)

ANPP
Dr. Meriem Sellam
Coordinator at the Direction Of Registration
Pharmaceutical Products
The National Agency for Pharmaceutical
Products
(ANPP)

Iraq MoH
Dr. Mohammed Al-Rufaye
Prime Pharmacist
Chairman of Re/Registration Committee
Iraq Ministry of Health