AGENDA

DAY 1 | 6 MARCH 2023

GCC REGULATORY AFFAIRS PHARMA SUMMIT

"Forces of Regulatory Changes & Pharma Innovation in the GCC Region"

8:00 - 9:00

Breakfast Registration
Meet Up in the Lobby

9:00 - 9:15

Morning Welcome

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

Welcome from Titanium Sponsor: Utrace & advanco

Mr. Hasan Verinc
Director of Professional Services
advanco

Mr Konstantin Ivanov
Co-founder and CEO
Utrace

9:15 - 9:20

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

9:20 - 10:30

Session 1: Under the Patronage of NHRA Pharma Regulatory Authorities Updates

Moderated by:
Dr. Dina Fathy
Senior Director, Regulatory Affairs
Middle East Sub-Regional lead
MSD

Gulf health Council
Dr. Hajed M. Bin Hajed
Deputy General Director
Gulf Health Council

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

Q&A Panel Discussion

AGENDA

DAY 1 | 6 MARCH 2023

GCC REGULATORY AFFAIRS PHARMA SUMMIT

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

11:00 - 12:00 **Session 2: GCC National Regulatory Authority Updates**

Moderated by:
Dr. Amani Mansour,
Director, Head of Regulatory Affairs - Gulf
Pfizer

UAE Regulations MOHAP

Dr. Hanady Shourrab, Pharmacist,
Drug Dept.
MOHAP

Dr. Lamia Mohammed,
Snr Pharmacist, Pharmacist,
Drug Dept.
MOHAP

Oman Regulations, Oman MoH

Dr.Amani Salim Ali Al Siyabi
Section Head (Reg. of Herbal
Medicines and Health Products),
Drug Control Department
Ministry of Health – Oman

Q&A Panel Discussion



AGENDA

DAY 1 | 6 MARCH 2023

GCC ATORY AFFAIRS RMA SUMMIT

12:00 - 13:00 **Session 3: Regional Regulatory and Pricing Challenges**

Moderated by:
Dr. Yousra Farid
RA & Quality Director
Abbott

Critical and comparative analysis of Marketing Authorization procedures in the GCC

Dr. Safa' H. Abu Gharbiah
Senior Director Regulatory Affairs – MENA
Hikma

Regulatory Pricing Environment in MENA Region

Dr. Sara Chaito
Head of Regulatory Department - MENA
Biologix

Q&A Panel Discussion



Dr. Nadia Younis
Managing Partner
Stellar Pharma Consultancy

13:00 - 14:00 **Conference Photo Group Shot**
Lunch and Networking Break

14:00 - 15:15 **Session 4: Clinical Trials**

Moderated by:
Dr. Inas Chehimi
Senior Director - Head of Regulatory Affairs - Middle East and Africa
Novartis

EMA & FDA Detection methods of challenged non-detectable Clinical Trials manipulations & regulatory adjustments

Prof. Dr. Osama Abd Elrahman
Regulatory Affairs Expert
MoH, Directorate General of Pharmaceutical Affairs, General Director Office, Oman

The UAE: A Global Hub for Research and Innovation

Dr. Marie Ibrahim
Associate Director of Regulatory Affairs and Pharmacovigilance
IROS

Q&A Panel Discussion and Q&A Abu Dhabi



Dr. Khuloud Bin Rafeea
Director Drugs & Medical Products Division
Department of Health - Abu Dhabi

GCC Quality Conferance
NEW
10th March 2023
9:00 - 5:00
www.pramagcc.com

AGENDA
DAY 1 | 6 MARCH 2023

15:15 - 16:15

Session 5: Pharma Manufacturing in the GCC

Moderated by:
Dr. Khalid Rozza
Regulatory Affairs Lead
GEM
Acino

Contract Manufacturing
Dr. Hakima I. Hoseh
RA and Due diligence
Associate Director
Hikma

Local Manufacturing
Dr. Rawya Al Kredly
Head of Medical Affairs Dept.
Julphar

Q&A Panel Discussion and Q&A Abu Dhabi



Dr. Riyadh Azhari
Drug Registration Specialist,
Drug Department
MOHAP

16:15 - 17:00

Session 6: Quality introduction - TQ Pharma Quality Manufacturing Practice GmP

Moderated by:
Dr. Yasmeen Lafi
Regulatory Affairs Specialist
ADCANPharma

The Quality guideline m RNA
Dr. Zakiya Al-Kurdi
Public Policy and Regulatory Affairs Senior Manager, EMEA
US Pharmacopeia

Challenges facing tech transfer with vaccines from regulatory perspective
Dr. Abobakr Abasaeed El Hag
Regulatory Affairs Supervisor
ADCANPharma

17:00 - 17:15

Coffee and Networking Break

17:15 - 18:00

Round Table discussions with Authorities

Table 1:
UAE Regulations MOHAP
Dr. Riyadh Azhari
Drug Registration Specialist
Drug Department
MOHAP

Moderated by: Dr. Yousra Farid

Table 2:
Oman Regulations, Oman MoH
Dr. Amani Salim Ali Al Siyabi
Section Head (Reg. of Herbal Medicines and Health Products),
Drug Control Department
Ministry of Health – Oman

Moderated by: PRA Consultancy

Table 3:
NHRA
Dr. Mariam Al Jalahma
CEO
National Health Regulatory Authority
NHRA

Moderated by: PRA Consultancy

AGENDA

DAY 2 | 7 MARCH 2023

8:00 - 9:00

Breakfast Registration
Meet Up in the Lobby

9:00 - 9:05

Morning Welcome and Honorary Mentions
Honeywell

Ms. Eda Degen
Account Manager EMEA
Honeywell

9:05 - 10:30

Session 1: Track and Trace Overview with a Focus on UAE

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

How to comply with Pharma Track and Trace Regulations for Manufacturers, Distributors/3PL, Pharmacies and Hospitals

Mr. Santosh Balbhadra Trivedi
Senior Product Manager
Track & Trace
Honeywell

Mr. Varun Shekhar Singh
Product Management Lead
Track & Trace SaaS Platform
Honeywell

Future Plans for Tatmeen, the UAE National Repository
Mr. Baha Abu Salem
Program Director
Evoteq

Q&A Panel Discussion




Dr. Fahad AlZahrani
Regulatory Affairs Director - GCC
Janssen

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10:30 - 11:30

Session 2: Track and Trace and Serialization

Moderated by:
Dr. Ebla Khadra
Regulatory Affairs Specialist
Takeda

How do we see the future of Track and Trace?

Mr. Hasan Verinc
Director of Professional Services
advanco

Mr Konstantin Ivanov
Co-founder and CEO
Utrace

Looking at the current Track and Trace in Bahrain
Mr. David Todd
CEO
Medical Value Chain

Q&A Panel Discussion




Dr. Mariam Al Jalahma
CEO
National Health Regulatory Authority
NHRA

Bara'a
For Pharmaceutical Patent Consultation

Contact us for:

- Legalized Freedom to Operate report (**FTO**)
  complying with the SFDA Regulatory patent linkage initiative (January 1st, 2023)
- Patent Landscape Analysis report (**PLA**)
  Understanding drug product's patent status in MENA region
- Patent Design-Around report (**PDA**)
  Constraining Patent's By-pass strategies
- Introducing the IP language to your company
  Pharmaceutical patent customized training for different functions

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11:30 - 12:00 Coffee and Networking Break

12:00 - 13:15 Session 3: Data Integrity and Digitalization

Moderated by:
Dr. Marielouise AbiHanna
Business Development Lead
Scigeniq

GxP Data Integrity
Dr. Mazen Boughanem
Global Quality Director
Strategic Compliance
Bausch Health

Digital Transformation
Dr. Marielouise AbiHanna
Business Development Lead
Scigeniq

Q&A Panel Discussion

Mr. Shekhar Kapoor,
Senior Strategy Consultany
Siemens Advanta Consulting

Dr. Mahmoud Elghandour
Regulatory Affairs Pharmacist
GMP auditor
MOHAP

GCC
ATORY AFFAIRS
RMA SUMMIT

13:15 - 14:15

GCC Pharma Regulatory Award 2023 Announcement and Lunch and Networking Break

14:15 - 15:15

Session 4: GCC Pharma Supply Chain and Logistics

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

The added value and role of RAFED
Mr. Ahmed Al Bastaki
Chief Commercial Officer (CCO)
Rafed

Regulatory Affairs DOH-Abu Dhabi
Dr. Maryam Ahmed Sayed Mahdi
Specialist Drugs Accreditation Drugs & Medical Products Division
Department of Health (DOH)

Q&A Panel Discussion

15:15 - 15:30

Quick Coffee Break

GCC
GULATORY AFFAIRS
HARMA SUMMIT

15:30 - 16:30

Session 5: Intellectual Property Protection in Pharma

Moderated by:
Dr. Farida Alayan
Intellectual Property (IP) and Regulatory Affairs (RA) Consultant
in the Pharmaceutical Industry

Sustaining pharmaceutical innovation -
The Role of Intellectual Property Rights
Dr. Rania Ashraf
Director Government Affairs and Policy
GCC
Janssen

Freedom to Operate
Regulatory Patent Linkage
Dr. Fouad Darras
CEO
Bara'a

Legal Aspect
Ms. Norah Arif
Contracts & Business Development Manager
Partner
NKL

Q&A Panel Discussion




Mr. Ahmad Saleh
Partner and Head of Innovation
Patents and Industrial Property (3IP)
Al Tamimi

16:30 - 17:15

Session 6: Regulatory Affairs Invited Governments

Moderated by:
Dr. Safa' H. Abu Gharbiah
Regulatory Affairs Director - MENA
Hikma

Jordan MoH
Dr. Rania Rawabdeh
Regulatory Pharmacist
Registration Department
JFDA

17:15 - 18:00

Round Table discussions with Authorities

Table 1:
Jordan -JFDA
Rania Rawabdeh
Regulatory Pharmacist
Registration Department
JFDA