

AGENDA

22 MARCH 2021



8:00 - 9:00

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Breakfast Registration Meet Up at the Network Lobby



9:00 - 9:30

Inauguration and Keynote Presentation



H. E. Dr. Amin Hussain Al Amiri

UAE Assistant Undersecretary of Public Health Policy and Licensing Sector

Ministry of Health and Prevention, United Arab Emirates

Introduced and Welcomed by



Dr. Mona Al Moussli

Managing Director

PRA Consultancy

9:30- 10:30

Session 1 GCC Regulatory Updates in the Pharma Market



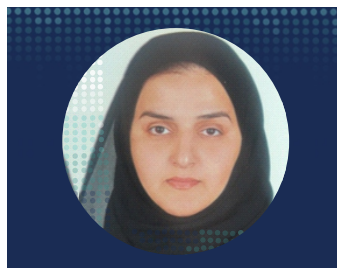
Moderated by

Dr. Samia Kanawati

Area PR & Communications Lead
Eastern Europe, Middle East & Africa - EEMEA

Allergan

Please share your questions in the Auditorium Chatbox for the Moderator to ask the Panel.



Oman Regulations

**Ph. Nisreen
Mohammad Nassr**
Director of Drug Control

Oman MoH



Bahrain Regulations

Dr. Mariam Al Jalahma
CEO

National Health Regulatory
Authority (NHRA)

10:30- 11:00

Coffee and Networking Break Meet Up at the Network Lobby or Visit the Exhibition Zone

Meet up with
HIKMA
at the Exhibition
Zone

*Enter from the Lobby



11:00 - 11:45

Session 2 Regulatory Time lines GCC Study Moderator Jeff



Speaker

Reham Alassily

Associate Director Global
Regulatory Affairs.

IQVIA



Moderated by

Dr. Jeffery Kemprecos

Government Affairs and
Public Policy Executive

GSK

11:45- 12:45

Session 3 GCC Regulatory Updates in the Pharma Market



Moderated by

Dr. Inas Chehimi

Regulatory Affairs Head Middle East
and Africa

Novartis

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questions in the
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ask the Panel.



KSA Regulations

Dr. Nasser Alqahtani

Executive Director for Drug
and Pharmaceutical Affairs

1st Central Health Cluster –
Ministry Of Health (MOH)
KSA



Kuwait Regulations

Dr. May Boshaiabah

Drug Registration
Department

Kuwait MoH



Kuwait Regulations

Dr. Donia Bastakia

Head of Drug Registration
Department

Kuwait MoH

12:45- 13:15

Session 4 Track and Trace GCC



Moderated by

Rehab AbdelAziz

Regulatory Affairs &
Pharmacovigilance Manager
MENAT

Aspen Health Care FZ LLC



Speaker

Baha AbuSalem

Program Director - Tatmeen

EVOTEQ

13:15 - 14:15

**Lunch and Networking Break
Visit the Exhibition Zone,
Network in the Lobby
or Join the Group Chat**



**Meet up with
IQVIA
at the Exhibition
Zone**

**Enter from the Lobby*

14:15 - 15:45

Session 5 Recognizing and Rewarding Pharma Innovation

Please share your
questions in the
Auditorium Chatbox
for the Moderator to
ask the Panel.



Moderated by
Dr. Nadia Younis

Public Affairs, Policy & Regulatory, MENA

Stellar Pharma Consultancy



Value Based Pricing

Dr Panos Kanavos

Associate Professor of
International Health Policy
in the Department of
Health Policy

London School of
Economics and
Political Science



**Value of Innovation in
Pharmaceuticals**

Dr Amr Elsharkawy

Director, Health Economics
and Market Access

Johnson & Johnson



Panelist

Dr Jeffery Kemprecos

Government Affairs and
Public Policy Executive

GSK

15:45 - 16:00

Coffee and Networking Break

- if you have pre booked to be part of the Round Table Discussions you can enter now.



Take the time & fill out the Feedback form in the Auditorium

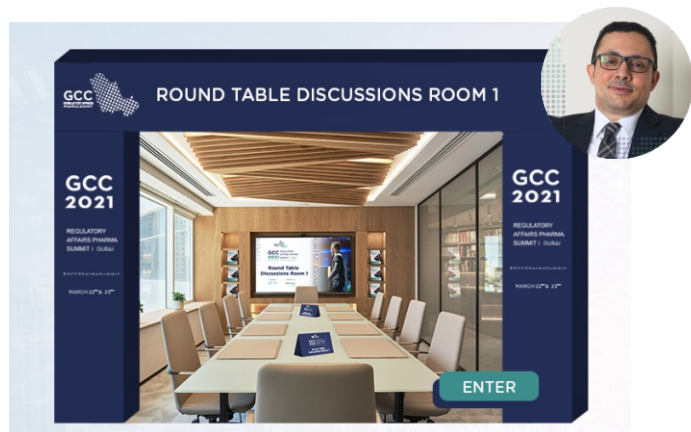
Networking Lobby & Exhibition Zone is OPEN to all



16:00 - 16:45

ROUND TABLE DISCUSSIONS

UAE - Round Table Room 1



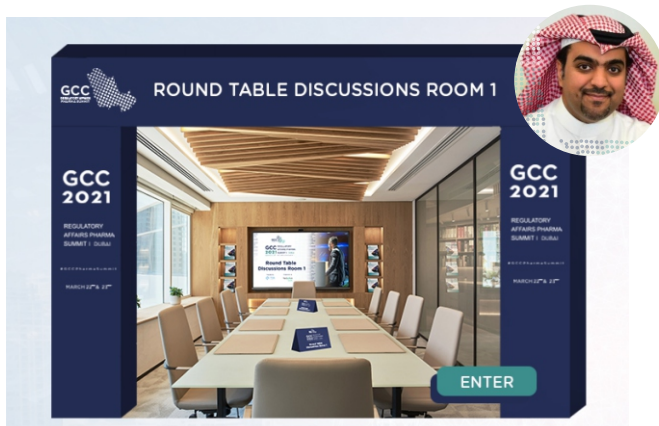
Oman - Round Table Room 2



17:00 - 18:00

ROUND TABLE DISCUSSIONS

KSA - Round Table Room 1



Bahrain - Round Table Room 2



18:00

END OF DAY !

Keep an eye out for today's wrap up and highlights on our Social Media Pages and join the Conversation.

AGENDA

23 MARCH 2021



8:00 - 9:00

Breakfast Registration Meet Up at the Network Lobby

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9:00 - 9:30

Morning Welcome and Honorary Mentions Pharma Regulatory Award 2021 GCC Announcement



Dr. Mona Al Moussli
Managing Director

PRA Consultancy

Pharma Regulatory
Award 2021 GCC
Announcement



9:30- 11:00

Session 1: COVID-19: Regulatory & Commercial View in the Region

Please share your
questions in the
Auditorium Chatbox
for the Moderator to
ask the Panel.

Moderated by



Dr Shaimaa Elmeligy

Technical Director - Middle East, North
Africa & Turkey

Aspen Health Care FZ LLC



**Role of National
Pharmaceutical
Companies in COVID-
19 Battle**

Sattam Alghodyyr
Director, Regulatory Affairs

SPIMACO



**Oxford university and
AstraZeneca
partnership towards
broad and equitable
access to COVID-19
Vaccine**

Qutaiba AlManaseer
Government Affairs Director,
Middle East & Africa

AstraZeneca



**CRO Business
Operations during
COVID Pandemic,
Jordan experience**

Dr. Enas Hasan
General Manager

PRU

10:45 - 11:15

Coffee and Networking Break
Meet Up at the Network Lobby or
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Meet up with
PRU Consultancy
at the Exhibition
Zone
***Enter from the Lobby**

11:15 - 11:40

Session 2
GCC Variations GL and Regulatory tools for efficient
Life Cycle Management, where do we stand?



Moderator:
Dr. Dina Fathy
Regulatory Affairs Director
Gulf

MSD



Sylvie Meillerai
Director of Global CMC Policy
Lead of the EFPIA ME network
LCM Task Force for CMC

MSD Europe Inc.

11:40 - 12:00

Session 3
What is e-labeling and why it is emerging
as a global topic of importance?



Moderator:
Dalia Fouad
Global Regulatory Affairs
MiddleEast Zone Head

Sanofi



Ronnie Mundair:
Regional Labelling
Head

Pfizer

12:00 - 13:00

Session 4
Biosimilars and the Access



Dr Safa' H. Abu Gharbiah
Regulatory Affairs Director
MENA

HIKMA



Keith Watson
Vice President

Celltrion Inc.

13:00 - 14:00

Lunch and Networking Break
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GCC
Regulatory Affairs

CHAT ROOM

JOIN US

**Meet up with
PRA Consultancy
at the Exhibition
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**Enter from the Lobby*



14:00 - 14:20

Session 5 **GCC eCTD 4.0 - Mission or Vision?**



Frank Dickert

Senior Business Development

Extedo

**Have you booked your
spot at the eCTD
Workshop Spot yet?**
[shaun@hubplus-
event.com](mailto:shaun@hubplus-event.com)

14:20 - 15:00

Session 7 **Regulatory Affairs Invited Governments**

**Please share your
questions in the
Auditorium Chatbox
for the Moderator to
ask the Panel.**



Moderator: Dr. Yousra Farid

Head of Regulatory Affairs & CDQA
EPD-Gulf & Emerging Markets
Scientific Office Manager - UAE

ABBOTT



**Jordon
Regulatory Affairs**

Wesal Alhaqaish
Director General
Technical Assistant /
Jordan Food & Drug
Administration

JFDA



**Kurdistan
Regulatory Affairs**

Salam Waiss
Registration
Department Manager

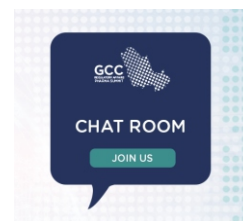
KMCA (Kurdistan
Medical Control
Agency)

15:00 - 15:30

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Coffee and Networking Break

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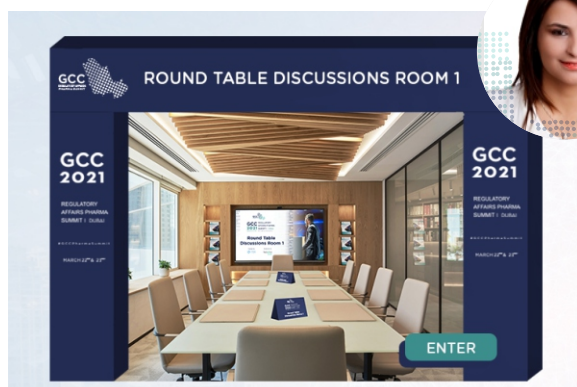
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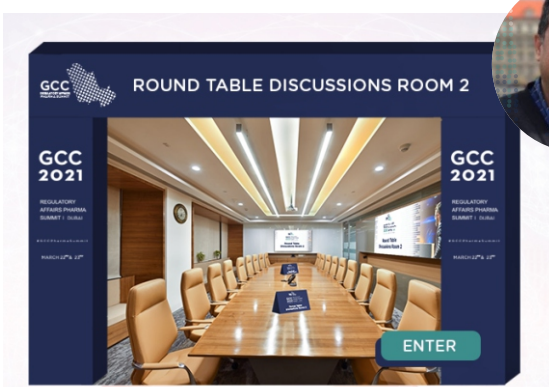
15:30 - 16:00

ROUND TABLE DISCUSSIONS

Jordan - Round Table Room 1

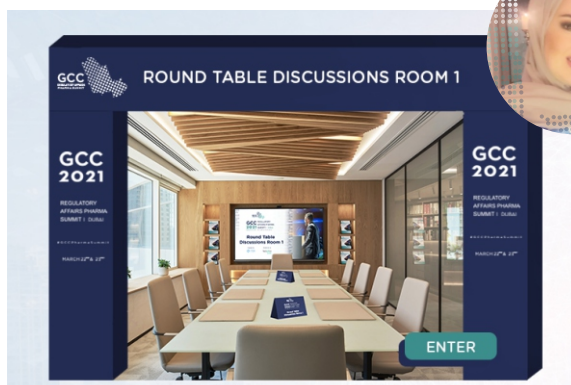


Kurdistan - Round Table Room 2



16:15 - 16:45

Kuwait - Round Table Room 1



17:00

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