

GCC
REGULATORY AFFAIRS
PHARMA SUMMIT



5th GCC REGULATORY AFFAIRS PHARMA SUMMIT 2020

Post Event Report

Date - 22nd & 23rd July

Venue - **Virtual (online)**

Powered by - PRA Consultancy

Organizer - Hubplus Events

www.pramagcc.com

Education Partner - Dubai Pharmacy College





THE VISION

In 2015, PRA Consultancy, realized the importance to bridge the gap between Regulatory Authorities and the Pharma Industry. They launched a platform where Regulatory Authorities could discuss new and updated regulations in the Pharmaceutical market with the Pharma Industry.

With the support of Ministry of Health UAE, the GCC Regulatory Affairs Pharma Summit was launched and after its success it became an annual institution for GCC Countries and neighboring invitee countries. The Summit presented all the Authorities under one event providing transparency and stabilizing regulations in the region.

At this time the UAE government was developing into a smart city and was moving its application process to a digital medium. The GCC Regulatory Affairs Pharma Summit became a perfect platform to communicate the new processes to the

Industry. In addition, it presented opportunity for all GCC Countries to symbiotically advance their Regulatory application processes and through discussion and knowledge sharing improved the processes of the GCC region and streamlining GCC Pharma Regulations.

The Region is still growing, and many new Regulations are issued for the Pharma Industry. The GCC Regulatory Affairs Pharma Summit created a platform where Pharma Industries could learn about the regulations and how they could enter and safely distribute their products through the GCC Market. It has become the premier event to connect Industry with the GCC Pharmaceutical Regulations Authorities.

This year, 2020, brought its own challenges and the GCC Regulatory Affairs Pharma Summit was successfully hosted Virtually, providing Industry Attendees from 19 different countries worldwide, from the EU, North America and Africa, opening a bigger Industry connection than ever before.

PRA Consultancy is looking to the future to bring the GCC Regulatory Affairs Pharma Summit to more Pharma Industry leaders and developers to support the growth of the Pharma Industry in our region.

Key Facts of the 5th GCC Regulatory Affairs Pharma Summit 2020

SPEAKERS

34

COUNTRIES

19

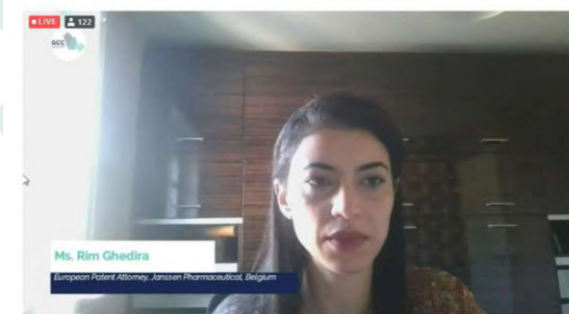
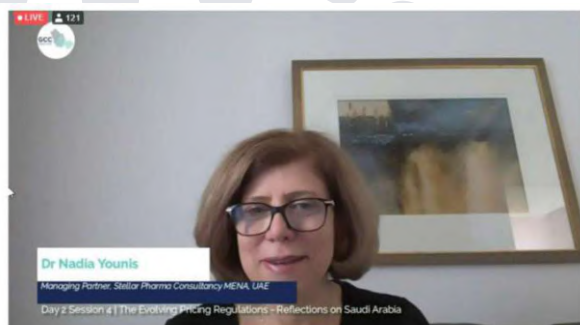
Attending from Europe,
Africa, North America
& the Middle East

ATTENDEES

300+

Pharmaceutical Industry

- Regulatory Affairs Directors, Managers, Executives and Associates
- Communications Managers
- Logistics Managers
- CEO's, COO's General Managers
- Pharma Manufacturer
- QA
- Market Access and Pricing Managers
- Supply Chain Managers
- Quality and Scientific Office Managers
- Registration Head, Managers
- Pharma Distributors
- Pharmacist



Dr Amin Al Amiri

About the Summit

The summit was a 2 days event and witnessed a series of Keynote Presentations, Panel Discussions, Case study Presentations and Break Out Discussions followed by a Q&A after each session. The Q&A sessions was particularly successful with well positioned questions delivering high end information to the delegates. Expert speakers joined in world wide to be part of the discussions.

Government Authorities 2020 GCC Regulatory Affairs Pharma Summit

- Ministry of Health and Prevention - UAE
- Ministry of Health - Oman
- National Health Regulatory Authority - Bahrain
- Ministry of Health - Morocco
- Ministry of Health - Kuwait

ROUND TABLE DISCUSSIONS

- Country specific Round Table Discussions gives Industry leaders the opportunity to connect directly with a specific country's Regulations Authority.
- Moderated by PRA Team members that will facilitate the Q&A and provide post event support for Regulations with the particular Country.
- Over 50 delegates per breakout session with direct contact to Regulatory Authority
- Clearly communicated Country specific information on hand.

United
Arab
Emirates

Kingdom
of Bahrain

State
of
Kuwait

Kingdom of
Saudi Arabia

Sultan of
Oman

“Very informative in a technical level. Excellent opportunity to meet and discuss different issues with Regulatory bodies as well as with brand and generic manufacturing representatives”

Safa Abu Gharbiah, Regulatory Affair Director - MENA, Hikma Pharmaceuticals

Participant Companies at the 5th GCC Regulatory Affairs Pharma Summit 2020



SPONSORS

The 2020 GCC Regulatory Affairs Pharma Summit was highly successful in spite of rolling out virtually in the middle of the COVID 19 pandemic. We were delighted to have our sponsors; SPIMACO and Extedo on board who supported this event immensely and were delighted to see more than 300 delegates for the event.

Extedo talked about the regulatory affairs at main event and announced its post event training of 2 days that was available to all the attendees of the summit. It was a truly rewarding event offering significant growth opportunities with the program focusing on knowledge transfer. E-networking opportunities was appreciated by the sponsors, speakers and participants alike



Social Media Reach

Industry Specific Niche Connections

Social Media Links:

www.linkedin.com/company/gccpharma

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22nd & 23rd JULY 2020, VIRTUAL EVENT
www.pramagcc.com
info@pramagcc.com

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GCC Regulatory Affairs Pharma Summit
6 July · 🌐

We are delighted to reveal our sponsor EXTEDO for the 5th GCC Regulatory Affairs Pharma Summit 2020 taking place on the 22nd & 23rd of #July 2020.
www.extedo.com
#GCCPharmaSummit #virtualconference #pharmaceutical

SPONSORS 2020

EXTEDO
eRegulatory Affairs

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). They focus on optimizing the clients' eRegulatory business processes and provide solutions covering the entire regulatory landscape. The EXTEDOsuite combines innovation with compliance, and quality with usability. Whether planning & tracking, product registration, submission publishing and lifecycle management, pharmacovigilance management and drug safety, they optimize every eRegulatory business process. Today, EXTEDO enables more than 35 regulatory authorities and 850 maintained customers across 60 countries to deliver Effortless Compliance.

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GCC pharma summit highlights improvements in production



The annual summit was hosted online with representatives from the pharmaceutical industry and healthcare administrations.

Business Bureau, Gulf Today

Recent initiatives in Gulf countries to facilitate patient access to new medicines and the advantages of integrating regulations related to drug trials and registration region wide were discussed at the GCC Regulatory Affairs Pharma Summit 2020, hosted in Dubai with the support of the UAE Ministry of Health and Prevention (MOHAP).

The annual summit, now in its fifth year, was hosted online in view of the global alert against COVID-19, with representatives from the pharmaceuticals industry and healthcare administrations analyzing key drivers of regulatory reforms in the region.

The importance of data and quality management in expediting drug registration and ensuring a safer community was also emphasised by the speakers, especially in the context of the COVID-19 crisis, which called for faster responses in terms of drug trials, approvals and import.

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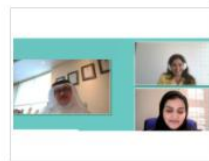
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المجلة الرئيسية / مجلة
 من مجلس التدوير العالمي | 28 أغسطس 2020
"قمة" الخبز للشؤون الدولية 2020 - شاهد الخبراء على التحديات في عمليات الإنتاج وبيئة التنظيمية للتعامل في ظل تفيد-19
 أعلنت عن الحدث في 22-23 يوليو الجاري.

رندة سفيارة
 تدعى إلى تكامل الشبكات الدولية، وتركز على الجودة لتعزيز العرض المحلية والعالمية
 بتكتم الصحة العامة بدعم من وزارة الصحة ووقاية المجتمع

هبة تاملت "قمة الخبز للشؤون الدولية 2020". كوني استمتعاً بما أراه من تدبير من وزارة الصحة ووقاية المجتمع في دولة الإمارات، التحديات العالمية التي أطمحها، دول مجلس التعاون الخليجي، يوجد تسهيل وصول المرضى إلى الأدوية الحديثة، وعرضاً على اللقاحات التطعيمية المتعلقة بتفاديل إندونيسيا وسنغافورة، من مثلاً، أمام المنطقة.



The "Gulf Pharmaceutical Affairs Summit 2020", hosted by the Emirates of Dubai, with the support of the UAE Ministry of Health and Prevention, discussed the recent initiatives launched by the countries of the Gulf Cooperation Council. With the aim of facilitating access for patients to new drugs, and the advantages of integrating regulations related to drug trials, and their registration in the various parts of the region.

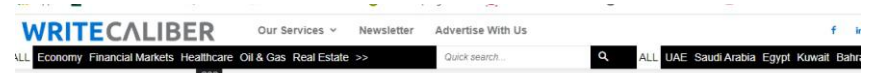
The summit was held in its fifth edition via the Internet under the precautionary measures... To limit the spread of the emerging "Corona" virus (Covid-19), and to witness representatives of the pharmaceutical industry and health care departments address the most important factors and main drivers of regulatory reforms in the region and their analysis.

Speakers at the virtual summit stressed the importance of data and quality management in accelerating drug registration. To ensure a safer society, specifically in light of the Covid-19 crisis, which imposed on everyone a faster response in terms of drug trials, approvals and imports.

During the summit, experts reviewed the UAE's experience in taking advantage of its competitive logistical network and the continuous transformation to the digital economy. The aim is to ensure the continuity of adequate supplies of health necessities throughout the region.

Dr. Amin Hussein Al-Ansi, Assistant Undersecretary for Public Health Policy and Licensing at the Ministry of Health and Community Protection in the United Arab Emirates, said during his keynote speech: "The pharmaceutical production process that is subject to a well-controlled and controlled system, along with the regulatory mechanism, and the globally superior Frontline Logistics system, are factors Support and empowerment for patients, communities, and global communities alike, especially in conjunction with efforts. To contain the outbreak of the Covid-19 virus.

As of July 19, the ministry had agreed to send 450 shipments of health care essentials and various hygiene and disinfection products, including COVID-19 diagnostic equipment, ventilators, personal protective equipment, intravenous treatment solutions, sterilizers and



GCC pharma summit highlights improvements in production and regulatory environment – ZAWYA

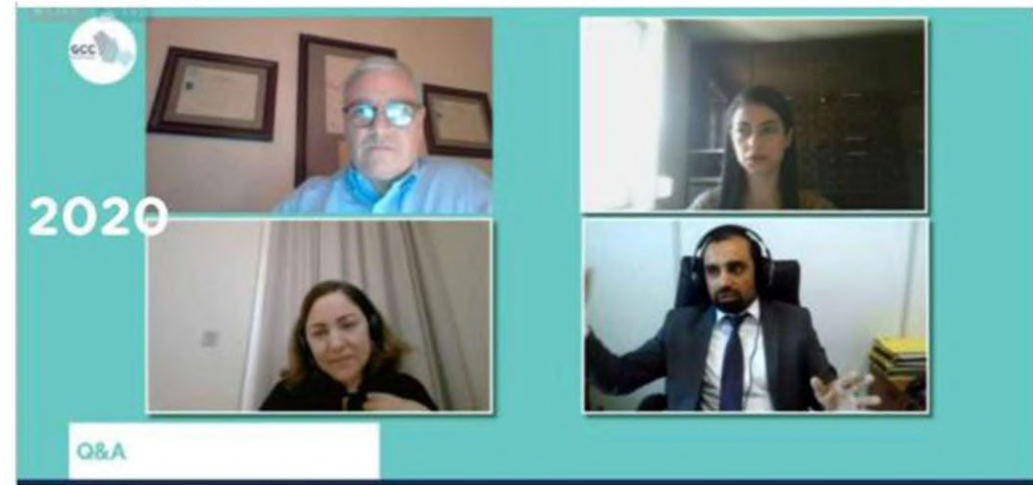
August 2, 2020
 Source Sector Country
 Zawya Economy GCC



GCC pharma summit highlights improvements in production and regulatory environment 5th Summit, supported by UAE Ministry of Health calls for stronger regional integration and focus on quality to maximise domestic and international opportunities Dubai: Recent initiatives in Gulf countries to facilitate patient access to new medicines and the advantages of integrating regulations related to drug trials and registration regionwide were discussed at the GCC Regulatory Affairs Pharma Summit 2020, hosted in Dubai with the support of the UAE Ministry of Health and Prevention (MOHAP) The annual summit, now in its fifth year, was hosted online in view of the global alert against COVID-19, with representatives from the pharmaceuticals industry and healthcare administrations analyzing key drivers of regulatory reforms in the region. The importance of data and quality management in expediting drug...read

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Virtual discussions; bringing the right people together in challenging times



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6th GCC REGULATORY AFFAIRS PHARMA SUMMIT 2021

**WE ARE GOING
HYBRID**

Powered by - PRA Consultancy
Organizer - Hubplus Events

Education Partner - Dubai Pharmacy College

Benefits of going Hybrid

Optional experience for attendees and speakers

Keeping the Personal Connection for on site attendees

Wider Reach for Authorities and Sponsors

More cost effective for Virtual Attendees

22 & 23 March 2021