

9th
Edition

POST EVENT REPORT 2024

GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT

22- 23 April 2024



24- 25 April 2024



26 April 2024



24- 25 April 2024

GCC REGULATORY
2024 AFFAIRS PHARMA
SUMMIT | DUBAI

22nd - 26th April 2024
Mövenpick Grand Al Bustan - Dubai, UAE

   @GCCPharma

#GCCRegulatoryAffairsPharmaSummit

www.pramagcc.com



22nd - 26th April 2024

#GCCRegulatoryAffairsPharmaSummit

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PRA
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hubplus
events



FOUNDERS' MESSAGE

We are delighted to extend our heartfelt gratitude to everyone who contributed to the success of the **9th edition of the GCC Regulatory Affairs Pharma Summit**. It was a remarkable event that brought together a diverse group of industry leaders, regulatory experts, and innovators dedicated to advancing pharmaceutical regulatory practices in the GCC region.

This year, we achieved several key outcomes that will have a lasting impact on our industry:

- **Enhanced Collaboration:** The summit served as a vital platform for fostering connections among regulatory authorities, pharmaceutical companies, and healthcare professionals. These collaborations are essential for promoting a unified approach to compliance and innovation.
- **Knowledge Sharing:** Through engaging sessions and workshops, participants gained insights into the latest regulatory updates, best practices, and emerging trends. We believe this knowledge equips all stakeholders to navigate the evolving regulatory landscape more effectively.
- **Strategic Partnerships:** We witnessed the formation of strategic alliances aimed at streamlining regulatory processes and enhancing patient safety. This reflects our collective commitment to improving healthcare outcomes across the region.
- **Commitment to Excellence:** The enthusiastic participation and feedback we received reaffirm our mission to advance regulatory affairs and ensure a sustainable future for the pharmaceutical industry in the GCC.

Thank you once again to all participants, speakers, and partners for making this summit a resounding success. Together, we are shaping the future of pharmaceutical regulation and paving the way for a healthier tomorrow.

Dr. Najiba Al-Shezawy
Co-Chairman
GCC Regulatory Affairs Pharma
Summit

Dr. Mona Al Moussli
Chairman
GCC Regulatory Affairs Pharma
Summit

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OUR VISION

GCC Regulatory Affairs Pharma Summit identified a pressing need to enhance communication between Regulatory Authorities and the Pharma Industry back in 2015.

To address this, they established a platform where these two entities could converge and discuss emerging regulations within the pharmaceutical sector. With the backing of the Ministry of Health UAE, this initiative gave rise to the annual GCC Regulatory Affairs Pharma Summit, a pivotal event for GCC Countries and their neighbors.

This summit serves as a nexus for all regulatory bodies, fostering transparency and harmonizing regulations across the region. Leveraging the UAE government's shift towards digital application processes, the summit effectively communicates these advancements to industry stakeholders. Moreover, it provides an avenue for GCC Countries to collaborate and enhance their regulatory frameworks through shared knowledge and discourse, thus streamlining regulations in the GCC Pharma sector.

As the region experiences exponential growth, the summit has evolved into a premier platform for pharmaceutical companies to stay abreast of regulatory updates and navigate the GCC market safely. The transition to virtual hosting in 2020, amidst the pandemic, demonstrated adaptability, with a notable 29% increase in online attendance in 2021. Subsequent years saw a remarkable 20% and 33% growth in onsite participation, respectively.

The 2023 summit, themed "Navigate Pharma Regulations with Ease & Amplify Commercial Success," introduced discussions on digitization, innovation, intellectual property protection, and patient-centric approaches. Through engaging sessions, panel discussions, and round tables over five days, the event propelled innovation within the industry.



Reflecting on a nine-year journey marked by continuous growth and acclaim, the 2023 GCC Regulatory Affairs Pharma Summit provided a unique opportunity for industry peers to convene face-to-face, fostering collaboration and facilitating new business ventures. Participants from the pharmaceutical and healthcare sectors seized the chance to develop, connect, and collectively advance the region's pharmaceutical regulations, ensuring safer medication for the people of the GCC.



KEY FACTS:

ATTENDEES

650

SPEAKERS

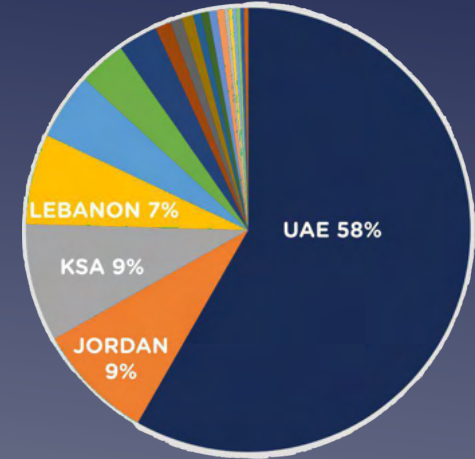
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COUNTRIES

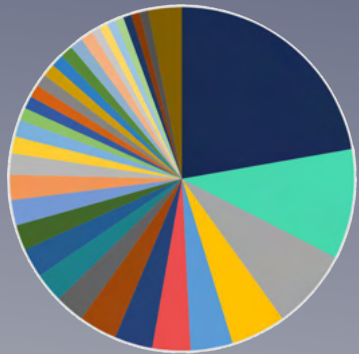
20

SPONSORS

19

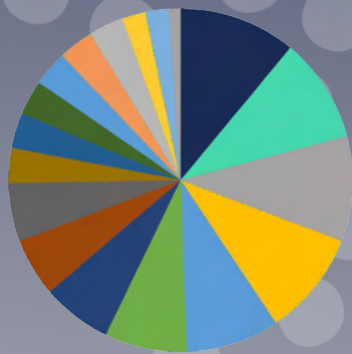


Regulatory Affairs Pharma Summit



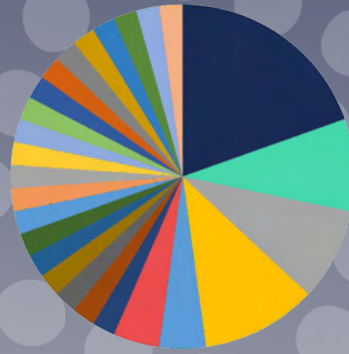
- RA Manager 22%
- RA Specialist 10%
- RA Director 8%
- Snr RA Manager 5%
- RA Supervisor 5%
- Head of RA and PV 4%
- RA Officer 4%
- Snr RA Associates 4%
- CEO 3%
- RA Executives 3%

Pharmacovigilance Training



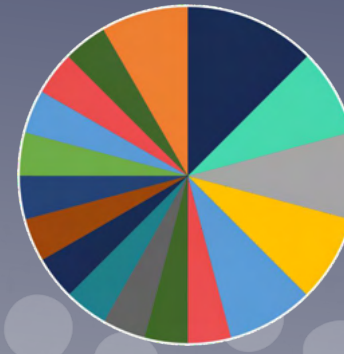
- RA Manager 11%
- Pharmacist in Charge/QPPV 10%
- Patient Safety Lead 10%
- PV Manager 10%
- PV Officer 9%
- Snr PV Specialist 8%
- RA Other 7%
- RA and PV Manager 5%
- PV Director 5%
- CEO 3%

Medical Tender and Business Talk



- Market Access & Tender Manager
- Business Development Manager
- CEO
- Director of Market Access, Regulatory & GovAffairs
- Regulatory Affairs
- VP Business Development & Partnerships
- Business Coordinator
- Commercial & Tenders Associate
- Commercial Excellence Lead
- Customer Operations Leader

Quality Conference



- Commercial Quality Officer
- Commercial Quality Senior Manager
- Government Affairs Director
- PHARMACIST
- Project Manager
- Quality & Technical Projects Manager
- Quality Lead
- RA Manager/QA Back up
- Regional Commercial Quality Lead
- Regional Commercial Quality Manager

- UAE 58%
- Jordan 9%
- KSA 9%
- Lebanon 7%
- Kuwait 5%
- Egypt 3%
- Iraq 3%
- Sudan 1%
- UK 1%
- Oman 1%
- Australia 1%
- Brazil
- Tunisia
- Turkey
- Bahrain
- France
- Kenya
- Portugal
- Switzerland
- USA

PARTICIPANTS 2024





Lobby & Networking



GCC Regulatory Affairs Pharma Summit

Over two dynamic days, the GCC Regulatory Affairs Pharma Summit 2024 convened key stakeholders from Regulatory Authorities and the Pharma Industry to explore crucial topics shaping the pharmaceutical landscape. The summit delved into emerging regulatory trends, and NRA Updates from Qatar, Oman, and Bahrain from the GCC region and invited Regulatory Authorities from Egypt, Jordan, Iraq, and Algeria. Discussions centered on Pharma Manufacturing, Biosimilars, Orphan Drugs, OTC Drugs, Regulatory Reliance, EPI, Ai influence, Data Governance & Track and Trace Serialization.



Governmental Authorities Round Table Discussions

During a series of engaging roundtable discussions over two days, representatives from National Regulatory Authorities (NRAs) in **Oman, Qatar, Bahrain, Jordan, Algeria, Egypt, and Iraq** convened at the GCC Regulatory Affairs Pharma Summit 2024. Heading each country's roundtable, the NRAs were exchanging insights with the attendees over the two days of the summit, on regional regulatory challenges and opportunities, emphasizing the importance of alignment and cooperation to streamline regulations across borders.



GCC Pharmacovigilance Training

The GCC Pharmacovigilance Training in 2024 aimed to equip the attended industry professionals across the Gulf Cooperation Council (GCC) region with the necessary skills and knowledge to monitor and evaluate the safety of pharmaceutical products, as it featured NRA updates from Kuwait & man, and invited regulatory bodies from Egypt, Jordan and Algeria.

Through interactive workshops, and on-the-spot team-lead activities, participants delved into pharmacovigilance principles, regulatory frameworks, and discussed latest trends' influences on the industry such as Ai. The training emphasized collaboration among pharmacovigilance and regulatory stakeholders to enhance drug safety and ensure the well-being of patients in the GCC countries.





Medical Tender & Business Talk

The Two-enriched days of Medical Tender and Business Talk 2024 encapsulated the event's core outcomes of highlighting key insights from industry stakeholders as well as national procurement agencies. The conference reflected fostering partnerships, identifying business opportunities, nurturing networking connections, and outlining actionable next steps in the tendering healthcare scope. Attendees gained valuable insights into the tendering advancements, discussed potential collaborations, and explored emerging trends in healthcare.

The event served as a platform for forging new partnerships, discovering business prospects, and solidifying industry relationships.





GCC Quality Conference

The GCC Quality Conference served as a pivotal platform in 2024 for fostering excellence and innovation in healthcare across the Gulf Cooperation Council (GCC) region. Through dynamic keynote speeches, interactive presentations, and insightful panel discussions, the conference convened quality professionals, and industry experts to exchange ideas and best practices in quality.

With a focus on patient-centric care, quality assurance, and continuous improvement, the conference underscored the commitment of GCC countries to elevate healthcare standards and enhance patient outcomes in the region.





GCC eCTD Training

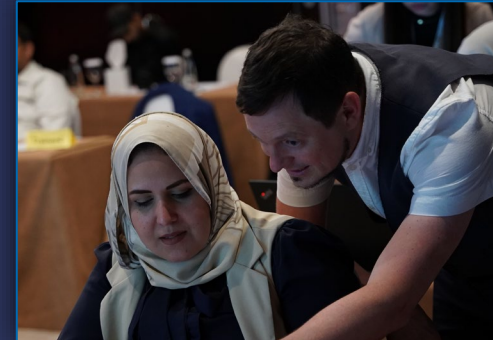
The GCC eCTD Training, held as part of the GCC Regulatory Affairs Pharma Summit 2024, was a significant event dedicated to advancing regulatory affairs expertise across the Gulf Cooperation Council (GCC) region. Sponsored by EXTEDO, this one-day workshop provided participants with comprehensive training on the electronic Common Technical Document (eCTD) format, a crucial aspect of pharmaceutical submissions.



Through detailed presentations, practical exercises, and expert-led discussions, the workshop equipped regulatory professionals with the knowledge and skills needed to navigate eCTD requirements effectively.



The training workshop highlighted the importance of accurate and efficient regulatory submissions in ensuring timely access to safe and effective medications, reinforcing the GCC's commitment to maintaining high standards in pharmaceutical regulations.

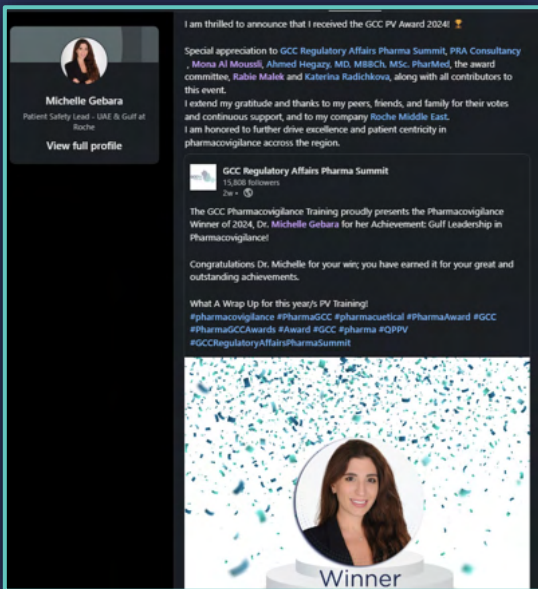
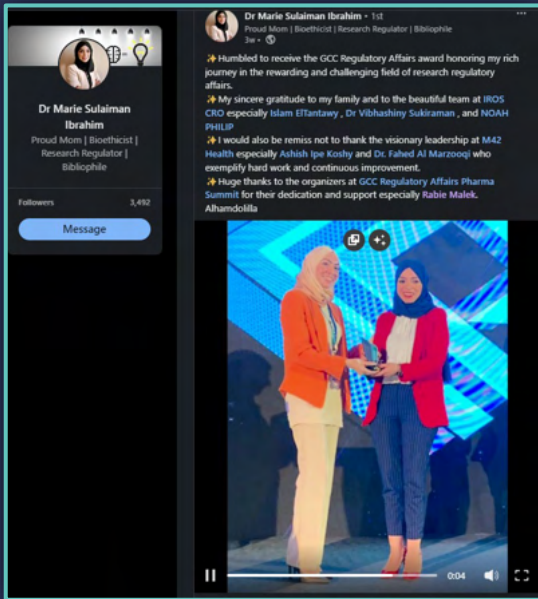


GCC Pharma Summit 2024 Award Winners:

Regulatory Affairs Winner



Pharmacovigilance Winner



Our Sponsors & Partners

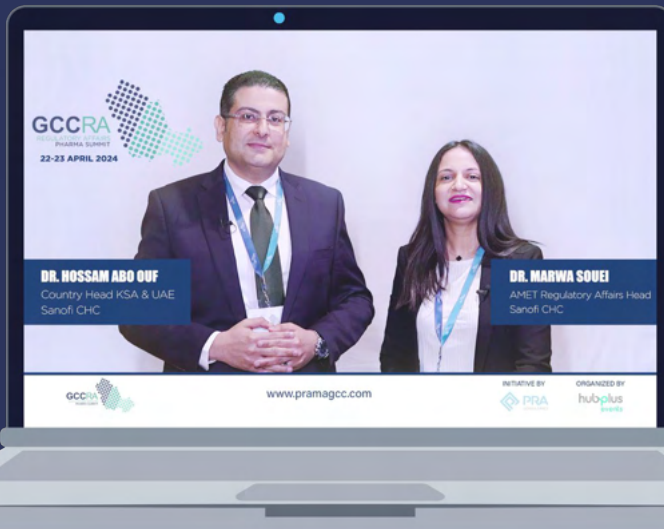
The 9th edition of the GCC Regulatory Affairs Pharma summit owes much of its success to the unwavering support and collaboration of our esteemed partners and sponsors. This premier event offered sponsors a unique platform to showcase their expertise and solutions to attendees hailing from various corners of the pharmaceutical landscape. Throughout the summit, our sponsors actively engaged in diverse activities, including delivering speeches, participating in panel discussions, and presenting their offerings at booths strategically placed in the pre-event lobby area. These engagements facilitated meaningful interactions with attendees, fostering relationships and catalyzing business development endeavors. We extend our heartfelt gratitude to all sponsors for their invaluable support and active participation, which significantly contributed to the resounding success of the 9th edition. As we look to the future, we eagerly anticipate further collaboration with our esteemed sponsors, steadfast in our commitment to cultivating an environment conducive to collaborative dialogue, knowledge sharing, and the advancement of regulatory processes and innovation within the pharmaceutical sector.



Principal Sponsor



Sanofi showcased its commitment to regulatory excellence by presenting innovative approaches to compliance and discussing the latest advancements in pharmaceutical research and development during the GCC Regulatory Affairs Pharma Summit, GCC Pharmacovigilance Training and the Medical Tender & Business Talk. Sanofi's representative team's presence and participation was highly valuable, in each session they were a part of during the four events.



Platinum Sponsor



Takeda highlighted its dedication to regulatory compliance by sharing innovative strategies and insights into pharmaceutical research and development advancements at the GCC Regulatory Affairs Pharma Summit as well as in the GCC Pharmacovigilance Training. Their team's active participation and valuable contributions enhanced discussions across various sessions during the event.



Honeywell

Honeywell provided invaluable expertise at the GCC Regulatory Affairs Pharma Summit and the GCC Quality Conference. Their presentations and discussions enriched the knowledge exchange among participants. In addition to them being present on stage, they were also actively involved in networking with all attendees at their table-top exhibition space.



Gold Sponsors



VISIOTT Traceable Packaging Solutions hosted informative take on the Track and Trace session showcased comprehensive solutions for regulatory advancement at the GCC Regulatory Affairs Pharma Summit. Their team's involvement in various discussions and workshops during the summit contributed to a deeper understanding of regulatory challenges and optimization strategies in the pharmaceutical sector. VISIOTT's dynamic team was always present in the exhibition space at their booth to network with attendees at the summit.

Gold Sponsors



Schlafender Hase demonstrated its expertise in regulatory affairs by being an integral part of the Regulatory Digitization: EPI session at the GCC Regulatory Affairs Pharma Summit. The team provided attendees with practical knowledge about Schlafender's background and expertise, during the networking slots at their exhibition space



Abbott participated actively in discussion on Regulatory Reliance at the GCC Regulatory Affairs Pharma Summit 2024. The presented insights provided during the session left attendees with an impactful touch of knowledge, which was carried on by meeting Abbott's representatives during the networking time at their exhibition space.



ACG showcased its advanced manufacturing solutions designed to meet regulatory requirements at the GCC Regulatory Affairs Pharma Summit in the Track and Trace session. Through demonstrations and presentations, they highlighted how their machinery and services contribute to compliance and efficiency in pharmaceutical production, enhancing the summit's focus on regulatory excellence. ACG's team was highly-active with delegates that came to meet them and get to know them at their table-top exhibition space.



Silver Sponsors

hikma.

IPSEN



tabuk
pharmaceuticals

Julphar

الخليج للصناعات الدوائية
Gulf Pharmaceutical Industries



Associate Sponsors



Strategic Partner



PRA Consultancy is honored to have participated as the **Strategic Partner** at the **GCC Regulatory Affairs Pharma Summit 2024**. This prestigious event brought together leading regulatory experts, industry professionals, and key stakeholders to address critical developments and opportunities shaping the pharmaceutical sector in the GCC.

As a Strategic Partner, PRA Consultancy actively contributed to the Summit's success by engaging in meaningful discussions, participating in networking opportunities, and sharing insights during stage sessions. Their presence underscored a commitment to fostering collaboration, driving regulatory excellence, and supporting innovation in the pharmaceutical industry.

We extend our appreciation to the organizers and all participants for delivering such a valuable and impactful event. PRA Consultancy remains committed to contributing to the region's regulatory advancements and looks forward to future collaborations that further strengthen the pharmaceutical landscape.



GCC Quality Conference Sponsors

Gold Sponsors:



Silver Sponsor:



Opening the GCC Quality Conference together, the GCC Quality sponsors, shared the objectives of this year's first ever GCC Quality Conference with a focus on the Commercial Aspect of Quality. The Gold sponsors for this year were AbbVie and Takeda, and the Silver sponsor for the conference was Bayer.



Marketing the GCC Pharma Summit

Website:

<https://pramagcc.com/>

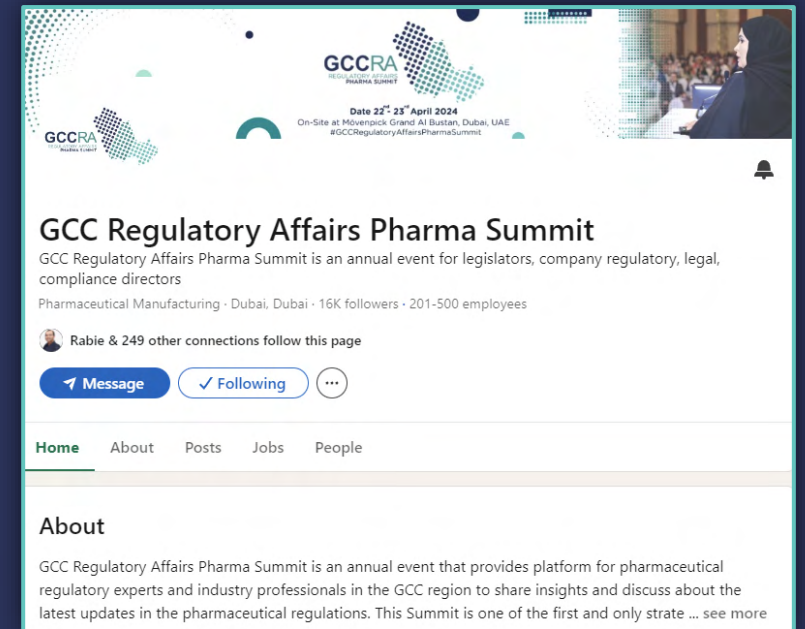


Social Media:

 <http://www.linkedin.com/gccpharma>

 <http://www.twitter.com/gccpharma>

 <http://www.facebook.com/gccpharma>



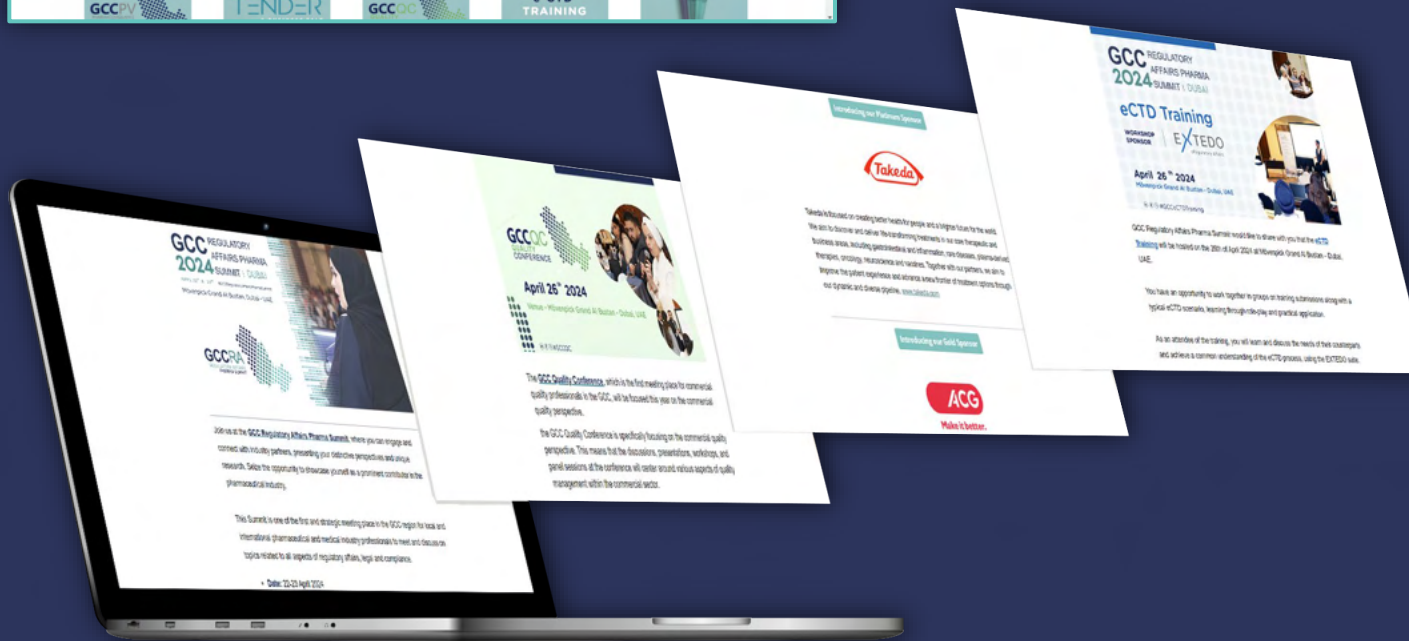
Email Campaigns

Database

15,000+ Subscribers

Top Regions

UAE, Bahrain, Qatar, Kuwait, Iraq, Jordan, Egypt, Algeria, Turkey



Social Media Shares & Mentions

Monica Foyez - 1st
Regulatory Affairs & Pharmacovigilance Manager at Pharmovigilance, Bach...
It was a pleasure attending this year's GCC Regulatory Affairs Pharma Summit and Pharmacovigilance Training.
This was an enriching experience. It provided an excellent opportunity to stay abreast of industry updates, meet with old colleagues, and connect with new partners.
Thanks PRA Consultancy and Hubplus Events.
#GCCRegulatoryAffairsPharmaSummit #PharmacovigilanceTraining2024

TOPRA - The Organisation for Professionals in R...
37,466 followers
After a great first day at the 9th GCC Regulatory Affairs Pharma Summit #2024 in #Dubai (UAE), day 2 is now fully underway. Our Chief Executive Kevin P. and Head of #Membership Jitesh Mishra are enjoying making new contacts and extending the #TOPRA network in the region.
This summit is a pioneering platform in the region, uniting government representatives, industry leaders, and solution providers to delve into the latest #Regulations shaping the #pharmaceutical landscape. Thank you Dr Mona AJ Mousall, Dr. Najiba Al Shezawy and the #GCC #Pharma #Summit team for allowing us to be a part of it.
Find out more <https://hbk.in/dg/vh0zq>
Joining Samira and 18 others
1 comment · 2 reposts

Yusra Farid - 1st
Regulatory Affairs / Quality Assurance Director & Strategic Project Lead...
It was a great opportunity to drive important discussions around IA Reliance at the GCC Summit, along with engaging with regulators & industry leaders from different countries. Thanks GCC Regulatory Affairs Pharma Summit for always creating new opportunities to support exchanging insights & shaping the future of regulation!

ACS World
142,615 followers
ACS is currently participating in the GCC Regulatory Affairs Pharma Summit, Dubai UAE. Day 1 saw Mr. Shiva Vijayan take part in an insightful session on Regulatory Digitization: Track and Trace Serialization.
This Summit serves as a strategic meeting place in the GCC region for both local and international pharmaceutical and medical industry professionals to convene and engage in discussions on various topics related to regulatory affairs, legal matters, and compliance. See you on Day 2 today!
#makeitbetter #pharmaregulatory #trackandtrace #pharmaregulation

Gilbert Daher - 1st
Regulatory Affairs-GDD Senior Labeling Associate at Novartis Fund
1w · Edited ·
GCC Regulatory Affairs Pharma Summit
Glad to attend this yearly summit.
Great topics, discussions and presentations about the future of RA in the region.
Most importantly, was glad to reunite with my fellow RA colleagues from around the GCC. Jafar Al Shadi Amani Daher Joumana Jaber Synthia Abi Nakhoul Céline Abboud Jomana Mehdi Diana Zaarour Stephanie Saade Amjad Zaid Abdalla Quider Nivine Jaroudi

Rania Haggag - 1st
Pharmacovigilance Lead at Organon & Co.
I am thrilled to have had the opportunity to present at the GCC Pharmacovigilance Summit today, where I shared my insights and innovative solutions to bridge the Pharmaceutical industry faces in regulatory intelligence monitoring.
It was truly exhilarating to engage with regulatory experts and industry professionals from the GCC region and shed light on the importance of...
#CPVTraining #GCCPharmacovigilanceTraining #safetysummit #regulatoryintelligence #reforherhealth

Hussein Aboulazm - Following
Senior Regional Medical Training Manager ME @ Ego Pharma | CIPD Lea...
I'm honored to have been part of the GCC Regulatory Affairs Pharma Summit 2024 which is a hub of knowledge and networking.
During the summit, I had the exceptional opportunity to engage with Pharmacovigilance Officials from different esteemed authorities.
Moreover, I had the privilege of engaging with Industry Leaders from many esteemed Multinational Companies. The exchange of knowledge and experiences during the event has truly been enriching and will undoubtedly pave the way for advancements in this field.
#Pharmacovigilance #RegulatoryAffairs #GrowthOpportunities

Ayman Ismail - 1st
GCC Quality Executive (Gulf, Near East, & Saudi Arabia) at Haleson
I am glad that I had the opportunity to participate as a speaker in the GCC Quality Conference 2024 in Dubai through the GCC Regulatory Affairs Pharma Summit.
I am thrilled to represent Haleson through presenting and sharing insights about factors affecting Distribution Quality and Management of Excursions Handling through logistic cycles of pharmaceutical products.
Thanks to everyone who managed to organize such a great event for learning and sharing experiences. Looking forward to more similar events and opportunities.
#GCCQC #Healthcare #QualityAssurance #Pharmaceutical #UAE #GCCQualityConference

Sara Chalho - 1st
Regulatory & PV Manager at Biologix, MENA Region, MBA, Pharmacist
I was truly honoured to have the opportunity to participate as a speaker and share my insights on the Regulatory Landscape in Saudi Arabia during the 9th GCC Regulatory Affairs Pharma Summit on 22 April 2024.
The session covered several topics shedding light on the multiple registration pathways for NCEs and Biologics, the mechanisms and policy opportunities, the eligibility criteria for each framework, and ending the session with thought-provoking suggestions about new policy opportunities that will ensure a promising way forward.
I was thrilled to represent Biologix in this annual event that brings together regulatory professionals, regulatory authority representatives, regional distributors, multinational and regional pharmaceutical companies, and industry experts with discussions centered on advancing the regulatory standards and sharing best practices to better serve the medicines availability in sustainable manner to the patients in need.
Pleased to join my hand in such a dignified commitment to drive positive change. Thanks to the organizers of the event and Hubplus Events, and Congratulate

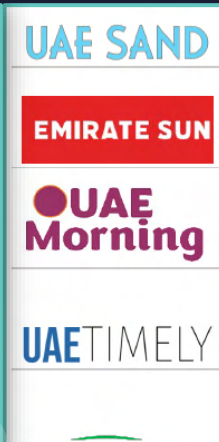
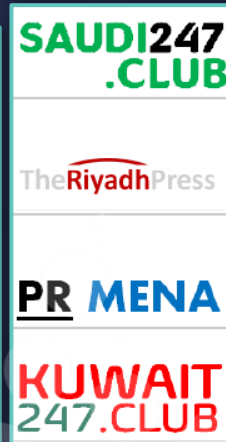
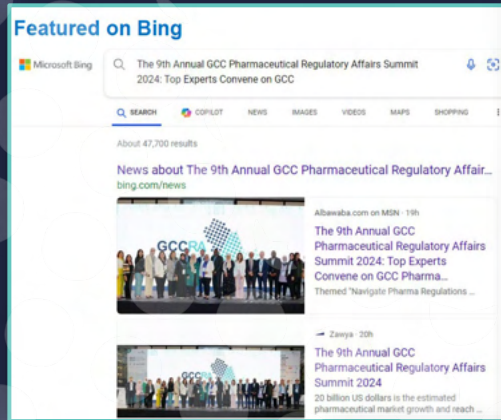
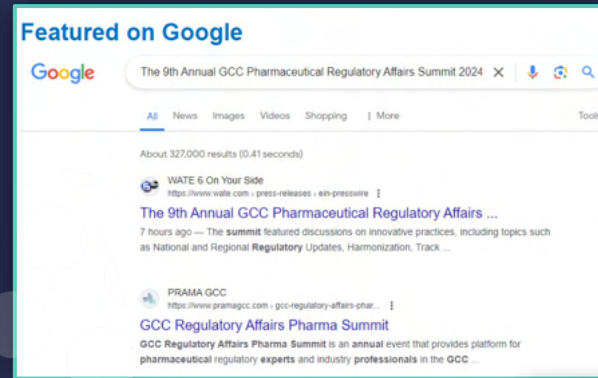
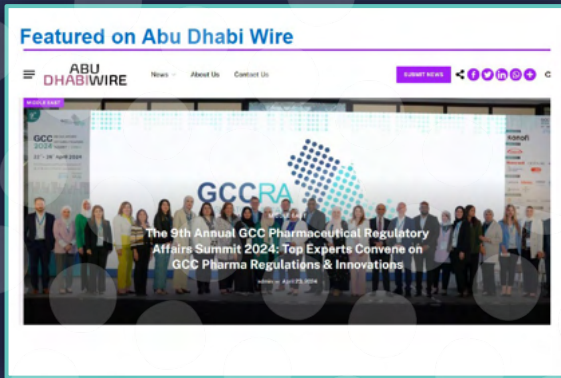
State Of Practices Consultancy Center (SOP)
888 followers
We extend our heartfelt gratitude to the organizers of the GCC Regulatory Affairs Pharma Summit 2024, GCC Pharmacovigilance Training 2024, and GCC Quality Conference 2024!
It was an honor to participate in this prestigious event and contribute to three insightful sessions. Our team gained valuable experience, connected with industry experts, and expanded our network, making the summit an incredibly successful and enriching experience.
A big thank you to everyone involved in making this event possible! Looking forward to future collaborations and continued growth in the regulatory affairs, Pharmacovigilance and quality.
#sopconsultancycenter #PharmacovigilanceCareer #pharmacovigilance #regulatoryaffairs #training #auditing

Elaf Abd - 2nd
Regulatory Affairs Manager, MENA region, at EVER Pharma
I had the pleasure of meeting brilliant minds and exchanging ideas at the GCC Regulatory Affairs Pharma Summit

Schlafender Hase
2,268 followers
We made it to Dubai!
Despite the record breaking rainfall Dubai received last week, the GCC Regulatory Affairs Summit hosted by Hubplus Events is in full swing.
Come say hi to Katarina Kresanikova and Monia Toumi!
I'm grateful for the opportunity to attend the GCC Regulatory Affairs Pharma Summit this year in Dubai with regulatory and cross-functional colleagues. The summit provided an excellent opportunity to discuss important topics and engage in fruitful discussions, with strong representation from various agencies, pharmaceutical companies, and other regulatory professionals within the region.

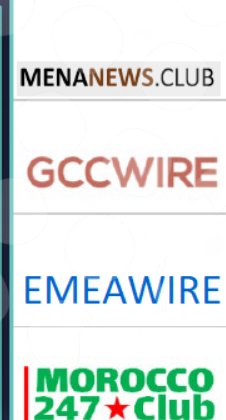
Regulatory Digitization: EPI
SESSION HIGHLIGHTS
Regulatory Digitization: EPI, moderated by Dr. Lamis Yousef from Pfizer, with Dr. Shatha Safi from Hikma Pharmaceuticals and Ms. Katarina Kresanikova from Schlafender Hase, along with the panelist from Jordan Food and Drug Administration الأستاذة الدكتورة رانيا محمد الربيعي, Mr. Mohammad Rabi.
Stay tuned for more updates!
In the meantime, check out the website for more insights and information: www.pramagcc.com
#regulatoryaffairs #pharmaceutical #GCCRegulatoryAffairsPharmaSummit #UAE #Healthcare #RA #GCCRegion #GCC #Pharma #Pharmaceutical #PharmacovigilanceIndustry

Certificate of Appreciation
"In Grateful Recognition of Your Valuable Support and Participation"
The Organizing Committee of the 9th GCC Regulatory Affairs Pharma Summit hereby extends its sincerest gratitude to...
GCC REGULATORY AFFAIRS PHARMA SUMMIT
Dubai - UAE
22 - 26 April 2024
Organized by PRA hubplus



PR & Mentions

The above press release about the GCC Regulatory Affairs Pharma Summit 2024, was distributed tp media in the GCC/ MENA including news sites, blogs and indexed by major search engines, with over 245 media outlets that published news release.





IN CONCLUSION

The 9th GCC Regulatory Affairs Pharma Summit has been an extraordinary success, marked by an impressive turnout and the active participation of National Regulatory Authorities (NRAs) from not just the GCC region, but also from across the broader Middle East.

Over the course of the week-long event, we were thrilled to witness the high level of engagement from attendees through meaningful networking opportunities, thought-provoking discussions, and interactive sessions that kept everyone captivated and informed.

Our incredible sponsors, brought knowledge, solutions, and support in all these aspects, together with our expert industry speakers, that had open discussions about the challenges and possible solutions with each other and the Regulators, forging continuous partnerships between the NRA's and Pharma Industry.

The overwhelming response has reinforced the importance of this platform as a space for collaboration, innovation, and regulatory advancements in the pharmaceutical sector.

As we wrap up this milestone 9th edition, we are already setting our sights on the future and are excited to announce that preparations are underway for the 10th edition, slated for 2025.

We look forward to building on the success of this year's summit and continuing to provide an environment where key stakeholders can come together to shape the future of pharmaceutical regulation in the region.

Event Management
HubPlus Events

