



Under the Patronage of



ACRAS

Aesthetic & Cosmetic Regulatory Affairs
SUMMIT MIDDLE EAST 2022

8 & 9 NOVEMBER

Venue: Marriott Hotel, Al Jaddaf, Dubai



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WELCOME TO...

ACRAS is an annual event that provides platform for aesthetics cosmetics and medical device regulatory experts and industry professionals in the Middle East region to share insights and discuss about the latest regulatory updates.

This Summit is one of the first and strategic meeting place in the Middle East region for local and international aesthetics, cosmetics and medical industry professionals to meet and discuss on topics related to all aspects of regulatory affairs, legal and compliance.

ACRAS is an excellent platform for companies within the designated fields to further profile their brand in the region.

Over the course of two days, 30+ speakers will analyze and discuss the important factors affecting the aesthetics, cosmetics and medical device regulatory markets.

A gathering of 150+ international and local experts and professionals

will come together to network and share knowledge on the specifics and initiatives in regulatory affairs in the Middle East region.

Regulatory Affairs in the cosmetics, aesthetics and medical device industries, serves as the interface between the regulatory authority and the project team, and is the channel of communication with the regulatory authority as the project proceeds, aiming to ensure that the project plan correctly anticipates what the regulatory authority will require before approving the product.

It is the responsibility of Regulatory Affairs to keep abreast of current legislation, guidelines, and other regulatory intelligence.

The Regulatory Affairs department plays an important role in giving advice to the project team on how best to interpret the rules, which is why ACRAS, the Aesthetics and Cosmetics Regulatory Affairs Summit was founded to unite and connect industry leaders and governmental entities under the aim to innovate and update all stakeholders about regulations in the aesthetics, cosmetics and medical device sectors.

Healthcare Regulations **Expert in Middle East**

Agency Representation

Pharmacovigilance

Regulatory Affairs

Market Access



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Compliance (GxP)

Our Mission is YOUR Success!



Dr. Mona Al Mousli

Founding Letter



“It is essential to begin every day with gratitude, and it is far more important this year than ever.”

The last 2 years showed me how fortunate I am to work with a team that refuses to give anything less than 110%. Even in the darkest days and struggles of the pandemic, PRA Consultancy team rallied beside each other for the sake of our clients and to maintain excellence, where we guided our clients through some of their toughest decision-making situations to date as well as aiding and assisting them to find the impossible answers, solutions and clarity when little else made sense at that time.

With today's ever-changing laws and regulations, regulatory affairs expertise will begin to face some new challenges in 2022 while battling old ones simultaneously.

I cannot emphasize enough the importance and significance of staying up to date on emerging trends within the industry's regulations and the ongoing changes in law.

To all the regulatory affairs experts, you are playing an essential role in overcoming those challenges to plan the lifecycle of product and ensuring the maintenance of productivity and efficiency.

From conception and development to approvals and launches; each stage of the commercialization process in areas ranging from clinical data collection to

capturing and reporting adverse events includes your presence, expertise, and supervision.

That is why we ensure to host ACRAS, the Aesthetics & Cosmetics Regulatory Affairs Summit, annually and we are here, this year, on-site to assist you to understand and discuss the overall Regulatory landscape, Challenges and help you cope with the updates that are yet to be introduced in the cosmetics, aesthetics and medical device fields.

Over the upcoming 2 days, my aim is to have all the attendees build-on their various opportunities provided at this year's summit of learning, sharing, networking, and exploring.

In our unity in action and vision, we are stronger.

Thank you to all the governmental authorities and experts who have supported the cosmetics, aesthetics and medical device industries in the Middle East region.

On behalf of all of us at PRA Consultancy, we wish all the attendees an insightful, interactive and enjoyable time, full of knowledge with many new successful stories, during this year's Aesthetics & Cosmetics Regulatory Affairs Summit.

Sincerely,
Dr. Mona Al Mousli
Co-Founder and Managing Director of PRA Consultancy

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Dr. Najiba Al Shezawy

Founding Letter **hubplus**

With multiple years of dynamic industry experience under our belt, Hubplus Events offers unique, impactful, and engaging solutions that transform your events into unforgettable and cherished experiences.

As a progressive event's company, we've served thousands of corporate and official clients with our successful event management and production across the Middle East.

Our mission is to elevate the standards of innovative event management to deliver experiential events that engage and enthrall the target audience. As a leading event management company, our value and continuous commitment to our profession drive us to achieve excellence and surpass the expectations of our clients. For us, 'you' are at the heart of our services.

Our aim is to become the world-recognized event management company that offers robust, customized, and innovative solutions. By combining strategy, creative thinking and technical skills, we strive to catalyze industry development and surpass client expectations for each event we handle.

As an established and independent event management company, we work as your partner to transform your concept into innovative solutions that have maximum impact on your target audience. Our passionate and dedicated team of unique experts and personalities envisions and creates events according to your precise requirements with a focus on the accomplishment of your goals.

At Hubplus Events, we offer one-stop solutions for all your corporate and official event management needs.

From events management to promotion and production, we provide you with uniquely designed solutions that leave lasting impressions on your audience. We are a client-centric company that attains your vision through our in-depth industry knowledge, creativity, and expertise.

As the official organizers for the Aesthetics & Cosmetics Regulatory Affairs Summit - ACRAS, we've insured to upscale the delivery of managing, planning, and executing each edition to the high scale that this summit deserves.

Our creative and hardworking events' creatives and executers have combined their expertise and talents to produce the ACRAS and there is no doubt at all that each year, ACRAS will have its requirements fulfilled with an exceeding scale of professionalism and creativity.

This year, we ensured that the event planning for the summit will be memorable and focused on all the attendees and participants across the Middle East with the conceptualization and the execution.

As my final statement: "It takes a creative mindset, punctuality, precision and creativity to make an event come to life".



Dr. Mohamed Bahram Hamad

Regulatory Affairs Summit (ACRAS) & CEO of MidWell Middle East

I'm truly grateful for the opportunity to take part of the ACRAS, the Aesthetic & Cosmetic Regulatory Affairs Summit (ACRAS) of 2022 in its live event in Dubai - UAE, and under the patronage of Jordan Food and Drug Administration.

We are very fortunate this year to have the support of our partners and sponsors this year, and to the organizers that made ACRAS come to life this year.

Maybe some of you are asking why are we in ACRAS today?

Well because of Nefertiti, A global icon of beauty and power, born in the heart of ME, who inspired us to think about ACRAS: A summit which focuses on the latest Regulatory affairs in the Aesthetic, and Cosmetic industry.

There are an evidently high and fast demand needs to be regulated for both patients' safety and HCP satisfaction.

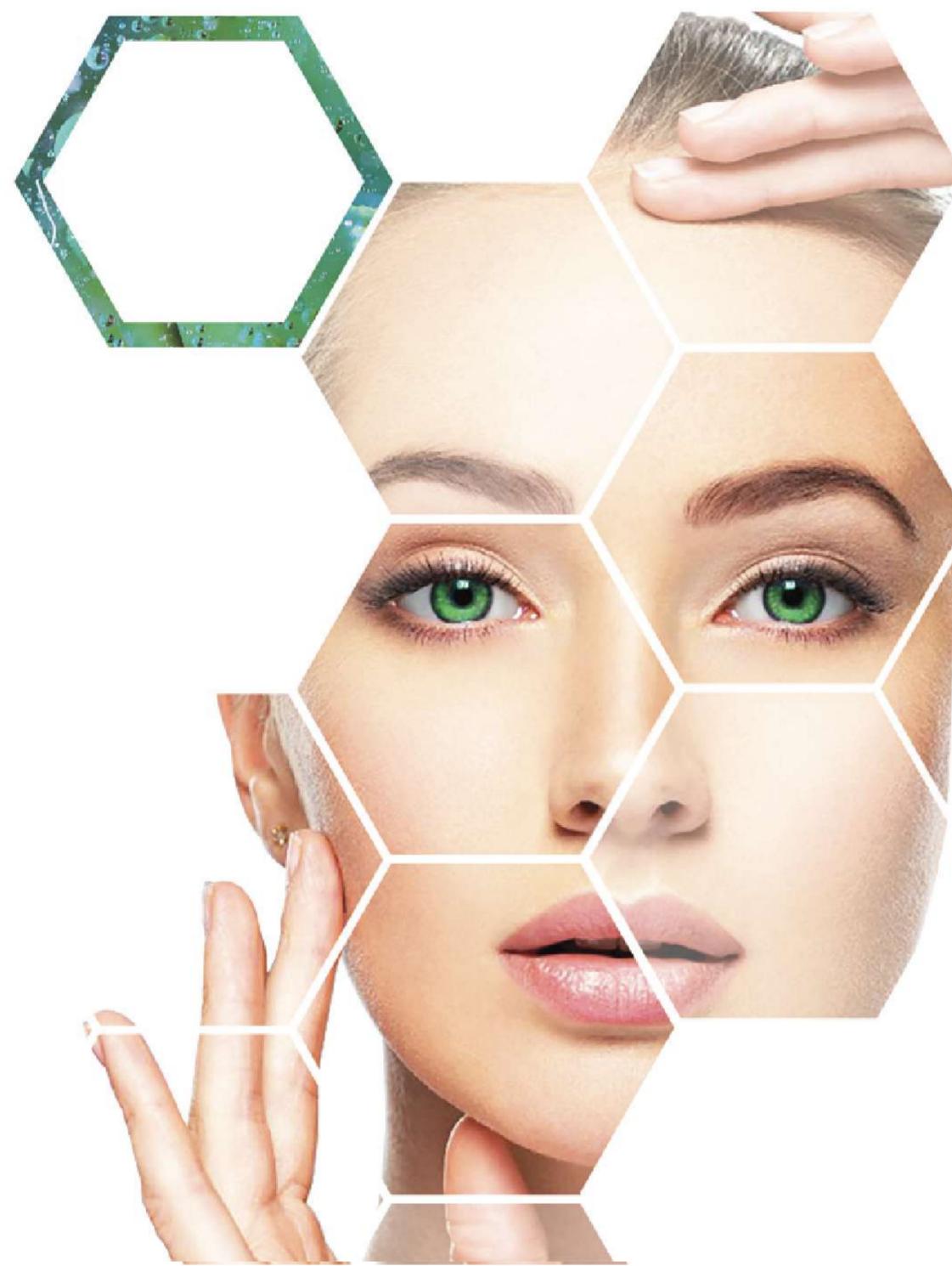
In this ACRAS 2022 summit, we'll host many sessions and panel discussions in different Regulatory topics, that will help each one of us to advance in skills we are interested in learning over the next 2 days. The noteworthy speakers, Key Authorities, Experts, and Industry players are going to provide an overview of the following 3 elements:

- The Evolving Aesthetic & Cosmetic segment in the Middle East, and it's Opportunities and Challenges
- New Aesthetic & Cosmetic related regulations and classification (cosmetics, Medical Devices, Medical Equipment and Toxin).
- Bridging the change in regulations with the same speed of the accelerating pace of Aesthetics & Cosmetic innovations.

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“Everything we do is finalized
to contribute to people’s
wellness and beauty”



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KEYNOTE SPEAKER

Professor Nizar N. Mhaidat

Director General of Jordan Food and
Drug Administration (JFDA)



Professor Mhaidat's professional profile includes him being the previous Head of the Government Procurement Department (GPD), and before that he was the Director General of General Supplies Department.

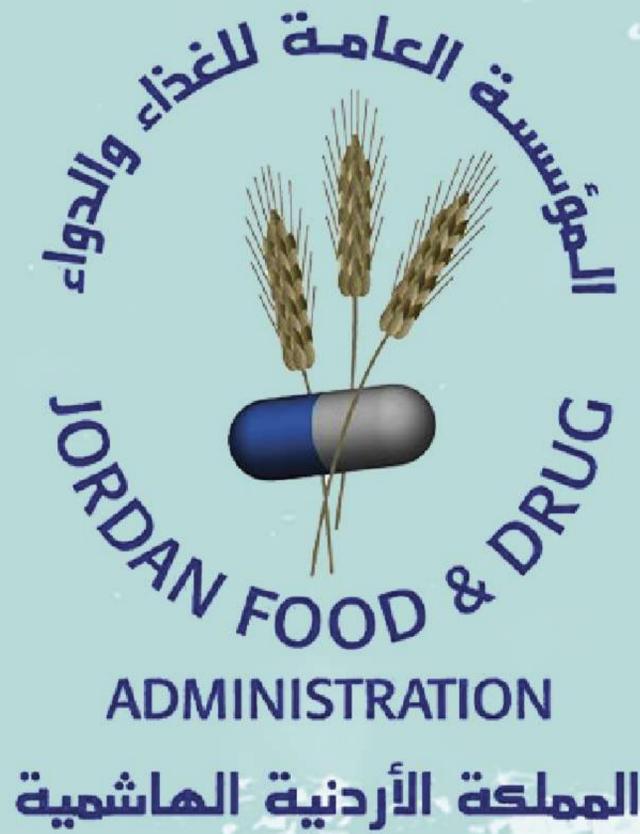
Adding to his professional career, he was also the Director General of Joint Procurement Department (JPD), and prior to that he was the Chairman of the Clinical Pharmacy Department at the Jordan University of Science & Technology (JUST).

As for Professor Nizar's educational background, he has the PhD Clinical Oncology & Immunology, 2006, Cancer Research Unit, Faculty of Medicine, The University of Newcastle, NSW, Australia.

He also holds a MS.c in Clinical Pharmacy, 2001, Faculty of Pharmacy, Jordan University of Science & Technology, Jordan & a BS.c in Pharmacy, 1998, Faculty of Pharmacy, Jordan University of Science & Technology, Jordan.



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Meet the JFDA Members



DR. SALEEM MOHAMMED
AL MAHROUQ



DR. ISHHAQ ABU HUESN



DR. SHATHA AL-QURAN



DR. RAND ZUHAIR FARRAJ



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8 & 9 NOVEMBER 2022

DAY 1: 8 November

9:00 - 9:15

Welcome to ACRAS

Presidents Foreword & Welcome

ACRAS Keynote Address

Dr. Mohamad Barham, ACRAS President

Prof. Nizar Mahmoud Mohsen Mhaidat, Director General,
Jordan Food and Drug Authority, JFDA

9:15- 11:15

Session 1: Medical Device Class Regulations

Overview of Medical Device Regulations in Jordan

Medical Aesthetic Devices Regulatory Updates, SFDA

New updates Registration Guidelines: Egypt

EU MDR Reclassification of Aesthetic Products

Panel discussion and Q&A - evolution of the regulations and registration pathways, key priorities & objectives

Moderated by: Samer El Sabban, Bausch Health

Dr. Shatha Al Quraan,
Head of Medical Devices Registration Dept, JFDA

Faisal A. Al Shehri,
Head of Medical Device Regulations and Standards Section
SFDA

Dr. Noha Al-Hariri,
General Director of Administration of Medical Device
Registration, EDA

Monir El Azzouzi,
CEO and Founder of Easy Medical Device

11:15 - 11:45 COFFEE and NETWORKING BREAK



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8 & 9 NOVEMBER 2022

DAY 1: 8 November

11:45 - 13:00

Session 2:

Aesthetics Future Trends and Patient Safety

Future trends and patient safety in facial aesthetics

Panel discussion: Patient Safety

Moderated by: Surobhi Chakravarty - Regenera Activa

Nazila Zoufaghari - NZI Aesthetic Consulting

Dr. Shatha Al Quraan, Noha Al-Hariri,
Faisal A. Al Shehri, Nazila Zoufaghari

13:00 - 14:00 - LUNCH and NETWORKING BREAK

14:00 - 15:00

Session 3: Vigilance

Aesthetic Vigilance

Materiovigilance EU changes

Panel and Q&A

Moderated by: Dr. Samah Ragab
RA and PV Lead for Middle East, Organon

Dr. Marian Anwar Benefit Risk & Therapeutic Area Lead,
Middle East & Africa

Monir El Azzouzi CEO Easy Medical Device



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8 & 9 NOVEMBER 2022

DAY 1: 8 November

15:30 - 16:00 - COFFEE and NETWORKING BREAK

16:00 - 17:00

Regulatory Round Table Discussions: Medical Device

- | | | |
|---------|----------------------|---|
| 1. JFDA | Dr. Shatha Al Quraan | Moderated by: Dr. Ahmed Razzouk, PRA Consultancy |
| 2. SFDA | Faisal A. Al Shehri | Moderated by: Lana Nabil - PRA Consultancy |
| 3. EDA | Noha Al-Hariri | Moderated by: Ayat Yousri / Aishvarya Apte- PRA Consultancy |

End of Day 1

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8 & 9 NOVEMBER 2022

DAY 2: 9 November

9:00 - 9:15

Morning Welcome

Dr. Mohamad Barham, ACRAS President

9:15- 10:00

Session 1: Classification of Cosmetic Product

Moderated by: Dr. Rima B. Nsheiwat, AMSA Netherlands

Borderline Cosmetics

Liliana Teles, Regulatory Affairs Manager, Critical Catalyst

Q&A and Discussion

10:00 - 10:45

Session 2: Patents

How to protect a beauty product? Patent Vs Trade Secret

Moderated by: Dr Ahmed Razzouk, PRA Consultancy

Fouad Darras, PhD, LL.M, Founder & CEO, Bara'a IP

10:00 - 11:15 - COFFEE and NETWORKING BREAK

11:15 - 13:30

Session 4: Non medicated Cosmetics

Moderated by: Tarek Hanoura,
Regulatory Affairs Manager, Palmolive/Colgate

Dubai Municipality Procedures for Registration
of Cosmetics Products

Hessa Jaffar Al Jawi , Acting Manager of Registration & Permits
Section, Health & Safety Department at Dubai Municipality

Non Medicated Cosmetics Regulatory
Requirements Bahrain

Dr. Husain Abdulaziz Jaafar, Head Of Consumer Products
Safety Group, Environmental Health Section, Bahrain MoH

Understanding the Registration Journey
of Cosmetics Products in Egypt

Dr. Heba Essam, General Manager General Administration of
Cosmetic Products Registration. Central Administration for
Pharmaceutical Products, Egyptian Drug Authority

Panel discussion and Q&A



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8 & 9 NOVEMBER 2022

DAY 2: 9 November

13:30 - 14:30 - LUNCH and NETWORKING BREAK

14:30 - 15:30

Session 4: Cosmoceuticals Regulation

Medicated Cosmetics Regulatory updates of Kuwait

Regulatory Requirements for Medicated Cosmetics Oman Health Products) Drug Control Department, Oman MoH

Panel Discussion

15:30 - 16:30

Session 5: Cosmetovigilance

Overview of the Importance of Vigilance in Cosmetics

Dr. Sali Daoud, Regulatory Affairs Specialist, ME, Africa & Turkey LVMH

Dr. Yusra Al Ajmi, Head of Materials & Cosmetics Dept, MoH Kuwait

Dr. Binu John, Senior Pharmacist, Drug & Food Control Dept, MoH Kuwait

Dr. Amani Al-Siyabi, Section Head (Reg. of Herbal Medicines and

Dr. Amani Al-Siyabi, Dr. Heba Essam

Iman Gad, Regional Regulatory Affairs, Local Drug Safety Unit Manager, Scientific Office Pharmacist in Charge, Menarini Group

Dr. Rima B. Nsheiwat, AMSA Netherlands



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8 & 9 NOVEMBER 2022

DAY 2: 9 November

16:30 COFFEE and NETWORKING simultaneously with Round Tables

16:30 – 17:00 – on demand

Round Table Discussions: Cosmetics

- | | | |
|-----------------------|-------------------------|---|
| 1. Dubai Municipality | Hessa Jaffar Al Jawi | Moderated by: Dr. Ahmed Razzouk, PRA Consultancy |
| 2. Bahrain MoH | Husain Abdulaziz Jaafar | Moderated by: Dr. Laila Saffaf - PRA Consultancy |
| 3. EDA | Dr. Heba Essam | Moderated by: Dr. Rima B. Nsheiwat, AMSA Netherlands |
| 4. Oman | Dr. Amani Al-Siyabi | Moderated by: Lana Nabil & Jenet Laxama - PRA Consultancy |

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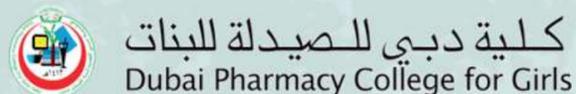
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10 NOVEMBER 2022

TRAINING DAY



Trainer: Ms. Abeer Awad,
Founder & GM
SIWAR Quality & Regulatory Consultation

**COSMETICS & AESTHETICS INDUSTRY TRAINING:
QUALITY AUDITING GUIDANCE PROGRAM**

9:00 - 13:00

09:00 - 09:15	Introduction of Trainer and Attendees
09:15 - 09:30	Training Objectives
09:30 - 10:30	Quality Management Principles
10:30 - 11:00	Coffee break
11:00 - 11:30	Structure of Quality Audit
11:30 - 12:00	The Audit Process
12:00 - 13:00	Interactive Session



Job titles attending ACRAS 2022

Head of Regulatory Affairs

Director- Regulatory Affairs

Regulatory Affairs Managers / Officers /
Executives / Coordinators

General Managers

Product Managers

Product Specialist

Market Access

Marketing Managers

Key Account managers

Government & Institutional Sales

Government Affairs

Business Owners

Distributors

Quality Assurance

Commercial Excellence

Supply Chain

Managing Directors

COO's





ACRAS

Aesthetic & Cosmetic Regulatory Affairs
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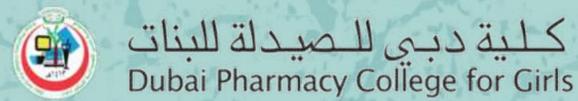
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