Pharmaceutical Regulations Summit

PRELIMINARY AGENDA

Main Conference: 2 & 3 May 2017
Workshop: 1 May 2017
Focus Day: 4 May 2017
The Address Dubai Marina, United Arab Emirates

CONFERENCE DAY ONE 2 MAY 2017

08:15 Registration and coffee

09:00 Chairperson's opening remarks

OVERVIEW OF THE PHARMA AND COSMETIC REGULATORY LANDSCAPE

09:10 UAE Opening Keynote Address

09:40 360° Regulators and Leadership panel: Moving towards more harmonisation and standardisation? Practical steps taken so far and further ideas for improvement
These dual panels of experts will discuss what the sector needs to do to create common guidelines, showcase some of the initiatives taken to move towards regional standardisation, as well as highlight what can be done to improve industry practices:

1. **09:40 - 10:00 Pharma panel**
2. **10:00 - 10:20 Cosmetic panel**
3. **10:20 - 10:40 Joint Q & A session**

Dr Anas Khalifa, Cosmetic Safety Expert, Dubai Municipality
Further panellists to be announced

10:40 Speed networking
An opportunity to meet leading regulators, directors, manufacturers and service providers in the region. Make sure you bring plenty of business cards!

10:55 Morning refreshments and networking

11:25 In perspective: The role and impact of innovation in the pharmaceutical industry today
This perspective keynote address will provide an in-depth look at the pharmaceutical industry today, as well as the regulations in place and recent reforms impacting the drugs developers and manufacturers. It will explore how innovation is driving and shaping the industry today and its impact on regulations.
Danilo Cassani, Area Head, Near East, Middle East and Africa, Takeda Pharmaceutical Company Limited

COUNTRIES IN FOCUS SERIES 1: REGULATIONS, SUBMISSIONS AND REGISTRATIONS

11:55 Country-in-focus keynote address: Spotlight on Jordan
The 'countries in focus' keynotes series will provide guidelines on how to do business with MENA countries and markets that are at the forefront of pharmaceutical and cosmeceutical innovation. Learn more about Jordan's mind-set when setting up framework and regulations. Improve your processes and timelines by understanding more of this country's requirements.
Dr. Hayel M. Obeidat, Director General, Jordan Food and Drug Administration

12:25 Headline thought-leadership keynote addresses

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13:05 Lunch and networking break

DRIVING INNOVATION, FASTER MARKET ACCESS AND IMPROVED PATIENT SAFETY

14:05 Break into stream sessions:

PHARMA STREAM	COSMETIC STREAM
14:05 Interactive panel: Pharma economics: Pricing regulation and unification • Price benchmarking and international competition: Establishing fair entry market prices that protect margins but are affordable to the patient • Understanding the impact of strict guidelines on market penetration • What is the effect of the immediate implementation of the reduced prices and on the stock of wholesalers? • Considering the pharma economics and dynamics of each country: The role of country wealth on product pricing and affordability **Dr. Kasem S Akhras, Head of Market Access, Middle East and North Africa, Novartis Pharma AG** **Adel Alzahrani, Senior Pharmacist, Pricing and PharmacoEconomics, Saudi Food and Drug Authority** **Dr Wisam Haddadin, Director Market Access EEMEA, Merck & Co. (MSD)** **Mr. Madhukar Tanna, Chief Operating Officer, Pharmax Pharmaceuticals FZ LLC**	**14:05 Interactive panel: The billion-dollar question: Is this product a drug, cosmetic or device?!** • Exploring the main differences between MENA countries • Ingredients and composition: How can you better determine if it's a drug or a cosmetic to simplify your registration process? • What are the common pitfalls to avoid? • Exploring the recent cases when a product is *not* a cosmetic *nor* a drug, but classified as a device. How does this impact your submission and registration processes? **Ph. Wesal Haqaish, Head of Drug Registration Department, Jordan Food and Drug Administration** Other speakers to be announced
14:45 Spotlight on: Counterfeit! Protecting patients and tackling counterfeit products through improved regional serialisation and labelling systems • Discover how serialisation can help combat counterfeit medicines, reimbursement fraud and theft in the supply chain • Track and trace: Assessing the impact of the new regulatory systems and its role on driving change across the MENA region	**14:45 Deep-dive: Dubai Municipality guidelines for cosmetic registrations and customs** • What are the particularities of doing business and import/export in the UAE? • Review the labelling requirements and consignment procedures in Dubai customs • Ensuring compliance and conformity throughout the process to avoid delays or possible sanctions

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• Understand the geographic complexities when implementing the new system • Review the timeframe for implementation and potential operational challenges • Feeling the squeeze: The impact of counterfeit on profit margins Speaker to be announced shortly	• What are the key commonalities and differences of customs requirements by GCC country? • Keeping up with changes to customs rules and regulations **Dr. Naseem Mohammed Rafee, Head of Consumer Products Safety Section, Dubai Municipality**
15:15 Afternoon refreshments and networking	**15:15 Afternoon refreshments and networking**
15:45 Thought-leadership keynote address	**15:45 Thought-leadership keynote address**
16:05 The Doctor's panel: Service delivery and feedback on new drugs In this innovative panel discussion, find out about the doctors' perspectives when it comes to testing new drugs and medicines on patients. At the end of the delivery chain, doctors are the best placed to provide us with insights themselves and on how their patients perceive new drugs and treatments: • What influence do GPs have on prescribing new drugs and how can you leverage it? • What type of information are doctors looking for? • What are their main reasons for prescribing new drugs as opposed to traditional ones? • What feedback do they receive from patients on new treatments available? Speakers to be announced shortly	**16:05 Insights on: Labelling claims and Pharmacovigilance. Understanding the requirements and managing future complaints** • A review of the common criteria for cosmetic claims • What are the codes of advertising practice you should refer to? • What should be mentioned on the layout? • Claims that require further guidance: "bio", "natural", "organic", "free from" and more • Dealing with fake products and complaints Speaker to be announced shortly
16:45 Chairperson's closing remarks	**16:45 Chairperson's closing remarks**
17:00 End of conference day one	**17:00 End of conference day one**

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CONFERENCE DAY TWO 3 MAY 2017

09:00 Registration and coffee

09:45 Chairperson's opening remarks

THE FUTURE OF PHARMA AND COSMETIC: BIOSIMILARS, BIOPHARMA, BIOTECH

09:55 Biotech keynote address: The rise of biosimilars
The latest wave of drugs and cosmetics is based on advanced research, which has seen the use of biotechnology-derived ingredients booming. With these products often claiming "drug-like" properties and benefits, the line between drug, cosmetic and medical research is becoming blurred. Therefore, procedures for submission and registration, as well as ensuring compliance throughout production can be extremely complicated. Learn more about the rise of biosimilars and how to navigate these changes.
Dr Talal S, Al Zaher B.Sc., PHD., MRSC, FRSB, Chief Scientist Biotechnology, Julphar Gulf Pharmaceuticals Industries

10:25 Sustainability focus: Exploration into natural beauty and 'bio' cosmetics across biopharma

- Gain some insights into nanoparticles. Why are they useful? What are the side-effects?
- What are the methods of manufacturing for nanoparticles?
- Macro-organic treatment: Ensuring they are effective but not harmful
- Natural beauty: Increasing the development of natural versus chemical products
- Are 'natural' beauty products actually safer?

Speaker to be announced shortly

10:55 Morning refreshments and networking

COUNTRIES IN FOCUS SERIES 2: REGULATIONS, SUBMISSIONS AND REGISTRATIONS

11:25 Country-in-focus keynote address: Spotlight on KSA
The 'countries in focus' keynotes series will provide guidelines on how to do business with MENA countries and markets that are at the forefront of pharmaceutical and cosmeceutical innovation. Learn more about the KSA's mind-set when setting up framework and regulations. Improve your processes and timelines by understanding more of this country's requirements.

11:55 Country-in-focus keynote address: Spotlight on Egypt
The 'countries in focus' keynotes series will provide guidelines on how to do business with MENA countries and markets that are at the forefront of pharmaceutical and cosmeceutical innovation. Learn more about Egypt's mind-set when setting up framework and regulations. Improve your processes and timelines by understanding more of this country's requirements.

12:25 Headline thought-leadership keynote addresses

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13:05 Lunch and networking opportunities

IMPACT OF REGULATIONS ON INVESTMENT DECISIONS AND COMPETITIVENESS

14:05 Investment panel: What is the impact of regulations on investment decisions?
This panel of expert will discuss how the changes in drug and cosmetic-safety regulations affect the way pharma, biopharma and cosmetic companies invest in innovation. The panel will review the effects on strategic decision, market access, innovation, investment and competitiveness.
Dr. Ahmed Emara, Group CEO & Managing Director, ReAya Holding
Dr. Rami Rajab, VP Market Access Emerging Markets, LivaNova, Chairman of MECOMED
Dr. Yacoub Haddad, Director of Government Affairs MEAP, AbbVie, Chairman of PHARMAG

PHARMACOVIGLANCE & GLOBAL COMPLIANCE

14:50 Pharmacovigilance insights: Identifying potential red flags

- Complying with legal requirements and preventing harm from adverse reactions: FDA vs country-specific guidelines
- What are the safety issues to be aware of?
- Is the QPPV qualification needed and how to become certified?
- Data: how to process it and how can you identify red flags

Omar Sawy Ahmed, Director - Arab League QPPV & Cluster Safety (Pharmacovigilance) Lead, Pfizer

15:30 Pharma and cosmetic compliance check-list: Complying with the EU requirements

- What are the similarities and differences in the definition of a drug and cosmetic product in EU and MENA?
- Ingredients and composition: What is allowed, restricted or banned?
- A close-up look at the introduction of Cosmetic Notification requirements and its applicability in the Middle-East
- Cosmetic: ethical considerations and animal testing ban
- What regulations need to be more specialised and tailored for the Middle East?

Speaker to be announced shortly

16:10 Chair's closing remarks

16:15 End of conference day two

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MEDICAL DEVICES FOCUS DAY 4 MAY 2017

Discovering the impact of the EU-MDR within the Middle East device market, acquiring faster device registrations & conducting successful compliant trials

09:30 Registration and coffee

10:00 Chair's opening remarks

10:10 Leadership panel: Impact of EU legislative reforms on MENA device-providers and regulators

- Understanding the new EU-MDR draft and its core changes for drug-makers and medical
- Assessing the ED-MDR impact for all stakeholders: patients and healthcare providers (safety and performance), regulators and notified bodies (regulations and classifications), payers (pricing and reimbursement) and manufacturers (lifecycle management)
- Planning for the future with effective transitions and creating roadmap for success

10:50 Device business development case study: Learning from the Middle East's largest medical device manufacturer

The current medical device market in the Middle East is primarily import-based, coming mostly from the United States and Germany. However, there are a few GCC manufacturers that have established themselves as successful exporters, such as Qatar German Company for Medical Devices that export to several countries within Europe, North America and Africa. In this deep dive case study session, explore what it takes to become the Middle East's largest medical device manufacturer and what this means for the potential for developing device manufacturing further in the region.

11:35 Morning refreshments and networking opportunity

12:05 Clinical trials: Conducting compliant clinical trials and post-market surveillance with medical devices in MENA

- What is the impact of the changing legislation (EU-MDR) on clinical evaluations?
- When can you refer to existing literature to show conformity and when do you need to use randomised controlled trials? The higher-risk devices case
- How can small and medium-size companies afford to carry out more trials when required?
- Evaluating the ethical considerations for more trials: potential barriers to innovation versus more safety and performance?

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12:35 Headline thought-leadership keynote address

Reserved for an exclusive partner

13:05 Lunch and networking opportunities

14:05 Quality Management focus: The new ISO 13485: 2016

ISO 13485:2016 provides requirements for organisations to be able to demonstrate a quality management system where medical devices and related services meet customer safety, quality and regulatory requirements. This session will review the new version of ISO 13485: 2016 and investigate the main changes and updates since ISO 13485: 2003, as well as its impact on device-manufacturers and medical professionals.

14:45 Spotlight on cosmetic-related device: Mesotherapy

Mesotherapy is more and more widely used in the Middle East countries, as people want to look younger. This session will highlight the uses of this aesthetic technique. Are there any side-effects? What are the advantages and inconveniences? What are the mode of actions? It will also explore the current regulations in place and if this technique is FDA-proofed and safe for the patient.

15:25 Chair's closing remarks

15:30 End of focus day

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PRE-EVENT WORKSHOP 1 MAY 2017

eCTD submission in practice

Workshop Overview:

The electronic Common Technical Document (eCTD) was designed to make regulatory submissions easier and more efficient for regulators and drug manufacturers. It also contributed to harmonising and standardising drug approval practices across many regions and regulatory agencies. However, its implementation and usage is not without challenges. This workshop will give you an overview of what eCTD is, what its objectives are and it will provide you with practical tools to perform submissions in your organisation. The course is designed for regulatory affairs managers and for those in the pharma business looking to expand their knowledge of eCTD science and its submission process.

Workshop Agenda:

09:30 Registration

10:00 Introduction of eCTD and its objectives

- Paper-based submission CTD versus electronic-based submission eCTD: What are the advantages and disadvantages of both?
- Introduction in the GCC countries - mapping who's using it and the regional differences
- What is the goal of eCTD and how can it be useful for your organisation?

10:40 Morning refreshments

11:00 Mastering the eCTD format

- Basic principles and structure: Backbone files, HTML and more
- Defining the eCTD roadmap for emerging markets and the Middle East in particular
- Assessing varying guidelines for submission content and formats in different countries

12:00 Case studies: Solving common implementation issues

Throughout various case studies, explore how eCTD was implemented in different organisations, find out about the common challenges and ways to overcome them

13:00 End of workshop

Facilitator to be announced shortly

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PACKAGES & PRICING

Package Type*	Super Early Bird Register before 26 January	Early Bird 1 Register before 23 February	Early Bird 2 Register before 30 March	Final Price Register after 30 March
GOLD PASS				
2-Day Conference & Focus Day & 1 Workshop	$2,699	$2,899	$3,099	$3,299
SILVER PASS				
2-Day Conference & Focus Day	$2,099	$2,299	$2,499	$2,699
BRONZE PASS				
2-Day Conference & 1 Workshop	$1,899	$2,099	$2,299	$2,499
STANDARD PASS				
Conference Only	$1,299	$1,499	$1,699	$1,899

*** 3 for 2 offer available for all packages including a conference pass**
*** Buy one get one free offer available for all past delegates**

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