Pharmaceutical Regulations Summit

1 - 4 May 2017
The Address Hotel Dubai Marina, Dubai, UAE

Workshop: 1 May 2017
Conference: 2 & 3 May 2017
Focus Day: 4 May 2017

UNDERSTANDING THE MENA REGION’S REGULATORY FRAMEWORK FOR FASTER DRUG, COSMETIC AND DEVICE REGISTRATION APPROVAL AND MARKET ACCESS

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With patient safety becoming an increasing focus of attention, the regulatory challenges in the Middle-East and North Africa are now more varied and complex than ever. Despite the many efforts noticed in the region, multiple interpretations of global guidelines, lack of transparency as well as delayed timelines for approval are just a few of the issues that regulatory affairs professionals know all too well.

It is true that some great work has been done via cooperation between countries over the last few years; however, there is still a need for more collaboration and harmonisation in standards across the MENA region.

The Pharmaceutical Regulations Summit will feature governments, regulatory authorities and expert insights from across the GCC and MENA to help you tackle and overcome these regulatory challenges, and ultimately help improve the drug, cosmetic and device approval processes for pharmaceutical, cosmeceutical, biopharmaceutical and medical device companies.

### THE BIGGEST REGULATORY AFFAIRS EVENT IN MENA AT A GLANCE:

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<td>PRE-EVENT WORKSHOP</td>
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### WHY YOU SHOULD ATTEND

**GET** the most up-to-date knowledge of regulations, registrations and post-market surveillance of pharma, cosmetics and medical devices

**HEAR** from competent authority bodies on their interpretations of rules and guidelines

**PARTICIPATE** in speed-networking and interactive exchange with regulators, directors and other compliance managers

**BENCHMARK** your regulatory practices with other leaders in the market

**MEET** and network with 150+ of your peers

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**PHARMACEUTICAL REGULATIONS SUMMIT IN NUMBERS**

- **150+** Conference Attendees
- **30+** Leading Authority and Industry Speakers
- **6** Practical Tailored Breakouts
- **50+** Focus Day Attendees
- **1** eCTD Workshop
- **4** Days of Dynamic Regulatory Learning and Exchange

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KEY THEMES PER INDUSTRY

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<th>PHARMA</th>
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<tr>
<td>● Regulations, Submissions and Registrations</td>
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<td>● Harmonisation and Common Guidelines</td>
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<td>● Pricing Regulation and Unification</td>
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<td>● Pharmacovigilance</td>
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WHO YOU WILL MEET

DIRECTORS, MANAGERS & PRACTITIONERS FROM LEADING PHARMACEUTICAL, BIOPHARMACEUTICAL, COSMECEUTICAL AND MEDICAL DEVICE COMPANIES, AS WELL AS REGULATORS AND GOVERNMENT AUTHORITIES RESPONSIBLE FOR:

- REGULATORY AFFAIRS
- COMPLIANCE
- REGISTRATION
- PHARMACOVIGILANCE
- LABELLING
- MARKET ACCESS AND PRICING
- QUALITY CONTROL
- DRUG DEVELOPMENT & MANUFACTURING
- DRUG SAFETY

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08:15 Registration and coffee
09:00 Chairperson’s opening remarks
Laura Castagno, Vice President Operations PQE Suisse and Partner, PQE

OVERVIEW OF THE PHARMA AND COSMETIC REGULATORY LANDSCAPE

09:10 Official summit inauguration by H.E Dr Amin Hussain Al Amiri and UAE opening keynote address H.E Dr Amin Hussain Al Amiri, Assistant Undersecretary of Public Health policy & Licensing Sector, UAE Ministry of Health & Prevention

09:40 Panel: REGULATORS AND LEADERSHIP PANEL – Future of regulations, harmonisation and global best-practices
This panel of industry and government 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. It will then explore the future of regulations and global best-practices to improve the current standards.
Dr. Dalia Murad, Head of Inspection and Control Department, Sharjah Medical District, MOHAP
Dr Anas Khalifa, Cosmetic Safety Expert, Dubai Municipality
Deepinder Singh, Group Head – Quality Improvement, KIMS Hospitals and Medical Centers (GCC)

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!

11:00 Morning refreshments and networking

11:30 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

12:00 COUNTRIES IN FOCUS SERIES 1: REGULATIONS, SUBMISSIONS AND REGISTRATIONS

12:00 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 cosmesceutical 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. Obiedat, Director General, Jordan Food and Drug Administration

13:05 Lunch and networking break

13:50 IN FOCUS: 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
Dr Wisam Haddadin, Director Market Access EEMEA, Merck & Co. (MSD)
Sameh Essa, Senior Market Access Manager, Gulf, AstraZeneca International

14:20 INTERACTIVE PANEL: The billion-dollar question: Is this product a drug, cosmetic or food?!
• 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? Or else?
• What are the common pitfalls to avoid?

14:50 Afternoon refreshments and networking

15:20 SPOTLIGHT ON: Counterfeit! Protecting patients and tackling counterfeit products through improved regional serialisation and labelling systems
• Reviewing international guidelines, such as the Joint Commission (medication management and utilisation within healthcare facilities)
• Understanding the geographic complexities of serialisation and labelling
• Exploring the timeframe for implementation and potential operational challenges, including transportation and cold chain
Mrs. Obaida Qatuni, Accreditation Head, Dubai Health Authority

15:50 PRACTICAL INSIGHT: Physicians’ practice towards ADRs reporting: Survey results
Underreporting of adverse drug reaction (ADRs) can constitute a major threat to pharmacovigilance. Dr Hegazy will present the results of a study that aimed to determine the practice and attitudes of physicians reporting ADRs. Find out about the context of the study and its main learnings.
Dr. Ahmed Hegazy, M.D., MBBCh, MSc. PharMed, Head of Global Drug Safety – Intercontinental Region, Merck

16:20 Chairperson’s closing remarks
Laura Castagno, Vice President Operations PQE Suisse and Partner, PQE

16:30 End of conference day one
9:00 Registration and coffee

9:45 Chairperson’s opening remarks
Laura Castagno, Vice President Operations PQE Suisse and Partner, PQE

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

9:55 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

10:35 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?
Dr Rajan Sadanandan, Medical Director, Dubai Heart Center

11:15 Morning refreshments and networking

COUNTRIES IN FOCUS SERIES 2: REGULATIONS, SUBMISSIONS AND REGISTRATIONS

11:45 COUNTRY-IN-FOCUS KEYNOTE ADDRESS: Algeria
Lessons learnt from other emerging markets: Development of a local biotech industry, what are the current challenges?
Dr. Yacine Sellam, Pharm.D., Ph.D., Assistant General Manager, Institut Pasteur of Algeria

12:15 ELECTRONIC SUBMISSIONS: Challenges and achievements
- Electronic dossiers and submissions: where are we worldwide?
- Challenges and achievements for the stakeholders: the industry from one side and regulators on the other side
- Case studies from the users and feedback from the authorities
Laura Castagno, Vice President Operations PQE Suisse and Partner, PQE

12:35 Lunch and networking opportunities

13:50 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. Rami Rajab, VP Market Access Emerging Markets, LivaNova, Chairman of MECOMED
Dream Samir, Secretary General, PhRMAG

PHARMACOVIGILANCE & GLOBAL COMPLIANCE

14:50 PHARMACOVIGILANCE INSIGHTS: Implementing risk minimisations measures
- Complying with PV (Pharmacovigilance) reporting requirements: Global vs Regional/country-specific guidelines
- What are the risk minimisations measures to be aware of?
- What are the benefits of the QPPV qualification?
- Adverse events data: Processing data and signal detection
Omar Sawy Ahmed, Director – Arab League QPPV & Cluster Safety (Pharmacovigilance) Lead, Pfizer

15:30 FUTURE TRENDS: The Future of Pharmacovigilance
This closing session will explore what the future of pharmacovigilance looks like. Starting with a review of where we are at and current scenario, this keynote address will delve into the following trends and areas:
- Knowledge process outsourcing
- Regulatory harmonization and cloud-based reporting to bring a robust global database of ADRs
- Data analytics
- Automation for non-value-adding tasks
- Digital health and social media
- Artificial intelligence
- Personalized medicine
Deepinder Singh, Group Head – Quality Improvement, KIMS Hospitals and Medical Centers (GCC)

16:10 Chair’s closing remarks
Laura Castagno, Vice President Operations PQE Suisse and Partner, PQE

16:15 End of conference day two

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09:30 Registration and coffee

10:00 Chair’s opening remarks
Dr. Mohammed Jawad, Founder & Managing Director, Lifetastic FZ-LLC

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 devices providers
• 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
Dr Anan Habu Hassan, Head of Medical Devices Section, Jordan Food and Drug Administration
Kenneth Seymens, Managing Partner, MedicaIQ; Former Chief Technology & Information Officer (CTIO), King Khaled Eye Specialist Hospital

10:50 CASE STUDY: Engaging with SFDA authorities pre and post market
In this deep dive case study session, explore techniques to engage with authorities, with a focus on the Saudi Food & Drug Authority (SFDA). This presentation will look at pre and post market submissions and registrations.
Dr Anan Habu Hassan, Head of Medical Devices Section, Jordan Food and Drug Administration

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?
Dr Anan Habu Hassan, Head of Medical Devices Section, Jordan Food and Drug Administration

13:05 Lunch and networking opportunities

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 SUPPLY-CHAIN PERSPECTIVE: What value-addition can regulations bring to the MENA devices market?
• A view on equipment regulations control: Who’s in charge of approval?
• Benefits of regulations and standardisation of the supply of medical devices
• Perspective from the healthcare providers: what are their preferences in buying equipment? How do they see the value-addition of regulations?
Sameer Saeed Ali, Head of Clinical Engineering & Medical Equipment Procurement, Prime Healthcare Group LLC

15:25 Chair’s closing remarks

15:30 End of focus day

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

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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

Facilitated by:
Jayaprakash Nallasami, Domain and IT Solutions/Consultant - Regulatory and IDMP

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WHY PARTNER?

• Build brand recognition as a leading advocate of transparency and efficacy in the region’s pharma regulations space
• Opportunities to share your best practices and technology with the region’s key stakeholders
• Create and nurture new partnerships with pharma, cosmetic and medical device regulators and companies
• Exclusive access for leading thought leaders and innovators via the programme
• Opportunities for the development of innovative partnerships and collaborations

Achieve your objectives by:

Releasing Tailored Research | Leading Bespoke Events & Roundtables | Hosting Networking Receptions | Interactive Engagement | Influencing Industry Thinking | Leading In-Depth Workshops | Putting Your Brand In Their Hands | Attending Onsite Meetings

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Sowmya Yellapa
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sowmya.yellappa@informa.com

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## Package Type

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* Buy one get one free offer available for all past delegates

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