SEMINAR

FORUM 40 YEARS

Electronic Regulatory Submissions in the Middle East

eSubmission in Saudi Arabia, the GCC, Oman, the UAE, Bahrain and Jordan - Legal, technical and commercial aspects

TOPICS

- eCTD requirements in Saudi Arabia, the UEA, Oman, Jordan and the GCC
- eSubmission portals: Do they work?
- What to keep an eye on: fees, validation issues, ...
- Agents' capabilities in e-services
- Current RA operational models in the MENA region

YOUR SPEAKERS

Dr Mohammed Saleem
Boehmert & Boehmert,
Representation Office Middle East and North Africa, JORDAN

Ala'a Saleem
Science Forum for Research & Consultancy (SIPS), Amman, JORDAN

1 OCTOBER 2019 IN HEIDELBERG

Aims and objectives

eCTD is the mandatory dossier format in many countries in the Middle East. Therefore, eSubmission becomes important. In most cases, a national partner is required for submission here.

This course helps you avoid process interruptions and validation issues, and provides advice on how to best collaborate with your local agents to ensure the marketing authorisation is granted and maintained.

Who should attend?

This unique course addresses the needs of employees in the healthcare industry involved in registering and maintaining marketing authorisations of drugs in MENA countries.

Regulatory operations and regulatory affairs managers in particular will benefit from the speakers' expertise.

Limited number of attendees

This seminar is limited to 20 participants. This limitation, a feature of all FORUM seminars, enables participants to thoroughly discuss the complex issues covered by the programme.

Your speakers

Dr Mohammed Saleem

Boehmert & Boehmert, Representation Office Middle East and North Africa, JORDAN

General Director of SIPS (Science Forum for Research & Consultancy). He has served as a senior consultant to many UN

Ala'a Saleem

Science Forum for Research & Consultancy (SIPS), Amman, JORDAN

Deputy General Director "Technical Affairs"

Additional meeting

May we also draw your attention to our seminar

- Known Substances - Regulatory Strategies in Europe, the Middle East and Russia/the EAEU on the 2 October 2019 in the same conference hotel.

You will find detailed information on www.forum-institut.com with webcode 1910236

By attending both courses, you will benefit from € 290.00 (+VAT) discount.

Your benefits

- Two experts with local know-how
- Firsthand information on eSubmission

Legal, technical and commercial aspects

Your programme 09:00 - 17:30

Overview of the current electronic regulatory landscape in the Middle East

- eCTD requirements in Saudi Arabia, the UAE, Oman, Jordan and the GCC
- Description of the preliminary portal system in Saudi Arabia, the UAE, Oman, Jordan and the GCC
- Ways and means of interacting with health authorities

eSubmission in Saudi Arabia

- How does the eSubmission portal work?
- Description of the process, including appointments and notifications
- Local partner powers in the electronic system
- What to keep an eye on:feesvalidation issuesthe consequences of interrupting the process
- Commercial activities affected by e-services

eSubmission at the central GCC office

- Using the eSubmission portal
- The review process
- Pricing strategy

eSubmission in Oman, the UAE, Bahrain and Jordan

- Current status of the portal system
- The review process
- Importing your submission process

Module 1 requirements in the GCC and Jordan

Work ethics in the electronic environment

- Agents' capabilities in e-services
- Agents' and principal duties in e-services
- Integrity and correctness of communications
- Security of confidential documents

RA operational models in the MENA region

- Current RA operating models
- Cost versus efficiency per model
- Selecting and implementing the right model

Update on RA in the MENA region

Electronic Regulatory Submissions in the Middle East

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

☐ Electronic Regulatory Submissions in the Middle East (1910235)

☐ Known Substances - Regulatory Strategies in Europe, the Middle East and Russia/the EAEU (Details at our webside and the webcode 1910236)

☐ Yes, I agree that FORUM Institut may inform me about events by: ☐ email; and/or ☐ telephone. I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date and venue
Tuesday, 1 October 2019 in Heidelberg
08:30 registration; 09:00 - 17:30 seminar
Heidelberg Marriott Hotel
Vangerowstr. 16 · 69115 Heidelberg
Tel. +49 6221 908-0 · Fax +49 6221 908-660

Fee
€ 1,090.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Fee for booking 2 courses
€ 1,890.00 (+VAT) for booking both courses:
- Electronic Regulatory Submissions in the Middle East (1 October 2019 - Webcode 1910235)

and
- Known Substances - Regulatory Strategies in Europe, the Middle East and Russia/the EAEU (2 October 2019 - Webcode 1910236)

You will benefit from a € 290 (+VAT) discount.

CANCELLATION POLICY

Our general terms and conditions (as of1 January 2016) apply and are available upon request.We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT

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