Webcast series

In cooperation with:

The First Accredited Diploma in Pharmacovigilance for the Middle East

Certified by Forum · Institut für Management GmbH, Germany

European GVP at a glance to better understand the new Common Arab Guidelines in Pharmacovigilance

Your webcasts at a glance

- Qualified person for pharmacovigilance (QPPV)
- Pharmacovigilance system master file (PSMF) and PSSF
- Drug adverse reactions and signal management
- Risk management plan (RMP) and risk management system
- Periodic safety update reports (PSUR)
- Pharmacovigilance inspection and audit readiness

Your benefits

- Twelve recorded webcasts with European pharmacovigilance experts
- Consolidated information at your work place within a short period of time
- Online assessment for certification after each webcast

www.forum-institut.com/pharmacovigilance-in-middleeast

Pharmacovigilance in the Middle East

Scope

Do you need detailed information about the European Pharmacovigilance framework in order to understand and implement the new Common Arab Guidelines in Pharmacovigilance in your country? We would like to invite you to join our 12 recorded webcasts, where European and Middle East experts will inform you of the concepts and challenges in drug safety that you need to remain compliant with your current PV legislation.

Each webcast will be a two-hour webcast, delivering the information with supporting slides (also for your personal download). You can start at any time and are able to retrieve the webcasts and additional documents from our e-learning centre for six full months. An online assessment completes each webcast, giving you the possibility to receive a accredited certificate after all 12 webcasts.

Please find more details at www.forum-institut.com/pharmacovigilance-in-middleeast

Quality guaranteed!

The FORUM Institut für Management GmbH is one of the leading conference and seminar specialists in Europe. We are dedicated to provide high-quality training for pharmaceutical professionals and executives. As a Life Train signatory FORUM Institut follows defined quality criteria by IMI (Innovative Medicines Initiative of the European Union) and is an active partner in further developing and optimising the quality standards.

Your Experts

Dr Mohammed Saleem

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

General Director of SIPS (Science Forum for Research & Consultancy)

Dr Tanja Peters

Boehringer Ingelheim Pharma GmbH & Co. KG

Head PV Intelligence & Deputy EU-QPPV

Dr Axel Thiele

Pharmacovigilance consultant and auditor

More than 35 years experience in the pharmacovigilance department at the German competent authority, responsible for referral procedures and the introduction of pharmacovigilance inspections

Dr Reinhard Nibler

Dr Nibler & Partner

Pharmacovigilance Consultant

Dr Ulrich Vogel

Boehringer Ingelheim International GmbH

Head Strategic Data Analysis, Global Pharmacovigilance

Sven Schirp

Boehringer Ingelheim Pharma GmbH & Co. KG

Head of Global Pharmacovigilance Writing

Dr Angela van der Salm

DADA Consultancy

Director Pharmacovigilance, Managing partner

Further information is available at
www.forum-institut.com/pharmacovigilance-in-middleeast

Your programme

1) Introduction to pharmacovigilance – EU
Dr Tanja Peters

- History of drug safety
- Why pharmacovigilance?
- Important definitions
- Desired vs. adverse reaction
- Important elements of a modern PV system

2) Pharmacovigilance in the Middle East – Direct transfer of EU PV legislation?
Dr Mohammed Saleem

3) Pharmacovigilance system master file (PSMF)
Dr Axel Thiele

- GVP Module II – Regulatory background
- Format and content
- Maintenance at a glance
- National peculiarities and PSSF

4) Drug adverse reactions
Dr Reinhard Nibler

- Sources of drug adverse reactions
- Causality and benefit-risk assessment
- Reporting timelines in Middle East vs. reporting timelines in Europe
- Special cases (off-label use, overdosage, etc.)
- MedDRA, a short overview

5) Signal management
Dr Ulrich Vogel

- Signal – An intuitive concept in a regulated framework
- Signal stages: detection, validation, confirmation, analysis, assessment
- Statistical and qualitative methods
- Data collection, decision making and communication
- Process implications for the MAH

6) Risk management plan
Sven Schirp

- Scope
- Important definition
- Structure & Content
- Interference with other pharmacovigilance documents

7) Risk management system
Dr Angela van der Salm

- Risk minimisation measures and performance measuring
- Risk communication (DHPC letter, etc.)
- Post-authorisation safety studies (PASS)

8) Periodic safety update reports (PSUR)
Sven Schirp

- For which products are PSURs mandatory?
- Interval, data lock points and period
- PSUR format and content
- Interference with other pharmacovigilance documents
- How to gather and evaluate data for PSURs

9) Pharmacovigilance inspection and audit readiness
Dr Axel Thiele

- Fundamentals of inspections and audits: regulations, occurrence, types and aims
- Strategic planning and preparation – pitfalls
- Communication with the inspector/auditor
- Report, typical findings and follow-up measures

10) Qualified person for pharmacovigilance (QPPV)
Dr Tanja Peters

- Duties and responsibilities
- Qualifications
- QPPV vs national responsible person
- Pecularities in MENA

11) PSURs and RMPs – Tips for international markets
Sven Schirp

- Global planning of PSUR schedules: solutions and strategies
- How to ensure alignment of local RMPs with global RMPs

12) Interpreting and implementing new PV requirements
Dr Tanja Peters

- Regulatory background
- What is PV intelligence about?
- Sources and what is relevant?
- Public commenting
- Impact assessment
- Coordinating implementation activities
- Efficient communication pathways

Pharmacovigilance in the Middle East

Aims of this webcast series

After attending all webcasts, you will

- understand the European pharmacovigilance framework as a basis for local Middle East pharmacovigilance guidelines;
- be familiar with the differences in the Middle East;
- know the sources of adverse reactions and signals, and their impacts on patient safety;
- understand the structure and content of safety update reports;
- be able to provide information required for the PSMF, the relevant PSSF and the risk management plan;
- be able to assist in audits and future inspections; and
- be familiar with the duties and responsibilities of the qualified person for pharmacovigilance

Benefits

- Twelve recorded webcasts about European GVP
- Recorded webcasts available at our e-learning centre for six months.
- Detailed documentation downloads
- Online assessment after each webcast
- Personal certificate

Who should attend?

This webcast series will be of benefit to all those working in pharmacovigilance or in related departments requiring essential drug safety expertise. Basic pharmaceutical knowledge is recommended but not a prerequisite.

How to join our webcast series

In order to join in our webcast, you will need a standard PC with a current browser, a soundcard, speakers or a headset, and a reliable Internet connection. You will receive login details for our e-learning centre where you can find all webcasts, documentation and online tests.

For registration please use

Contact@sipsmena.com
or our registrationform at
www.forum-institut.com/pharmacovigilance-in-middleeast

Registration: +962 6 5512561 or email: Contact@sipsmena.com

- **Registration: +962 6 5512561**
- **Conference-No. 19 12 201**

- **Fee:**

Personal subscription
The membership fee of € 800,– for 12 recorded webcasts is due upon registration and includes **one** personal account. Membership may be started at any time.

Group subscription
Would you like to the webcasts as a group? Group subscription for 3 and more from the same group will be legible for group discount of 20% of personal fees.

- **Questions and information:**

Please feel free to contact me if you have any questions.
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- **Further information:**

Further information about the programme, the experts, our partners and the registration procedure is available at www.forum-institut.com/pharmacovigilance-in-middleeast.