GMP/GDP Workshop (GMDP)

DGRA workshop for members on September 16th, 2014 at Wissenschaftszentrum Bonn, Ahrstraße 45, 53175 Bonn, Germany

10.00 a.m. - ca. 5.00 p.m.

Importing medicinal products from third countries and their distribution within the European Union

- Guaranteeing GMP in third countries
- EDQM certificates and certificates from public authorities in the states of origin
- Requirements in the guidelines on Good Distribution Practice (GDP)
- Monitoring of wholesalers and intermediaries
- GMDP databases – European and National

Moderator: Prof. Burkhard Sträter, Law Firm Sträter

Speakers: Dr. Florence Benoit-Guyod, EDQM
Dr. Susanne Quellmann, Köln
Tobias Könnecke, District Government of Darmstadt
Dr. Darius-Jean Namdjou, Grünenthal GmbH
Ralf Rest, BfArM
Prof. Burkhard Sträter, Law Firm Sträter
Christian Wolf, arvato Healthcare
Programme:

10.00 a.m.  Keynote speech
Monitoring of API Good Manufacturing Practice in third countries by EDQM and EMA - requirements and international collaboration
Dr. Florence Benoit-Guyod, Head of Inspection Team EDQM

11.00 a.m.  Coffee break

11.30 a.m.  Monitoring the importing of medicinal products from third countries
  ▪ Requirements of the import permit in accordance with Section 72 AMG
    ▪ Local inspections
    ▪ Repeat testing in the EU
    ▪ Active Substances
Tobias Könnecke, District Government of Darmstadt

12.15 p.m.  GMDP databases at the EMA and at DIMDI
  ▪ Status and maintenance
Prof. Burkhard Sträter und Dr. Susanne Quellmann

1.15 p.m.  Lunch

02.30 p.m.  Monitoring of the distribution and transport by wholesalers and intermediaries in the EU
  ▪ GDP
Christian Wolf, arvato Healthcare

3.15 p.m.  Ensuring GMP compliance for active pharmaceutical ingredients (APIs) imported to the European Union
  ▪ API import to EU – why significantly regulated?
  ▪ Role of the finished product manufacturer in assessing GMP compliance of APIs
  ▪ Current API import legislation in EU including GMP requirements – Consequences of Falsified Medicines Directive
  ▪ Comparison to EU: Legislation on API import in selected non-EU countries
Dr. Darius-Jean Namdjou, Grüenthal

04.00 p.m.  Coffee break

04.30 p.m.  Consequences of GMP deficiencies for marketing authorisations
Ralf Rest, BfArM

Ca. 5.00 p.m.  End

(Programme subject to change without prior notice)
Information and organisational references please turn over
Date:
Tuesday, September 16th 2014
Start: 10.00 a.m.
End: around 5.00 p.m.

Venue:
Wissenschaftszentrum Bonn, Ahrstraße 45, D-53175 Bonn, phone: 0228/302-0

Participation fees:
For DGRA members and M.D.R.A. students course XIV / XV: € 250

(The Casino/canteen is open for lunch -not included)

Cancellation terms:
Up to two weeks before the first day of the conference (Sept. 2nd, 14): € 50; up to one week before the first day of the conference (Sept. 9th, 14): 50% of fee; late cancellations: full conference fee if a substitute participant (DGRA member) cannot be put forward.

In the event of cancellation by the organizer, any fees already paid will be fully reimbursed.

Conference language:
English

Note:
Photographers will accompany the workshop. Some photographic material will be published.
Workshop documents will include a list of participants.

Room reservation:
A limited number of rooms are available for participants at special rates in the hotels listed below. When making reservations (up to 4 weeks before the workshop) please refer to “DGRA”.

- Hotel Königshof, Bonn-City
  Phone: 0049-228/26010
- Hotel Maritim, Bonn
  Phone.: 0049 – 228/8108-0
- Hotel Residence, Bonn-City
  Phone: 0049 - 228/2697703
- Villa Godesberg, Bonn-Bad Godesberg
  Phone: 0049 - 228/830060

More available rooms for direct booking
www.bonnhotels.de (incl. public transport), www.hrs.de

Registration:
As a DGRA member please use the application form at www.dgra.de or contact us at info@dgra.de

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