

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 Könnicke, 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, Grünenthal*
- 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

DGRA-Office

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Mit der Deutschen Bahn ab 99,- € zu jeder
DGRA-Veranstaltung hin und zurück,
informieren Sie sich hier:
[http://dgra.de/deutsch/dgra/aktuelles/2014/
Reisen-Sie-bequem-zu-Ihrer-DGRA-
Veranstaltung](http://dgra.de/deutsch/dgra/aktuelles/2014/Reisen-Sie-bequem-zu-Ihrer-DGRA-Veranstaltung)