

21st DGRA Annual Congress

May 23th and 24th, 2019 in Bonn

In the former Assembly Room of the German Bundestag
("Plenarsaal")

- Brexit, Relocation of EMA
- Big Data
- Clinical Trials
- Neue Gesetzgebungsverfahren
- Medizinprodukte-Verordnung – aktueller Sachstand

with

Prof. Dr. Guido Rasi

European Medicine Agency (EMA), London /
Amsterdam

Dr. Christa Wirthumer-Hoche

Austrian Medicines and Medical Devices
Agency, Wien

Prof. Dr. Karl Broich

Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Bonn

Prof. Dr. Klaus Cichutek

Paul-Ehrlich-Institut (PEI), Langen

Nikolai C. Brun

Danish Medicines Agency (DKMA), Copenhagen

Thomas Müller

Bundesministerium für Gesundheit (BMG),
Berlin

Dr. Mark Goldammer

Paul-Ehrlich-Institut (PEI), Langen

Dr. Ulrich Granzer

Granzer Regulatory Consulting & Services,
München

Prof. Burkhard Sträter

Kanzlei Sträter Rechtsanwälte, Bonn

Dr. Isabelle Stöckert

Bayer AG, Wuppertal

Dr. Heike Wollersen

Bundesverband der Arzneimittel-Hersteller e.V.
(BAH), Bonn

Moderation: Prof. Burkhard Sträter

Kanzlei Sträter Rechtsanwälte, Bonn

The Program on May 23th 2019

- 9.30 a.m.** **Opening of the Annual Congress and introduction to Sessions**
Dr. Ulrich Granzer, Granzer Regulatory Consulting & Services
- 9.45 a.m.** **Relocation of EMA, Challenges and Consequences**
Prof. Guido Rasi - Executive Director EMA
- 10.30 a.m.** **Realignment of the EU-network: Perspectives from the Management Board and NCA**
Dr. Christa Wirthumer-Hoche, Chairman of Management Board EMA, Head of the Austrian Medicines and Medical Devices Agency
- 11.00 a.m.** **Coffee Break**
- 11.30 a.m.** **Impact of the Brexit from an Industrial Perspective**
Dr. Isabelle Stöckert, Bayer AG
- 12.00 p.m.** **HMA / EMA Joint Big Data Task force initiative
Presentation of the Report and next steps**
Nikolai C. Brun, Chair of joint HMA/EMA Task Force on Big Data; DKMA
- 12.45 p.m.** **Lunch**
- 1.45 p.m.** **From Big Data to Real World Data: hype or meaningful for regulators?**
Prof. Dr. Karl Broich, President BfArM
- 2.30 p.m.** **Application of Big Data strategies and technologies in proteomics and individualised therapeutic vaccines**
Dr. Mark Goldammer, Member of joint HMA/EMA Task Force on Big Data; PEI
- 3.00 p.m.** **Clinical Trials: First in men and complexe study designs**
Prof. Dr. Klaus Cichutek, President PEI

- 3.45 p.m. Panel discussion**
- 4.15 p.m. Coffee Break**
- 4.30 p.m. DGRA General Membership Meeting**
(ends around 5.30 p.m.)
- 7.00 p.m. Pre-Dinner Speech**
Reception and Buffet

The Program on May 24th 2019

- 9.30 a.m. Award Ceremony “Walter-Cyran-Medaille”**
- 10.00 a.m. Einleitung zu neuen Gesetzgebungsverfahren**
Prof. Burkhard Sträter, Kanzlei Sträter Rechtsanwälte
- 10.30 a.m. Arzneimittelüberwachung, ATMPs und Post-Marketing-Daten: Aktuelle Gesetzesvorhaben**
Thomas Müller, BMG
- 11.15 a.m. Panel discussion**
- 11.30 a.m. Coffee Break**
- 12.00 p.m. Die neue Medizinprodukte-Verordnung – aktueller Sachstand**
Dr. Heike Wollersen, BAH
- 1.00 p.m. Panel discussion**
- 1.30 p.m. Lunch / Dinner**

(There maybe changes to the program)

Dates:

May 23, 2019, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	4.30 p.m.	
Rheinhotel Dreesen	7.00 p.m.	Pre-Dinner Speech, Reception
May 24, 2019, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions

Venue:

World Conference Center Bonn Platz der Vereinten Nationen 2 Plenarsaal 53113 Bonn	Rheinhotel Dreesen Rheinstraße 45-49 D-53179 Bonn
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Registration fees:

For DGRA members: € 680
For non-members: € 830

Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: € 360

Cancellation terms:

Up to two weeks before the first day of the conference (including 8-May-2019): € 50; up to one week before the first day of the conference (including 15-May-2019): 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 languages:

English (Morning of May 23) and German

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 please refer to "DGRA"/DGRA Annual congress.

Rheinhotel Dreesen
Bonn-Bad Godesberg
Tel.: +49 (0) 228 / 8202-0

Hotel Rheinland Bad Godesberg
Bonn-Bad Godesberg
Tel.: +49 (0) 228 / 82 00 0-0

Intercity Hotel
Bonn-Innenstadt
+49 228 926181-0

HOTEL MYPOPPELSDORF
Bonn-Innenstadt
Tel.: +49 (0) 228 26 910

More hotel rooms can be booked directly on the internet:

<http://www.bonn-region.de/events/dgra-2019.html>

Each participant booking his room via the above link of the Tourismus & Congress GmbH will receive a Congress ticket in PDF format with the booking confirmation.

This entitles the participants to use the bus line SB 60 from Airport Cologne / Bonn to Bonn Hbf, the train line 66 from the ICE station Siegburg - Bad Honnef, and other buses and trains within the city of Bonn on arrival and departure day. In addition, participants can use the local public free of charge with the Congress ticket during the Congress in the area of Bonn, Cologne, St. Augustin, Siegburg and Königswinter (Verkehrsverbund Rhein Sieg Area).

Registration:

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