

# 20th DGRA Annual Congress

## Anniversary

**June 14th and 15th, 2018 in Bonn**

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

- Relocation of EMA
  - Consequences for the MA-System in Europe
  - Position of EMA – and national competent Authorities
- Medical Devices Regulations in the EU, Challenges for Notified Bodies and Pharmaceutical Industries
- Implementation of Clinical Trial Regulation, Pilot Procedures in BfArM and PEI - Outcomes

with

**Prof. Dr. Guido Rasi**

European Medicine Agency (EMA), London

**Dr. Christa Wirthumer-Hoche**

Chairman of Management Board EMA, Head of AGES, Wien

**Prof. Dr. Karl Broich**

President of Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

**Prof. Dr. Klaus Cichutek**

President of Paul-Ehrlich-Institut (PEI), Langen

**Dr. Rainer Edelhäuser**

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG), Bonn

**PD Dr. Thomas Sudhop**

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

**Dr. Wiebke Löbker**

Head of BfArM Innovation Office, Bonn

**Dr. André Berger**

Provisional Head of Paul-Ehrlich-Institut (PEI) Innovation Office, Langen

**Dr. Ulrich Granzer**

Granzer Regulatory Consulting & Services, München

**Stephanie Schmitz**

PARI GmbH, Starnberg

**Dr. Max Wegner**

Bayer AG, Wuppertal

**Moderation: Prof. Burkhard Sträter**

Kanzlei Sträter Rechtsanwälte, Bonn

# The Program on June 14th 2018

**Moderation: Prof. Burkhard Sträter**

**9.30 a.m. Opening of the Annual Congress and introduction to Sessions**

*Dr. Ulrich Granzer, Granzer Regulatory Consulting & Services*

**09.45 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 the Management Board and President of AGES Austria*

**11.00 a.m. Coffee Break**

**11.30 a.m. Impact of the Brexit from an Industrial Perspective**

*Dr. Max Wegner, Bayer AG*

**12.00 p.m. EU Telematics Strategy 2025 - Implications of Brexit and beyond**

*Prof. Dr. Karl Broich, President BfArM*

**12.45 p.m. Lunch**

**1.45 p.m. Potential Breakthroughs in Advanced Therapies and Biotherapeutics Medicinal Products CAR-T-Cell et al.**

*Prof. Dr. Klaus Cichutek, President Paul-Ehrlich-Institut*

**2.30 p.m. Sponsor Perspective**

*Dr. Ulrich Granzer, Granzer Regulatory Consulting & Services*

**3.00 a.m. Scientific Advice from the Innovation Centers in Paul-Ehrlich-Institut and BfArM**

*Dr. André Berger, PEI*

*Dr. Wiebke Löbker, BfArM*

**4.00 p.m. Coffee Break**

**4.15 p.m. DGRA General Membership Meeting and board elections**  
(ends around 5.30 p.m.)

**7.00 p.m. Pre-Dinner Speech**  
*Reception and Buffet*

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## **The Program on June 15th 2018**

**9.30 a.m. Award Ceremony “Walter-Cyran-Medaille”**

**10.00 a.m. Medical Device Regulation EU, Challenges for Notified Bodies and Manufactures**  
*Dr. Rainer Edelhäuser, ZLG*

**10.45 a.m. Provisions for Certified Products and Renewal of Certifications**  
*Stephanie Schmitz, PARIGmbH*

**11.30 a.m. Coffee Break**

**12.00 a.m. Implementation of Clinical Trial Regulation – Outcomes of Pilot Procedures in BfArM**  
*PD Dr. Thomas Sudhop*

**1.15 p.m. Panel discussion**

**1.45 p.m. Lunch / Dinner**

**(There maybe changes to the program)**

**Dates:**

June 14, 2018, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	4.00 p.m.	
Hotel Königshof	7.00 p.m.	Pre-Dinner Speech, Reception
June 15, 2018, Plenarsaal, Bonn	9.30 a.m.	Presentations and Discussions

**Venue:**

World Conference Center Bonn Platz der Vereinten Nationen 2 Plenarsaal 53113 Bonn	Hotel Königshof Adenauerallee 15 D-53111 Bonn
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**Registration fees:**

For DGRA members: € 680	Student discount: Students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: € 360
For non-members: € 830	

**Cancellation terms:**

Up to two weeks before the first day of the conference (31-May-2017): € 50; up to one week before the first day of the conference (7-June-2018): 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 June 14) and German

Some photographic material will be published.

**Note:**

Photographers will accompany the workshop.

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.

Derag Livinghotel Kanzler  
Bonn-Innenstadt  
Tel.: +49 (0) 228 / 6844160

Hotel Königshof  
Bonn-Innenstadt  
Tel.: + 49 (0) 228 / 26010

IntercityHotel Bonn  
Bonn-Innenstadt  
Tel.: +49 (0) 228 / 926181 0

Villa Godesberg  
Bonn-Bad Godesberg  
Tel.: +49 (0) 228 / 83 006-0

More hotel rooms can be booked directly on the internet:

<http://www.bonn-region.de/events/dgra-2018.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](http://www.dgra.de) or contact us at [info@dgra.de](mailto:info@dgra.de)  
DGRA-Geschäftsstelle, Adenauerallee 15, D-53111 Bonn, Fax: +49 (0) 228/368 26 47