

# 23rd DGRA Annual Congress

**September 13th and 14th, 2021 in Bonn**

in the former Assembly Room of the German Bundestag  
(Plenarsaal) and virtual.

All speakers will participate on site, audience participation is also possible via Zoom.  
Please register accordingly. [A Covid-19 vaccination certificate is required for participation.](#)

- EMA: Our Way in Pharmaceutical Strategy and International Collaboration
- HTA
- Digitalization of the Healthcare System
- Development Challenges in New Vaccines

with

**Emer Cooke**

European Medicines Agency (EMA), Amsterdam

**Dr. Max Wegner**

Bayer AG, Wuppertal

**Dr. Christa Wirthumer-Hoche**

Austrian Medicines and Medical Devices Agency,  
Wien

**Dr. Ulrich Granzer**

Granzer Regulatory Consulting & Services,  
München

**Prof. Dr. Karl Broich**

Bundesinstitut für Arzneimittel und  
Medizinprodukte (BfArM), Bonn

**Dr. Lars Nickel**

Bundesministerium für Gesundheit (BMG),  
Berlin

**Prof. Dr. Klaus Cichutek**

Paul-Ehrlich-Institut (PEI), Langen

**Dr. Anna Silke Hammerbacher**

Daichi-Sankyo Europe GmbH, München

**Dr. Rainer Edelhäuser**

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

**PD Dr. Thomas Sudhop**

Bundesinstitut für Arzneimittel und  
Medizinprodukte (BfArM), Bonn

**Prof. Dr. Dr. med. Thomas Thum**

Institutsleiter des Fraunhofer-Instituts für  
Toxikologie und Experimentelle Medizin ITEM  
und Chief Scientific Officer, Cardior  
Pharmaceuticals, Hannover

**Dr. Andreas Franken**

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

**Moderation:**

**Prof. Dr. Karl Broich and  
Prof. Burkhard Sträter**

## The Program on September 13th 2021

- 9.30 a.m.**            **Opening of the Annual Congress and Introduction to Sessions**  
*Dr. Ulrich Granzner, Granzner Regulatory Consulting & Services*
- 9.45 a.m.**            **EMA: Our Way in Pharmaceutical Strategy and International Collaboration**  
*Emer Cooke, Executive Director EMA*
- 10.30 a.m.**          **EU Regulatory Network: Lessons learned from the Pandemic**  
*Dr. Christa Wirthumer-Hoche, Chair of Management Board EMA, Head of the Austrian Medicines and Medical Devices Agency*
- 11.00 a.m.**          **Coffee Break**
- 11.30 a.m.**          **New Roles in Digitalization, Data Science and Health Care Research**  
*Prof. Dr. Karl Broich, President BfArM*
- 12.00 p.m.**          **Industry Perspective on the Current Regulatory Climate**  
*Dr. Max Wegner, Bayer AG*
- 12.30 p.m.**          **Panel discussion**
- 12.45 p.m.**          **Lunch**
- 1.45 p.m.**            **Fighting the Pandemic: Contributions of the PEI**  
*Prof. Dr. Klaus Cichutek, President PEI*
- 2.30 p.m.**            **Micro RNAs: A new Class of Substances for the Therapy of Diseases**
  - From the laboratory to proof of concept in animals and humans
  - Experience with regulatory authorities*Prof. Dr. Dr. Thomas Thum*

- 3.15 p.m.**      **EU-HTA-Regulation**  
    ➤ Status of Procedure – German Positions and Initiatives  
*Dr. Lars Nickel, BMG*
- 3.45 p.m.**      **HTA meets Regulatory Affairs**  
*Dr. Anna Silke Hammerbacher, Daiichi-Sankyo Europe GmbH*
- 4.15 p.m.**      **Panel discussion**
- 4.30 p.m.**      **Coffee Break**
- 4.45 p.m.**      **DGRA General Membership Meeting**  
*(ends around 5.30 p.m.)*
- 7.00 p.m.**      **Pre-Dinner Speech**  
*Reception (6.30 p.m.) and Buffet*

## **The Program on September 14th 2021**

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

**10.00 a.m. Medical Device Regulation (MDR) – an Update**

*Dr. Rainer Edelhäuser, Director ZLG*

**10.45 a.m. Digitalization of the Healthcare System Electronic Product Information (e-PI)**

- Projects on national/European/international level
- Key Principles for access and dissemination
- Electronic Paper or Structured Information approach

*Dr. Andreas Franken, BAH*

**11.30 a.m. Coffee Break**

**12.00 p.m. Clinical Trial Regulation – an Update**

- Outcomes of Pilot Procedures in BfArM

*PD Dr. Thomas Sudhop, BfArM*

**1.00 p.m. Panel discussion**

**1.30 p.m. Lunch**

**(There may be changes to the program)**

**Dates:**

September 13, 2021, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	4.45 p.m.	
Rheinhotel Dreesen	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
September 14, 2021, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions

**Venue:**

World Conference Center Bonn	Rheinhotel Dreesen
Platz der Vereinten Nationen 2	Rheinstrasse 45-49 ·
Plenarsaal	D-53179 Bonn
53113 Bonn	

**Registration fees:**

Participation in face-to-face event:

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 € (face-to-face event), 250 € (virtual)

Participation virtual via Zoom:

For DGRA members: € 300

For non-members: € 450

**Cancellation terms:**

Cancellation will be charged with a processing fee of 50 €.

In case of short-term cancellation (2 weeks before) 50 % of the registration fee will be charged.

One week before the event the full fee has to be paid, unless a substitute participant (DGRA member) is named.

**Conference languages:**

English (Morning of September 13) and German

**Note:**

Photographers will accompany the workshop.

Some photographic material will be published.

Workshop documents will include two lists of participants (attending and online 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.

Ameron Königshof  
Bonn-Innenstadt  
[reservierung@hotel-koenigshof-bonn.de](mailto:reservierung@hotel-koenigshof-bonn.de)  
keyword „DGRA120921“

Rheinhotel Dreesen  
Bonn-Bad Godesberg  
[reservierung@rheinhoteldreesen.de](mailto:reservierung@rheinhoteldreesen.de)  
keyword "DGRA-Jahreskongress"

Boutiquehotel Dreesen GmbH & Co.KG  
Mirbachstrasse 2a  
53173 Bonn  
[info@boutiquehoteldreesen.de](mailto:info@boutiquehoteldreesen.de)

Intercity Hotel  
Bonn-Innenstadt  
[reservations.bonn@intercityhotel.com](mailto:reservations.bonn@intercityhotel.com)  
Keyword „DGRA“

**More hotel rooms can be booked directly on the internet:**

<https://www.bonn-region.de/events/dgra2021.html>

Each participant booking her/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

The registration is binding. After receipt of the registration a written confirmation will be sent.