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.

➢ 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. 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

Dr. Rainer Edelhäuser
Direktor der Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG), 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. Max Wegner
Bayer AG, Wuppertal

Dr. Ulrich Granzer
Granzer Regulatory Consulting & Services, München

Dr. Lars Nickel
Bundesministerium für Gesundheit (BMG), Berlin

Dr. Anna Silke Hammerbacher
Daiichi-Sankyo Europe GmbH, München

PD Dr. Thomas Sudhop
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

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 Granzer, Granzer 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. Rheinhotel Dreesen 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 Student discount: Registered students of MDRA course and delegates of organizations
For non-members: € 830

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
keyword „DGRA120921“
Rheinhotel Dreesen
Bonn-Bad Godesberg reservierung@rheinhoteldreesen.de
keyword „DGRA-Jahreskongress“

Boutiquehotel Dreesen GmbH & Co.KG
Mirbachstrasse 2a reservations.bonn@intercityhotel.com
53173 Bonn Keyword „DGRA“
info@boutiquehoteldreesen.de

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 or contact us at 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.