

23rd DGRA Annual Congress

September 13th and 14th, 2021 in Bonn
In the former Assembly Room of the German Bundestag
(Plenarsaal)

- Brexit, Relocation of EMA
- HTA
- Digitalisation of the Healthcare System
- Development Challenges in New Vaccines

with

Emer Cooke

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

Dr. Rainer Edelhäuser

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

N.N. in (angefragt)

Dr. Max Wegner

Bayer AG, Wuppertal

Dr. Ulrich Granzer

Granzer Regulatory Consulting & Services,
München

Thomas Müller

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, 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.** **Änderungen bei EMA, DIMDI, BfArM - Industriesicht**
Dr. Max Wegner, Bayer AG
- 12.30 p.m.** **Panel discussion**
- 12.45 p.m.** **Lunch / Dinner**
- 1.45 p.m.** **Fighting the Pandemic: Contributions of the PEI**
Prof. Dr. Klaus Cichutek, President PEI
- 2.30 p.m.** **Development Challenges in New Vaccines**
 ➤ How to make a vaccine in record time?
N.N.
- 3.15 p.m.** **EU-HTA-Regulation**
 ➤ Status of Procedure – German Positions and Initiatives
Thomas Müller, 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.** **Title**
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 / Dinner**

(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.	
Hotel Königshof	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
September 14, 2020, 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:

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:

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 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.

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
53173 Bonn
info@boutiquehoteldreesen.de

Intercity Hotel
Bonn-Innenstadt
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 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.