

25th DGRA Annual Congress

May 4th and 5th, 2023 in Bonn

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

- Reform of EU
Pharmaceutical
Legislation
- ICMRA
- Big Data
- EU-HTA
- MDR
- CTIS
- UNICOM Project

with

Prof. Dr. Karl Broich

Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Bonn

Manuela Buxo

Sanofi Genzyme, Amsterdam

Prof. Dr. Klaus Cichutek

Paul-Ehrlich-Institut (PEI), Langen

Dr. Thomas Ecker

Ecker + Ecker GmbH, Hamburg

Dr. Angela Graf

Kanzlei Lückner MP-Recht, Essen

Jesper Kjær

Danish Medicines Agency (DKMA), Kopenhagen

Riccardo Luigetti

European Medicines Agency (EMA), Amsterdam

Georg Neuwirther

Austrian Medicines and Medical Devices Agency
(AGES), Wien

Florian Schmidt

European Commission, Brüssel

Beata Stępniewska,

Medicines for Europe, Brüssel

PD Dr. Thomas Sudhop

Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Bonn

Gabriela Zenhäusern (angefragt)

swissmedic, Bern

Moderation:

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

The Program on May 4th 2023

- 9.30 a.m.** **Opening and Introduction to Sessions**
Dr. Ulrich Gränzer and Prof. Burkhard Sträter
- 9.45 a.m.** **Reform of EU Pharmaceutical Legislation
Concept from the Perspective of the European
Commission**
Florian Schmidt
- 10.15 a.m.** **Impact on the Generic Market in the EU**
Beata Stepniewska
- 10.45 a.m.** **Coffee Break**
- 11.15 a.m.** **Impact for Research-Based Pharmaceutical Companies**
Manuela Buxo
- 11.45 a.m.** **Panel Discussion** (*What`s in for patients?*)
- 12.15 a.m.** **Lunch**
- 1.15 p.m.** **International Coalition of Medicines Regulatory
Authorities (ICMRA)**
• From Crisis Management to better Regulation
Riccardo Luigetti
- 1.45 p.m.** **Experiences from the Perspective of a National
Regulatory Authority**
Prof. Dr. Klaus Cichutek
- 2.15 p.m.** **ICMRA / Pharmaceutical Quality Knowledge
Management System (PQKMS) as Example for
Working Together**
Gabriela Zenhäusern
- 2.45 p.m.** **Panel Discussion**

- 3.15 p.m.** **Coffee Break**
- 3.45 p.m.** **Relevance of Big Data for Regulatory Procedures**
Jesper Kjær
- 4.15 p.m.** **Health Data Lab at BfArM – Concepts for Use and
Evaluation / Interaction with European Activities
(EHDS)**
Prof. Dr. Karl Broich
- 4.45 p.m.** **Discussion**
- 5.10 p.m.** **Break** (*no Catering*)
- 5.15 p.m.** **DGRA General Membership Meeting**
(ends around 5.45 p.m.)
- 7.00 p.m.** **Pre-Dinner Speech**
Reception (6.30 p.m.) and Buffet

The Program on May 5th 2023

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

10.00 a.m. **The UNICOM Project**
Georg Neuwirther

10.30 a.m. **Upcoming EU-HTA: How can Pharmaceutical
Industry prepare? Now!**
Dr. Thomas Ecker

11.15 a.m. **Coffee Break**

11.45 a.m. **Clinical Trial Regulation – an Update**
PD Dr. Thomas Sudhop

12.15 p.m. **Medical Device Regulation**

- Implementation Problems
- Extension of the Transitional Periods

Dr. Angela Graf

1.15 p.m. **Final Discussion**

1.30 p.m. **Lunch**

(There may be changes to the program)

Dates:

May 4th, 2023, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	5.15 p.m.	
La Redoute	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
May 5th, 2023, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions

Venue:

World Conference Center Bonn	La Redoute
Platz der Vereinten Nationen 2	Kurfürstenallee 1
Plenarsaal	D-53177 Bonn
53113 Bonn	

Registration fees:

Participation in face-to-face event:

For DGRA members: € 690

For non-members: € 870

Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: 390 €.

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 May 4th) and German

Note:

Photographers will accompany the congress.

Some photographic material will be published.

Congress 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 „DGRA“

Boutiquehotel Dreesen GmbH & Co.KG
Mirbachstrasse 2a
53173 Bonn
info@boutiquehoteldreesen.de

More hotel rooms can be booked directly on the internet:

<https://www.bonn-region.de/events/dgra-jahreskongress-2023.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.