

15th ANNIVERSARY OF BADI CONFERENCE

Under the Motto **“MEET THE REGULATORS“**

(with **EMA**  **EMA** & **BDA** )

Regulatory Affairs Update Conference

09 October 2025

Grand Hotel Millennium - Sofia, Bulgaria, Hall Da Vinci, 89B Vitosha Blvd.



DRAFT PROGRAMME

- 11.30 - 12.30** **Registration and Welcome Coffee**
- Session 1** **Moderators*: Tatyana Benisheva, Birka Lehmann, Ekaterina Genova**
- 12.30 - 13.00** **Welcome and Opening Speeches – Dobriana Sidgimova**
- The challenges, achievements and a future plan of BADI over the 15 years**
BADI and Barbara Sickmueller, President German DGRA)
- 13.15 - 14.00** **Strategy management at the competent authority in Bulgaria**
Bogdan Kirilov, Executive Director Bulgarian Drug Agency, BDA
- 14.00 -14.45** **Seizing opportunities in a changing medicines landscape**
Emer Cooke, Executive Director European Medicines Agency, EMA
- 14.45 - 15.30** **New provisions in the pharma legislation - will they solve the challenges of the coming years concerning pharmaceuticals?**
Christa Wirthumer-Hoche, former Head of the Austrian Medicines and Medical Devices Agency, and former Chair EMA Management Board”
- 15.30 - 16.00** **Coffee break**
- Session 2** **Moderators*: Tatyana Benisheva, Brigitte Franke-Bray, Lena Gebert, Louise Kirkegaard**
- 16.00 - 16.45** **Discussion of the current changes in the EU pharmaceutical legislation 2025**
Barbara Sickmueller, President of the German Society for Regulatory Affairs ,DGRA

- 16.45 - 17.00** **The revision of the pharmaceutical legislation - a pivotal opportunity to strengthen Europe's global leadership in innovation.** *Dean Denev, Executive Director ARPharm, Bulgaria*
- 17.00 - 17.45** **Regulators' benefit-risk assessment as contribution to subsequent Health Technology Assessment**
Harald Enzmann, Head of Executive Department: EU and International Affairs, Federal Institute for Drugs and Medical Devices, BfArM, and former Chair of CHMP, EMA
- 17.45 - 18.15** **Regulatory Challenges after EU Accession**
Lubina Todorova, Bulgarian, CHMP Member, Director of Marketing Authorisation Department of Medicinal Products; Bulgarian Drug Agency, BDA
- 18.15 - 18.30** **Closing remarks**
Tatyana Benisheva, President BADI
- 18.30 - 22.00** **Cocktail and Life Programme (Networking Party)**
*Moderators: Members of BADI Advisory Board

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