BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

JUNE 04, 2021 | 9:30 am – 4:00 pm |Digital event only via Cisco Webex

DRUG REGULATORY AFFAIRS – UPDATE

Annual Virtual Meeting of BADI

THE LECTURERS

WWW.BADIBG.ORG

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Prof. Dr. rer. nat. Barbara Sickmüller is a pharmacist. She studied and obtained her doctorate at the Philipps University in Marburg - Germany (1967-1974).

From 1977 she worked as a scientific executive at the Association of the German Pharmaceutical Industry (BPI) and took over the section "Drug Safety" of BPI in 1979. 1984/1985 she had a sabbatical year in the USA with training into US drug legislation. From 1988 she was appointed as head of the department "Medical affairs" and from 1997 Director of the Medicines and Pharmacy Division of BPI. In 2000 she was appointed as Deputy Director General of BPI.

Since 1987 until 2011 she gave yearly lectures in the department of Pharmacy, University of Marburg, and was appointed honorary Professor of the University of Marburg/Lahn (Januar 2000). In addition, she gave lectures for the Master of Drug Regulatory Affairs at the University in Bonn. She had further teaching assignments at the Universities of Frankfurt and Heidelberg on Pharmacovigilance and clinical trials, and has published numerous publications and book contributions in these regulatory areas.

The German Ministry of Health appointed her as Member of the Advisory Committee on prescription of pharmaceutical products, the Commission on Medicines for Children and Adolescents (KAKJ) and member of the Board of Trustees of the Institute for Quality and Efficiency in Health Care (IQWiG) and a member of the Board of Trustees of the German Agency for Health Technology Assessment (HTA) at DIMDI.

She was member of several Working Groups of the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization of Marketing Authorization Requirements (ICH) in the areas of pharmacovigilance and clinical trials.

Since March 2012 she has retired and is now active as Senior Scientific Advisor for BPI. Furthermore,she gives lectures on Pharmacovigilance and clinical trials at the Universities in Bonn, Heidelberg and Marburg.

In July 2014 she was appointed President of the German Association for Regulatory Affairs (DGRA)in Bonn and in October 2014 as member of the university council of the University of Applied Sciences of Central Hesse (THM) in Gießen.

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Dr. Birka Lehmann
Senior Expert Drug Regulatory Affairs

Head of Executive Department EU and International Affairs of the Federal Institute for Drugs and Medical Devices (BfArM) since October 2011 till March 2016.
Study of Human Medicines at the Free University Berlin (MD, PhD) and training at the Kinderklinik Norderney.
My working experience includes 9 years preclinical assessment in the division 'Pharmacology and Toxicology' of Federal Health Office. I served as head of unit 'Decentralised Procedure' (1996-2002) Federal Institute for Drugs and Medical Devices and as deputy head of EU Division (2000-2002) and supported the Committee Human Medicines Products of the European Medicines Agency (EMA) as expert.
From 2002 – 2006 I joined the European Commission, Directorate-General Enterprise and Industry as expert on secondment to in the unit 'Pharmaceuticals' responsible for inter alia Marketing Authorisation and implementation of Clinical Trials Directive.
From September 2006 till October 2011 I was head of the division 3 Marketing Authorisation procedure at the BfArM. Since 2007 I was member of the Paediatric Committee at the European Medicines Agency till end of 2015.
Lecturer:
Friedrich-Wilhelm-University Bonn (Master of Drug Regulatory Affairs) since 1999

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Marta Swierczynska
Senior Manager Regulatory Affairs at SFL

She leads projects focusing mainly on regulatory and medical aspects for medical devices, IVDs, and combination products. She advises clients on defining regulatory strategies for a broad range of products across different therapeutic areas. She uses her scientific knowledge and communication skills to produce high-quality materials specifically tailored to the client's needs. She prepares regulatory documents required for submission to Health Authorities and Notified Bodies in Switzerland and globally, such as briefing books, Clinical Evaluation Plans and Reports, as well as other Technical Documentation components.

Before joining SFL, Marta's academic research focused on endocrinology. This included postdoctoral research at the Center of Molecular Life Sciences of the University of Basel, Switzerland, and doctoral research at the Max Planck Institute of Molecular Cell Biology and Genetics in Dresden, Germany. She holds a PhD in Cell Biology from the Medical Faculty of the Technical University Dresden and is an alumna of the University of Warsaw, Poland.

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Karl-Heinz Loebel

After having studies Chemistry at Heidelberg University, Germany, Karl-Heinz started his professional career with a biotech start-up company specialized in phytopharmaceuticals before he switched to Regulatory Affairs.

For the last 16 years he has been affiliated to PHARMALEX in various leading Regulatory Operations roles and responsibilities, involving e-submission strategy development and project-management, in-house and on client premises. He is a much-acclaimed expert in electronic submissions and regulatory information management. Besides his ongoing tasks overseeing and supporting electronic submissions of all categories he also acts as the PHARMALEX lead consultant for e-submission and RIMS software implementation and customization projects. His eCTD experience covers all established eCTD regions as well as recent newcomers like GCC and EAEU countries.

For the clients in the PHARMALEX pharmacovigilance portfolio, Karl-Heinz co-ordinates XEVMPD data acquisition and maintenance activities. As an industry representative he is a member of the European Medicines Agency's XEVMPD Implementation Working Group and the SPOR/IDMP Implementation Task Force.

His public appearances include recurrent training courses on eSubmission, RIM and SPOR/IDMP for Forum Institute, Pharmaceutical Training International, DIA and lectures on eSubmission topics at various German Universities.

Within PHARMALEX Karl-Heinz currently holds the position of Director, Principal Consultant Regulatory Operations & Industry/Agency Liaisons.

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Prof. Dr. Folker Spitzenberger, PhD (Molecular Biology), Chemist (Diploma), Drug Regulatory Affairs (Master, MDRA), Fachhochschule Lübeck, University of Applied Sciences, Focus area of clinical/scientific work. Drug and medical device regulatory affairs, standardization, quality management, conformity, assessment, accreditation, laboratory medicine, in vitro diagnostic medical devices ; Experience in international projects. Since 2005 until present experience as consultant, scientific expert, advisor for WHO, EU, PTB and other organizations in numerous international projects related to regulatory affairs, quality assurance, quality management, biosafety/biosecurity, accreditation/certification and standardization of medical/health laboratories. Membership of Scientific Societies /Relevant Professional Bodies

1. ISO TC 212: „Clinical laboratory testing and in vitro diagnostic test systems“
2. CEN TC 140 „Clinical laboratory testing and in vitro diagnostic test systems“
3. German Standards Committee DIN NAMed „Quality Management in medical laboratories“ with the following functions: 1. Member and Chair of the German delegation; 2. Chairman of CEN TC 140 WG 3; 3. Chairman of the German standards committee. Member of the Scientific Board of DIW-MTA e. V.

Training and Education: International work experience as senior scientist, quality assessor and quality expert for all kinds of quality systems related to the: In vitro diagnostic medical devices (IVDMD) sector including branches as accreditation and designation (German Accreditation Body DAkkS; Central Authority of the Laender for health protection regarding medicinal products and medical devices ZLG); Certification and GMP (International projects for WHO, EU and others); risk assessment and vigilance (Paul-Ehrlich-Institute PEI); Disease control and prevention (Robert Koch-Institute RKI).

Numerous publications and projects in the field of quality assurance/quality management,
Standardization and regulatory affairs related to the IVDMD sector.

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Veska Gergova graduated University of Sofia "St. Kliment Ohridski" in 2012 with a Master's degree in Law. In 2017 she obtained Master's degree in Public Health and Health Management from the Medical University of Sofia, Faculty of Public Health. Since 2018 she is a PhD Candidate at the Medical University of Sofia, Faculty of Public Health. Her professional experience started as a Legal Advisor in the Legal Department of Bulgarian Drug Agency. Since September 2019, she is Head of Division "Legal Service, Human Resources and International Cooperation" in Bulgarian Drug Agency. She is interested in Administrative Law and Pharmaceutical Law.

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Margarita Strokova, MD has master's degree in Medicine from Medical University, Sofia and Master of Business Administration from New Bulgarian University, Sofia. Joined Pharma Industry in 1997 and has extensive experience in pharmaceutical marketing, scientific communication, Medical Governance and Pharmacovigilance (for products both under clinical trials and marketed). Worked for over 13 years as local person responsible for Pharmacovigilance in GSK Bulgaria and has 3 years experience as Local Country Medical Head. In Feb 2021 joined IQVIA as Associate Manager, Safety Operations Team.

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Daniela Cherneva, PhD

Daniela Cherneva graduated from Sofia University “St. Kliment Ohridski” in 2008 with a Bachelor’s degree in Russian philology. In 2011 she graduated from New Bulgarian University in Sofia with Master’s degree in International Business and in June 2015 she obtained a Master’s degree in Public Health and Healthcare Management from the Faculty of Public Health of the Medical University in Sofia. In April 2021 Daniela obtained a PhD in the Faculty of Public Health, Medical University in Sofia with a dissertation on “Challenges in front of the reference pricing of generic medicines in Europe”.

She has 13 years of experience in the Regulatory Affairs, currently in the position of Regulatory Affairs Manager in Medochemie Ltd. Bulgaria.
During her professional life she gained broad experience not only in Regulatory Affairs, but also in pricing and reimbursement, market access, pharmacovigilance, life-cycle product management, etc. Daniela has more than 16 publications and conference participations in the field of Regulatory Affairs and is a member of the Bulgarian Association for Drug Information (BADI) and the International Society for Pharmacoeconomic and Outcome Research (ISPOR).

danicherneva@gmail.com

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Prof. Tatyana Benisheva - Dimitrova, DSc., President of BADI is a professor in the Faculty of Public Health at Medical University, Sofia. After receiving an EC-CADREAC scholarship she completed master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn and later in 2010 a Master degree in "Public Health" at the Medical University of Sofia, Bulgaria.
She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has over 10 years of experience at the Bulgarian Drug Agency (BDA). As the first president of the National Council on Prices and Reimbursement of Medicinal Products 2013-2014 she started an EU-project-OPAC for establishing of electronic database of medicinal product.

As a managing director of consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) she developed activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012). She was involved like an expert in the project of the European Commission - PLAC assignment medicinal product pricing in Serbia, in 2016. Prof. Benisheva is member of DIA and DGRA and Board member of the EAMEA, Advisory council at the DIA in Europe, since 2017. Her 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal product) is complemented by more than 100 publications in the regulatory science field of medicines.