

## Curriculum Vitae

### Personal information Tatyana Benisheva

#### Work experience

At the moment Professor at the Medical University - Sofia, Bulgaria in Drug Regulatory Affairs.

She was a Director of the "Drug Policy" Department at the Ministry of Health (MoH) (2000-2005) when the EC clinical trials and drug legislation was elaborated before the EC-join of Bulgaria.

Her over 10 years of experience at the Bulgarian Drug Agency (BDA) help her to duties in her professional career.

As the first president of the Bulgarian HTA Competent Authority (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. At that time she involved the Bulgarian HTA competent authority (National Council on Prices and Reimbursement) in the EUnetHTA network.

Her regulatory experience was accumulated as CRO- Betaconsult Pharma Ltd. (2007-2013) and BORA-Clinical Research Organisation, where was involved in drug regulatory and clinical trials management in different therapeutic fields.

Expert of Thompson Reuters IDRAC was created (2006 -2012) thanks to her knowledge in the field of marketing authorization and pharmacovigilance and kept up to date till 2012 due to her expertise in the drug regulatory field.

#### Education and training

Professor Dr. Tatyana Benisheva-Dimitrova, MD, is a physician (October 1983 - 1985)

Currently professor at the Faculty of Public Health of the Medical University - Sofia, Bulgaria.

She was awarded an EU-CADREAC scholarship, which enabled her to complete a master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn (Germany).

Later, in January 2009, she obtained a master's degree in Public Health at the Medical University of Sofia, Bulgaria. Professor Tatyana Benisheva, DSCI, is part of the Department of Health Management and Health Economics at the Faculty of Public Health, Medical University. She began her academic career in January 2006 and was elected Vice Dean in 2012. She teaches medical students and master's and bachelor's programs related to health management, pharmaceuticals, medical devices, and cosmetic products at the Faculty of Public Health at MU-Sofia.

#### Additional information

##### Publications

##### Projects

Projects:

She has participated in various projects:

- Project "Development of Proposals for Improving Public Participation in the Pricing and Reimbursement of Medicines, Formation, and Accounting of Public/Budgetary Healthcare Expenditures in the Field of Medicines," funded by the "Good Governance" Operational Program, co-financed by the EU through the European Social Fund (2019-2021).-

"Operational Program Administrative Capacity" (OPAC): The National Council on Drug Pricing and Reimbursement was a beneficiary under this project, implemented with financial support from the Operational Program

"Administrative Capacity" 2007-2013, co-financed by the EU through the European Social Fund, Priority Axis III:

"Quality Administrative Service and Development of E-Governance," and executed under Contract 13-31-13/11.04.2014.

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##### Memberships

Memberships in Committees

- Member of the Permanent Commission on Healthcare and Sports at the National Evaluation and Accreditation Agency (2019-2024).

- Member of the Ethics Committee for Clinical Trials at the Ministry of Health and MedEthicsEU. (2024)

Membership in Bulgarian Organizations

- Chairperson of Bulgarian Association for Drug Information (BADI) - [www.badi.bg.org](http://www.badi.bg.org)

- Member of the Board of the Union of Bulgarian Medical Specialists

- Member of the Bulgarian Association for Public Health

- Member of the Bulgarian Association for Personalized Medicine

- Member of the Bulgarian Association for Patient Protection

Membership in International Organizations

- Advisory Council Europe of DIA (ACE - DIA) 2010- 2018

- DGRA, Drug Regulatory Affairs - [www.dgra.de](http://www.dgra.de) (since 2005)

- IFAPP - International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine - Board

Member - [www.ifapp.org](http://www.ifapp.org)

#### Other Relevant Information

Awards

-"Golden Panacea" Award (2010) from the Academic Council of MU-Sofia

-Honorary Award SIGMUS LAUDIS (2024) from the Academic Council of MU-Sofia  
- Award for the 2006 Graduate Class at the University of Bonn, Germany

**Publications**

With over 25 years of experience in drug regulatory affairs (lifecycle management and market access of medicinal products), she has authored more than 150 publications in clinical and drug regulatory field and three monographs, with over 100 citations in the field of pharmaceutical regulatory science.