



## Curriculum Vitae

Personal information **Lyudmil Antonov**

### Work experience

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1. Employer: Bulgarian Drug Agency
  - Start date: 10.2004
  - End date: Present
  - Position: Chief Expert
  - Activities: Assessing medicinal products dossiers Issuing Marketing Authorisations
  - Country: Bulgaria
2. Employer: Diagnosis C & S Ltd.
  - Start date: 02.2001
  - End date: 10.2004
  - Position: Medical Statistician and IT Manager
  - Activities: Statistics support of clinical trials Administration of the corporate IT System
  - Country: Bulgaria
3. Employer: Institute of Genetic Engineering
  - Start date: 09.1987
  - End date: 01.2001
  - Position: Biostatistician and Research Associate
  - Activities: Statistical support of research activities
  - Country: Bulgaria
4. Employer: Institute of Molecular Biology
  - Start date: 08.1983
  - End date: 08.1987
  - Position: Biostatistician
  - Activities: Statistical support of research
  - Country: Bulgaria
5. Employer: Medical Academy, St Naum University Hospital in Neurology, Psychiatry and Neurosurgery
  - Start date: 06.1980
  - End date: 07.1983
  - Position: Statistician
  - Activities: Statistical analysis of results from clinical trials Set\_up of experimental design
  - Country: Bulgaria

### Education and training

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1. Subject: Molecular and Computational Biology
  - Start date: 10.1975
  - End date: 06.1980
  - Qualification: Master of Science (M.Sc.)
  - Organisation: Sofia University St. Kliment Ohridski
  - Country: Bulgaria
2. Subject: Bio- and Medical Statistics
  - Start date: 01.1981
  - End date: 05.1983
  - Qualification: Post\_Diploma Qualification
  - Organisation: Medical Academy, Sofia
  - Country: Bulgaria
3. Specialisation on a joint VT-IGE project
  - Start date: 09.1988
  - End date: 05.1992
  - Qualification: Graduate Student
  - Organisation: Virginia Polytechnic Institute & State University
  - Country: USA
4. Subject: Microbiology, Virology and Immunology
  - Start date: 06.1992
  - End date: 07.1995
  - Qualification: Doctor of Philosophy (Ph. D.)
  - Organisation: Institute of Genetic Engineering
  - Country: Bulgaria

### Additional information

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#### Publications

1. Chakarska, Deniza and Lyudmil Antonov. Application of intuitionistic fuzzy sets in plant tissue culture and in vitro selection, Notes on IFS, 1(1):70-73, 1995
2. Todorovska E., Atanassova A., Antonov L., Atanassov A. Studies on the mouse rpL32 pseudogene family: features of a new member, Biological Chemistry, 378(12):1531-5, PubMed ID (PMID):9461352, 1997
3. Atanassov I, Antonov L., Russinova E., Atanassov A. Expression of an anther-specific chalcone synthase-like gene is correlated with uninucleate microspore development in Nicotiana sylvestris, Plant Molecular Biology, 38(6):1169-78, PubMed ID (PMID):9869422, 1998
4. Todorovska E., Antonov L., Dudov K. RFLPs in human genome detected by human ribosomal protein cDNA probe, Biotechnology and Biotechnological Equipment, 10(2-3): 10-17, 1996

5. Antonov L., Atanassov A., Dudov K. Site-specific inactivation of bacterial genes involved in plant soft rot, *Biotechnology and Biotechnological Equipment* 9(1):14-28, 1995
6. Vayda M., Yang Z., Antonov L., Butler W. Hypoxic stress inhibits aerobic wound-induced resistance and activates hypoxic resistance to bacterial soft rot, *American Potato Journal*, 69(4):239-253, DOI 10.1007/BF02853878, 1992
7. Antonov L., Milanov K. Antibodies to myelin basic protein in multiple sclerosis: a long-term study, *Bulletin of the Institute of Neurology, Psychiatry and Neurosurgery*, 27:65-68, 1983
8. Milanov K., Antonov L., Manolova Z. Microcomplement fixation with myelin basic protein as a test for multiple sclerosis, *Bulletin of the Institute of Neurology, Psychiatry and Neurosurgery*, 27:69-72, 1983
9. Antonov L. and Milanov K. Inhibition of synaptic acetylcholinesterase by antibodies found in sera of schizophrenic patients, *Bulletin of the Institute of Neurology, Psychiatry and Neurosurgery*, 6:105-108, 1982
10. A. Stoimenova, Lyudmil Antonov. Biological, biotechnological and biosimilar medicinal products, *Annual for Hospital Pharmacy*, 1(1): 16-24, 2015
11. A. Stoimenova, A. Savova, Lyudmil Antonov. Quality assurance aspects of the biotechnological medicinal products. Chapter 9 in *Biotechnological medicines: from the laboratory to the patient*. St. Kliment Ohridski University Publishing House. Sofia, 2016
12. Fauconnier A., Antonov L. Manufacturing and quality control issues: Quality development of biosimilar medicinal products. Chapter 5 in *Biosimilar Drug Product Development*, Vol. 216 of *Drugs and the Pharmaceutical Sciences Series* (L. Endrenyi, P. Declerck, Sh.\_Ch. Chow, eds.), CRC Press, Taylor & Francis Group, LLC, Boca Raton, FL, 2017
13. Bogdan Kirilov, Lyudmil Antonov, E. Grigorov. Dynamics and sources of adverse drug reaction reports related to COVID-19 vaccines in Bulgaria (in Bulgarian). *Sotsialna medicina*, Medical University-Varna, 2023

## Projects

- Small nuclear RNAs and spliceosomes in eukaryotes, 1978-1980, MSc. Thesis
- Immunological activities of myelin basic protein in multiple sclerosis, 1980-1983
- Sequence analysis of ribosomal RNA genes in eukaryotes, 1983-1986
- Comparative analysis of pectate lyase genes from the bacterium *Erwinia carotovora*, 1987-1992, Ph. D. Dissertation
- Sequence analysis of chalcone synthase gene from *Nicotiana tabacum*, 1993-1996
- Sequence analysis of the mouse L32 pseudogene family, 1997-2000
- Statistical analysis of clinical bioequivalence studies at Diagnosis C & S Ltd., 2001-2004
- Statistical analysis of the pharmacovigilance database at the Bulgarian Drug Agency, 2020-Present

## Memberships

- BWP Member, EMA, 2009-Present
- TIGes Member, EMA, 2008-2013
- CMDh Member, EMA, 2015-2021
- Member of the Editorial Board of "Biotechnology and Biotechnological Equipment", 1997-2001
- Member of Bulgarian Association for Medicinal Information, 2011-Present

## Other Relevant Information

- Evaluation team member for the statistical part of the CP procedure for GAZIVARO (obinutuzumab), Roche Registration Ltd.
- Evaluation team member for the statistical part (Design space) of the veterinary CP procedure for Imrestor (Pegbovigrastrim), Elanco GmbH
- Consultant for the scientific advice (statistical part, Q4) of RGB-03 (Rituximab biosimilar to Mabthera), Gedeon Richter Plc., EMEA/H/SA/2222/1/FU/2/2014/III
- Consultant for the scientific advice (statistical part) of Repatha (evolocumab), Amgen
- Consultant for the scientific advice (statistical analysis of stability studies) of Focetria (influenza vaccine H1N1V (surface antigen, inactivated, adjuvanted), Novartis Vaccines and Diagnostics s.r.l.
- Core Team Member on Reflection Paper "Statistical Methodology for the comparative assessment of quality attributes in drug development", EMA Project
- Moderator at Session 3 "Statistical Considerations in Setting Acceptance Criteria" at Expert Workshop on Setting Specifications for Biotech Products, 9 Sept. 2011, EMA