

Curriculum Vitae

Personal information **Gianina-Nicoleta Andrei**

Work experience

1. Employer: National Medicines Agency
 - Start date: 072000
 - End date: 072004
 - Position: Biologist, Biological Products Evaluation and Control Department, Specific Microbiology Laboratory
 - Activities: _ Testing of biological products (e.g. sterility, concentration, identity) _ Quality Assessment of Biological Medicinal Products (national procedures)
 - Country: Romania
2. Employer: National Medicines Agency
 - Start date: 082004
 - End date: 072009
 - Position: Specialist Biologist, Biological Products Evaluation and Control Department, Cell Cultures Determinations and Specific Microbiology Laboratory
 - Activities: _ Testing of biological products (e.g. sterility, concentration, identity) _ Implementation of new tests (e.g. assay, thermal stability) _ Quality Assessment of MA / renewal of MA / variation to a MA applications for Biological Medicinal Products (national procedures, MR/DC procedures)
 - Country: Romania
3. Employer: National Agency for Medicines and Medical Devices
 - Start date: 082009
 - End date: 112012
 - Position: Senior Biologist, Biological Products Evaluation and Control Department, Cell Cultures Determinations and Specific Microbiology Laboratory
 - Activities: _ Testing of biological products (e.g. concentration, identity, assay, thermal stability) _ Quality Assessment of MA / renewal of MA / variation to a MA applications for Biological Medicinal Products (national procedures, MR/DC procedures) _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures, VHP procedures)
 - Country: Romania
4. Employer: National Agency for Medicines and Medical Devices
 - Start date: 092010
 - End date:
 - Position: Deputy Head of Biological Products Evaluation and Control Department
 - Activities: Specific duties / responsibilities of the head of department during her absence periods
 - Country: Romania
5. Employer: National Agency for Medicines and Medical Devices
 - Start date: 122012
 - End date:
 - Position: Head of Cell Cultures Determinations and Specific Microbiology Laboratory
 - Activities: _ Managerial responsibilities _ Testing of biological products (e.g. concentration, identity, assay, thermal stability) _ Quality Assessment of MA / renewal of MA / variation to a MA applications for Biological Medicinal Products (national procedures, MR/DC procedures) _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures, VHP procedures)
 - Country: Romania
6. Employer: National Agency for Medicines and Medical Devices from Romania, Directorate of Medicines Quality Control
 - Start date: 012017
 - End date:
 - Position: Head of Cell Cultures Determinations and Microbiology Laboratory
 - Activities: _ Managerial responsibilities _ Testing of medicinal products (e.g. concentration, identity, assay, thermal stability, sterility, microbiological examination of non-sterile products, microbiological assay of antibiotics, bacterial endotoxins) _ Quality Assessment of MA / renewal of MA / variation to a MA applications for Biological Medicinal Products (national procedures, MR/DC/CP procedures) _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures, VHP procedures)
 - Country: Romania

Education and training

1. Subject: Faculty of Biology, University of Bucharest
 - Start date: 101995
 - End date: 061999
 - Qualification: Biologist
 - Organisation:
 - Country: Romania
2. Subject: Faculty of Biology, University of Bucharest
 - Start date: 101999
 - End date: 022001
 - Qualification: Master degree in Genetics
 - Organisation:

- Country: Romania
- 3. Subject: QUASARO s.r.l.
 - Start date: 052009
 - End date:
 - Qualification: "ISO 9001:2008 Quality Management" _ Certificate
 - Organisation:
 - Country: Romania
- 4. Subject: European Medicines Agency _ The Committee for Advanced Therapies (CAT)
 - Start date: 042011
 - End date:
 - Qualification: Training for Advanced Therapy Medicinal Products (ATMPs) Assessors
 - Organisation:
 - Country: United Kingdom
- 5. Subject: European Medicines Agency
 - Start date: 092011
 - End date:
 - Qualification: Assessor training on evaluation of quality, safety and efficacy of blood products
 - Organisation:
 - Country: United Kingdom
- 6. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 092014
 - End date:
 - Qualification: Training course for auditors of the MJA/MJV Scheme of the OMCL Network
 - Organisation:
 - Country: France
- 7. Subject: World Health Organization
 - Start date: 022016
 - End date: 032016
 - Qualification: Global Learning Opportunities for Vaccine Quality (GLO/VQ) Product Evaluation for Marketing Authorization training course
 - Organisation:
 - Country: Turkey
- 8. Subject: Scientific Institute of Public Health
 - Start date: 092016
 - End date:
 - Qualification: MMR potency assay training
 - Organisation:
 - Country: Belgium
- 9. Subject: Federal Institute for Drugs and Medical Devices (BfArM)
 - Start date: 102017
 - End date:
 - Qualification: Analytical and functional assessment of biosimilars
 - Organisation:
 - Country: Germany
- 10. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 092018
 - End date:
 - Qualification: Training on what's new/ different in ISO 17025:2017
 - Organisation:
 - Country: France
- 11. Subject: European Medicines Agency
 - Start date: 092018
 - End date:
 - Qualification: GMP for ATMPs training
 - Organisation:
 - Country: United Kingdom

Additional information

Publications

Lazar V, Cernat R, Balotescu C, Boulean F, Andrei G, Stewart_Tull D (2004): Study of cell surface hydrophobicity and its correlation with bacterial adherence capacity to catheter sections. Clinical Microbiology and Infection, volume 10, supplement 3, p. 609
 Adiaconitei F, Andrei G (2005): Thiomersal in vaccines and its influence on vaccinated children. The first National Conference of OBBCSSR, Bucharest, p. 19

Projects

Memberships

since 2011: Alternate Member of the Biologics Working Party (BWP) 2013_10.2020: Alternate Member of the Committee for Advanced Therapies (CAT)

Other Relevant Information

2010: presentation on "Foray into the quality assessment field of biological products", project for "Increasing the expertise in pharmaceutical regulatory field _ CERF", University of Medicine and Pharmacy "Carol Davila", Bucharest
 2011: presentation on "Common deficiencies met in the evaluation of biological products", project for "Increasing the expertise in pharmaceutical regulatory field _ CERF", University of Medicine and Pharmacy "Carol Davila", Bucharest
 2011: presentation on "Stability and quality of medicines", project for "Increasing the expertise in pharmaceutical regulatory field _ CERF", University of Medicine and Pharmacy "Carol Davila", Bucharest