



Curriculum Vitae

Personal information Madalina Doru

Work experience

1. Employer: National Medicines Agency _ Biological Products Control Department
 - Start date: 03.2001
 - End date: 08.2005
 - Position: Biologist
 - Activities:
 - _ Quality control of Biological Products for human use by serological methods
 - _ Evaluation for grant of marketing authorisation and related activities for biological products for human use (combined/multivalent vaccines) (since december 2003)
2. Employer: National Medicines Agency _ Biological Products Evaluation and Control Department
 - Country: Romania
 - Start date: 09.2005
 - End date: 11.2010
 - Position: Specialist Biologist
 - Activities:
 - _ Quality control of Biological Products for human use by serological and immunochemical methods
 - _ Evaluation for grant of marketing authorisation and related activities for biological products for human use
3. Employer: National Agency for Medicines and Medical Devices _ Biological Products Evaluation and Control Department
 - Country: Romania
 - Start date: 12.2010
 - End date: 08.2013
 - Position: Head of Laboratory for Serological Determinations _ Specialist Biologist
 - Activities:
 - _ Management of laboratory activities
 - _ Organization, planning, co_ordination, monitoring and control of the laboratory activity.
 - _ Quality control of Biological Products for human use by serological and immunochemical methods
 - _ Batch release activities
 - _ Quality Assessment of biological products for granting of marketing authorizations
4. Employer: National Agency for Medicines and Medical Devices _ Biological Products Evaluation and Control Department
 - Country: Romania
 - Start date: 09.2013
 - End date: 02.2016
 - Position: Head of Laboratory for Serological Determinations, Physico_chemical Determinations and Immunochemistry _ Senior Biologist
 - Activities:
 - _ Management of laboratory activities
 - _ Organization, planning, co_ordination, monitoring and control of the laboratory activity.
 - _ Quality control of Biological Products for human use by serological and immunochemical methods
 - _ Batch release activities
 - _ Quality Assessment of biological products for granting of marketing authorizations (national procedures, MR/DC procedures)
 - _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures)
5. Employer: National Agency for Medicines and Medical Devices _ Biological Products Evaluation and Control Department
 - Country: Romania
 - Start date: 03.2016
 - End date: 12.2016
 - Position: Head of Laboratory for Serological Determinations _ Senior Biologist
 - Activities:
 - _ Management of laboratory activities

- _ Organization, planning, co_ordination, monitoring and control of the laboratory activity.
 - _ Quality control of Biological Products for human use by serological and immunochemical methods
 - _ Batch release activities
 - Quality Assessment of biological products for granting of marketing authorizations (national procedures, MR/DC procedures)
 - _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures)
 - Country: Romania
6. Employer: National Agency for Medicines and Medical Devices _Medicine Quality Evaluation and Control Department
- Start date: 01.2017
 - End date: 02.2018
 - Position: Head of Laboratory for Immunochemical and Serological Determinations _ Senior Biologist
 - Activities:
- Management of laboratory activities
- _ Organization, planning, co_ordination, monitoring and control of the laboratory activity.
 - _ Quality control of Biological Products for human use by serological and immunochemical methods
 - _ Batch release activities
 - Quality Assessment of biological products for granting of marketing authorizations (national procedures, MR/DC procedures)
 - _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures)
 - Country: Romania
7. Employer: National Agency for Medicines and Medical Devices _Medicine Quality Evaluation and Control Department
- Start date: 03.2018
 - End date: 09/2019
 - Position: Head of Physicochemical, Immunochemical and Serological Determinations of Biological Medicines and Pharmacotoxicology Laboratory _ Senior Biologist
 - Activities:
- _ Management of laboratory activities
- _ Organization, planning, co_ordination, monitoring and control of the laboratory activity.
 - _ Quality control of Biological Products for human use by serological and immunochemical methods
 - _ Batch release activities
 - Quality Assessment of biological products for granting of marketing authorizations (national procedures, MR/DC procedures)
 - _ Quality Assessment of clinical trial applications for Biological Medicinal Products (national procedures)
 - Country: Romania
8. Employer: National Agency for Medicines and Medical Devices _Medicine Quality Evaluation and Control Department
- Start date: 05.2018
 - End date:
 - Position: Quality Assurance Responsible
 - Activities:
- Implementation and management of a quality assurance system based on ISO/IEC 17025 in the Medicine Quality Evaluation and Control Department
- Country: Romania

Education and training

1. Subject: Faculty of Biology, University of Bucharest
 - Start date: 10.1996
 - End date: 06.2000
 - Qualification: Biologist, University degree
 - Organisation:
 - Country: Romania
2. Subject: Faculty of Biology, University of Bucharest, (Romania)
 - Start date: 10.2000
 - End date: 02.2002
 - Qualification: Master degree in Genetics
 - Organisation:
 - Country: Romania
3. Subject: CEFOR (Centre de Formation des Enseignants dans la Domaine des Science de la Vie Espace Europeen de la Difusion des Connaissances et de Reflexions Prospectives) and Bucharest University
 - Start date: 0.52002
 - End date:
 - Qualification: Certificate
 - Organisation:
 - Country: Romania
4. Subject: The European Directorate for the Quality of Medicines of the Council of Europe (EDQM)
 - Start date: 10.2009
 - End date:
 - Qualification: Certificate
 - Organisation:

- Country: France
5. Subject: European School for the Assessment of New Medicines, University of Rome tor Vergata
 - Start date: 05.2010
 - End date:
 - Qualification: Certificate
 - Organisation:
 - Country: Italy
 6. Subject: National Institute for Biological Standards and Control (NIBSC), South Mimms, Hertfordshire, England
 - Start date: 05.2012
 - End date:
 - Qualification: Certificate
 - Organisation:
 - Country: United Kingdom
 7. Subject: UMF "Carol Davila"
 - Start date: 06.2013
 - End date:
 - Qualification: Certificate
 - Organisation:
 - Country: Romania
 8. Subject: European Medicines Agency
 - Start date: 11.2013
 - End date:
 - Qualification: Workshop on Characterisation of new clotting factor concentrates (FVIII, FIX) with respect to potency assays used for labelling and testing of post infusion samples
 - Organisation:
 - Country: United Kingdom
 9. Subject: European Medicines Agency
 - Start date: 10.2014
 - End date:
 - Qualification: Workshop on Viral safety of plasma_derived medicinal products with respect to hepatitis E virus
 - Organisation:
 - Country: United Kingdom
 10. Subject: North Carolina University, Golden LEAF Biomanufacturing Training and Education Center, supported by US Department of Health and Human Services
 - Start date: 06.2015
 - End date: 07.2015
 - Qualification: Fundamentals of cGMP Influenza vaccine manufacturing
 - Organisation:
 - Country: United States
 11. Subject: European Medicines Agency
 - Start date: 12.2015
 - End date:
 - Qualification: CAT webinar on ATMPs classification
 - Organisation:
 - Country: United Kingdom
 12. Subject: DOC Masco Group
 - Start date: 05.2016
 - End date:
 - Qualification: Seminar on Qualification and Validation in light of new Annex 15 and USP Chapters: Update 2016
 - Organisation:
 - Country: Romania
 13. Subject: AGES supported by the EU NTC
 - Start date: 09.2016
 - End date:
 - Qualification: Webinar on Validation of Analytical Methods
 - Organisation:
 - Country:
 14. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 11.2016
 - End date:
 - Qualification: EU BATCH RELEASE FOR HUMAN VACCINES: A PRACTICAL OVERVIEW FOR NEWCOMERS
 - Organisation:
 - Country: France
 15. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 06.2017
 - End date:
 - Qualification: Uncertainty of Measurement
 - Organisation:
 - Country: France
 16. Subject: State Institute for Drug Control
 - Start date: 10.2017
 - End date:
 - Qualification: Clinical Trials Regulation: Quality Assessment
 - Organisation:
 - Country:
 17. Subject: AGES supported by the EU NTC
 - Start date: 11.2017
 - End date:
 - Qualification: Webinar _ Reflection Paper on statistical methodology for the comparative assessment of quality attributes in drug development
 - Organisation:
 - Country:
 18. Subject: European Medicines Agency
 - Start date: 05.2018
 - End date:
 - Qualification: Workshop on statistical methodology for the comparative assessment of quality attributes in drug development
 - Organisation:
 - Country: United Kingdom
 19. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 06.2018
 - End date:
 - Qualification: Control Charts and Metrological Topics
 - Organisation:

- Country: France
- 20. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 10.2018
 - End date:
 - Qualification: Training session on Combistats
 - Organisation:
 - Country: France
- 21. Subject: European Medicines Agency
 - Start date: 11.2018
 - End date:
 - Qualification: BWP Assessors training on Overview of CHMP AR guidance
 - Organisation:
 - Country: United Kingdom
- 22. Subject: European Directorate for the Quality of Medicines & HealthCare (EDQM)
 - Start date: 05.2019
 - End date: 05.2019
 - Qualification: Workshop Actions to Address Risks and Opportunities
 - Organisation:
 - Country: Iceland
- 23.

Additional information

Publications

"Development of a documented quality system in testing laboratories", The first National Conference of OBBCSSR, Bucharest, p.27, 2005 .

"EU Administrative Procedure for Official Control Authority Batch Release _ Contribution to Quality and Safety Assurance of Biological Medicines", National Congress of Pharmacy from Romania, Iasi, September 2014

" Control by laboratory testing of transport and storage conditions for vaccines adsorbed " , National Conference of Pharmacy, Bucharest, November 2015

"OMCL role in assurance of quality and safety of vaccines", Conference of Medicine, Bucharest, September 2018

Projects

Memberships

Other Relevant Information