Curriculum Vitae

Personal information

Simona Russo

Work experience

1. Employer: Italian Medicines Agency (AIFA) _ Centralised Procedures Office
   - Start date: 022021
   - End date:
   - Position: Biologist _ Quality Assessor _ Senior GMP Inspector
   - Activities: With reference to quality aspects of biological medicinal products: assessment of dossiers for marketing authorization under th vaccines), assessment of national and EMA scientific advice. GMP inspections at drug substance/drug product manufacturing sites (NCA and Party (BWP)
   - Country: Italy
2. Employer: Italian Medicines Agency (AIFA) _ GMP MED Office
   - Start date: 042017
   - End date: 022021
   - Position: Biologist – Senior GMP Inspector
   - Activities: _ GMP inspections at DS/DP manufacturing sites _ Desk assessment of DP manufacturing sites applications _ Follow_up of DP procedures, mainly related to ATMPs and Biotech products manufacturing
   - Country: Italy
3. Employer: Italian Medicines Agency (AIFA)_ Manufacturing Authorizations Office
   - Start date: 082011
   - End date: 042017
   - Position: Biologist – Senior GMP Inspector
   - Activities:

     _Follow_up of GMP inspections;
     _Desk assessment of manufacturing sites applications (DS/DP);
     _DS/DP manufacturers GMP Inspections appointed by the NCA or the EMA (GMP Inspector);
     _Special focus on ATMPs, Vaccines and Biotechnological/Biological medicinal products.

     Sector: Good Manufacturing Practice

   - Country: Italy
4. Employer: S.I.F.I. S.p.A.
   - Start date: 012010
   - End date: 072011
   - Position: Clinical Development & Regulatory Affairs Manager
   - Activities:

     _Management of regulatory affairs activities needed to request and maintain a marketing authorization for a medicinal product or a CE mark
     _Maintaining relationship with Medicine Agencies, EMA, Notified Bodies and KOL;
     _Defining the non_clinical and clinical development strategy needed to supporta NDA;
     _Clinical Overview/Clinical Summaries issuing.

     Sector: Regulatory Affairs/Clinical Development/Ophthalmology

   - Country: Italy
5. Employer: S.I.F.I. S.p.A. (Italy)
   - Start date: 061999
   - End date: 122009
   - Position: Clinical Trial Manager / Clinical Development Manager
   - Activities:

     _Planning, execution and reporting of phase I–III clinical trials and medical devices' clinical investigations;
     _CTA filing and follow_up.

     Sector: Clinical Development/Ophthalmology

   - Country: Italy
6. Employer: Cell Biology Department of Rome University "La Sapienza" (Italy)
   - Start date: 111991
   - End date: 051998
   - Position: R&D Scientist
   - Activities:

     _Molecular and cellular biology laboratory methods.

     Sector: Cellular and molecular biology

   - Country: Italy

Education and training

1. Subject: Rome University "Tor Vergata" (Italy)
    - Start date: 112004
    - End date: 042005
    - Qualification: University Master Certificate in "Clinical Trials"
    - Organisation:
    - Country: Italy
2. Subject: University of Catania
    - Start date: 101997
    - End date: 062002
    - Qualification: Post_graduate School in "Clinical Pathology"
    - Organisation:
    - Country: Italy
3. Subject: Rome University "La Sapienza" (Italy)
    - Start date: 101994
    - End date: 061997
    - Qualification: Ph.D. in "Genetics and Molecular Biology"
    - Organisation:
    - Country: Italy
4. Subject: University of Catania
    - Start date: 101987
    - End date: 031991
    - Qualification: Degree in Biological Sciences
    - Organisation:
    - Country: Italy

Additional information

Publications

1)S.Russo,F.TatòandM.Grossi;"Transcriptionaldown_regulationofmyogeninexpressionisassociatedwithv_ras_inducedblockofdifferentiationinunestablishedquailmus
2)S.Russo,D.Tomatis,G.Collo,G.TaroneandF.Tatò;"MyogenicconversionofNIH3T3cellsbyexogenousMyoDfamilymembers:dissociationofterminaldifferentiationfromn
3)PapaV.;AragonaP.;RussoS.;DiBellaA.;RussoP.,andMilazzoG."Comparisonofhypotonicandisotonicsolutionscontainingsodiumhyaluronateonthesymptomatictreatm
4)PapaV.;RussoS.;RussoP.;DiBellaA.;SantoconoM.,andMilazzoG."Topicalnaproxensodiumforinhibitionofmiosisduringcataractsurgery.Prospective,randomizedclinic
5)G.Milazzo,V.Papa,P.Aragona,S.Russo,P.Russo,A.DiBella."Efficacyofsodiumhyaluronateeyedropsofdifferentosmolaritiesinthesymptomatictreatmentofdryeyepatie
6)P.Russo,V.Papa,S.Russo,A.DiBella,G.Pabst,G.Milazzo,A.Balestrazzi,A.Caporossi."Topicalnonsteroidalanti_inflammatorydrugsinuncomplicatedcataractsurgery:ef
7)S.Russo,V.Papa,A.DiBella,A.Favero,C.Radulescu,O.Gafencu,B.Carstocea,G.Milazzo."Dexamethasone_netilmicin:anewophthalmicsteroid_antibioticcombination.E
8)F.Faraldi,V.Papa,D.Santoro,D.Rasà,A.L.Mazza,M.M.RabbioneandS.Russo."Aneweyegelcontainingsodiumhyaluronateandxanthangumforthemanagementofpost_t
9)Faraldi,V.Papa,D.Rasà,D.SantoroandS.Russo."Netilmicin/dexamethasonefixedcombinationinthetreatmentofconjunctivalinflammation".ClinicalOphthalmology,7:

Projects

Memberships

Member (IT) at the EMA Biologics Working Party (BWP)

Other Relevant Information

Quality assessor of new MAA, line extension and variation procedures for biological products (mainly monoclonal antibodies and influenza vaccines). More than 1
a speaker. About 90 GMP inspections conducted (both national and international). Participation to several national Scientific Advice procedures as expert or coor
representative at the Joint CAT_IWG GMDP sub_Group regarding Good Manufacturing Practice for Advanced Therapy Medicinal Products (2018_2020) _ Member
the PIC/S drafting group on *"Aide Memoire on Tissues and Cellular Therapy Inspections"*