europass Curriculum vitae

PERSONAL INFORMATION

Marino Francesco

(Italy)

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Sex Male | Date of birth 04/05/1977 | Nationality Italian

WORK EXPERIENCE

01/09/2003–31/12/2004

Trainee

Istituto Superiore di Sanità, Rome (Italy)

- Experimental thesis on *" Detection and Quantification of the Parvovirus B19 in plasma pools: Development and validation of a method in PCR Real time"*
- Set up and validation of assay for the *Detection and Quantification of the Viruses in plasma pools (B19, HAV, HCV, HBV, HIV, WNV)*

01/01/2005–Present

Researcher

Istituto Superiore di Sanità, Rome (Italy)

-Control activity in the field of Biologicals :

- Batch release of Human Immunoglobulins and Plasma Pool Testing for viral markers (HBsAg, anti-HIV 1/2, HCV RNA, B19 DNA, HAV RNA) within the OMCL Network;
- Post-marketing surveillance, at National and European level, of Immunoglobulins and Biotechnological products. The latter activity is performed in the context of CAP (Centrally Authorized Products) Programme Surveillance Activity organized and planned yearly by EDQM.
- Participation in PTSs organised by EDQM for methods to be used for plasma pool testing and batch release of blood products.
- Participation in Biological Standardization Programme (BSP) for the establishment of new reference standards and the development of new/alternative test methods, in the context of Ph. Eur. and WHO activity.
- Development of reference materials for NAT assays and serological assay
- Physicochemical analysis of biologically active substances & products (HPLC, glycan mapping).
- Active involvement in drafting and verification of SOPs.
- Active involvement in drafting of texts and laboratory verification of test methods.

EDUCATION AND TRAINING

01/09/1996–02/11/2003

Doctor on Medicinal Chemistry

EQF level 5

Università "La Sapienza", Rome (Italy)

03/11/2004–04/07/2005

Pharmacist

Università "La Sapienza", Rome (Italy)

PERSONAL SKILLS

Mother tongue(s) Italian

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	B1	B1	B1	B1	B1

Levels: A1 and A2: Basic user - B1 and B2: Independent user - C1 and C2: Proficient user
Common European Framework of Reference for Languages

Job-related skills

Competent on HPLC system, UPLC system, Real Time PCR system Potency testing of specific immunoglobulins, Plasma pool testing for virus markers as part of the OCABR system. Preparation of reference material for NAT assays and serological assay

Digital skills

Competent with the most Microsoft Office programs

ADDITIONAL INFORMATION

Expertise

- Assessor for Biological Products (biosimilars, monoclonal antibodies, recombinant proteins, plasma derived products).
- Member of Group 6 (Biological and Biotechnological products) within the European Pharmacopoeia .
- GMP inspector.

Post-Marketing Surveillance on Centrally Authorised Products

1. Post-Marketing Surveillance on Centrally Authorised Products – *(HUMALOG100 UI/mL, Solution for injection)-CAP 2008/15*

2. Post-Marketing Surveillance on Centrally Authorised Products – *(INSUMAN Rapid, 100 UI/mL, Solution for injection)-CAP 2009/19* .

3. Post-Marketing Surveillance on Centrally Authorised Products *(Xolaire 150 MG) - CAP 2010/48* .

4. Post-Marketing Surveillance on Centrally Authorised Products *(Actrapid 100IU/mL) - CAP 2011/05*.

5. Post-Marketing Surveillance on Centrally Authorised Products *(Pegasys 135 µg) - CAP 2012/29*

6. Post-Marketing Surveillance on Centrally Authorised Products *(Revasc 15 mg) - CAP 2013/45*

7. Post-Marketing Surveillance on Centrally Authorised Products (*Liprolog, 100 U/ml - Solution for injection*) *CAP 2014/24*

8. Post-Marketing Surveillance on Centrally Authorised Products (*Insulin Human Winthrop Rapid, 100 IU/ml, Solution for injection*) *CAP 2016/22*

Assessment Centrally Authorised Products

1.Blincyto EMEA/H/C/003731
2.Strensiq EMEA/H/C/003794
3.Solumarv EMEA/H/C/003858
4.Spectrila EMA/H/C/002661
5.Oncaspar EMEA/H/C/003789
6.Portrazza EMEA/H/C/3886
7.Empliciti EMA/H/C/3967
8.Lartruvo EMEA/H/C/004216
9.Keytruda EMEA/H/C/003820/II/04
10.Amgevita EMA/H/C/004212
11.Ocrelizumab EMEA/H/C/004043
12.Keytruda EMEA/H/C/003820/II/08
13.Sarilumab EMEA/H/C/004254
14.Keytruda EMEA/H/C/003820/II/20

15.Keytruda EMEA/H/C/003820/II/26

Collaborative Studies

1.Marino F. in: "*International Collaborative Study to Establish Human Immunoglobulin BRP 3 (BSP068) – Biological Standardisation Programme"* European Directorate for the Quality of Medicines (EDQM) October 2005.

2.Marino F.in:*"Collaborative Study for the Replacement of the HBV DNA International Standard"* National Institute for Biological Standard and Control (NIBSC) 02/2006.

3.Marino F. in:"*WHO Collaborative Study to Establish a Replacement WHO International Standard for Hepatitis C Virus RNA Nucleic Acid Amplification Technology (NAT) – Based Assays"* – National Institute for Biological Standards and Control (NIBSC).

4.Marino F. in:"*Collaborative Study to Establish a World Health Organitation International Standard for parvovirus B19 DNA nucleic acid amplification technology (NAT)*- based assays (2009).

5.Marino F. in: "*Collaborative Study to Evaluate a Panel of HEV positive Sample* (2010).

6.Marino F. in:**"**Collaborative study to evaluate the candidate 2rd WHO International Standard for HAV for NAT- based assays" (2013)

7.Marino F. in:**"**Collaborative study to evaluate the replacement 3rd WHO International Standard for parvovirus B19 for NAT-based assays" (2013)

8.Marino F. in:**"** WHO Collaborative Study to assess the suitability of a candidate 3rd WHO International Standard for HBsAg" (2013).

9.Marino F. in **"**Collaborative study for the establishment of the human immunoglobulin 1 BRP replacement batches**"** (BSP122) (2016).

10. Marino F. in **"**Assessment of methods for determination of glycan composition of erythropoietin**"** (BSP144) (2017).

Publications and Abstracts

1.Marino F. in*: "International Collaborative Study to Establish Human Immunoglobulin BRP Batch 3 and Human Immunoglobulin (MolecularSize) BRP Batch 1"*– Pharmeuropa Bio 2006 – 1.

2.Marino F. in: *"Collaborative study for the calibration of HCV RNA, HBV DNA and HIV RNA reference preparations against the relative international standards".* Annali Istituto Superiore Sanità (ISS) 2007; Vol. 43, No 1: 69-76.

3.Giulio Pisani**, Francesco Marino**, Claudio Mele, Giuliano Gentili ISS, Roma. *"Importanza e ruolo della ricerca molecolaredi B19 nello screening deiplasmaderivati"* Esadia – Anno 2007.

4.G. Pisani, **F. Marino**, K. Cristiano, G.M. Bisso, C.Mele, F. Luciani, M. Wirz, G. Gentili and the EQA Participants (2008) *External quality assessment for thedetection of HCV RNA, HIV RNA and HBV DNA in plasma by nucleic acidamplification technology:a novel approach.* Vox Sanguinis 95:8-12.

5.PROGRAMMA ITALIANO DI VALUTAZIONE ESTERNA DI QUALITÀ PER LE TECNICHE DI AMPLIFICAZIONE GENOMICA (NAT) HCV RNA, HIV RNA, HBV DNA. ANNO 2008 - *CONFERENZA NAZIONALE DEI SERVIZI TRASFUSIONALI - Abstract Blood Transfusion 2009* PisaniG., Pupella S., **Marino F.** ,Cristiano K. , LucianiF., Wirz M. , Bisso G. , GaggioliA. , Calteri D., Vitali S., Mele C. ,Adriani D.W, Piccinini V., Colombo K. ,Marra C., Pini C. , Grazzini G.

6.G. Pisani,K. Cristiano, **F. Marino**, F. Luciani, G.M. Bisso, C.Mele, D. Adriani, G. Gentili, M. Wirz (2009) *Quantification of hepatitis C virus (HCV) RNA in a multicenter study:implications for management of HCV genotype 1-infected patients.* J. Clin. Microbiol. 2009Sep;47(9):2931-6.

7.G. Pisani,K. Cristiano, **F. Marino**, F. Luciani, G.M. Bisso, A.Gaggioli, C. Mele, S. Pupella, G. Grazzini e M. Wirz (2010) *External quality assessment programmes fordetection of HCV RNA, HIV RNA and HBV DNA in plasma: improvedproficiency of theparticipants observed over a 2-year period.* Vox Sanguinis 99:319-324.

8.S. A. Baylis, A. B. Heath and the Collaborative Study Group (2010) *World Health Organization collaborativestudy to calibrate the 3rd International Standard for Hepatitis Cvirus RNA nuclic acid amplification technology (NAT)-based assay.* Vox Sanguinis.

9.G. Pisani, S. Pupella, **F. Marino**[1], A.Gaggioli, V. Sambri, G. Rossini, M. Wirz[1],G. Grazzini and Interlaboratory Study Group (2011) *Interlaboratory Study to evaluate theperformance of laboratories involved in WNV RNA screening of blood and blood componentsby nucleic acid amplification testing in Italy.* (Blood Transfusion 2011;9:425-9).

10. Poster: **Marino F.**, Simeoni M, Miceli M, Bisso GM, Gaggioli A, Adriani D, Mele C,Luciani F, Cristiano K, Wirz M, Grazzini G, Pupella S., Pisani G. ed ilGruppo di studio anti-HBs "*Studio Interlaboratorio per la valutazionedei saggi analitici per il marcatore anti-HBS"* **Abstract 201** al XL

Congresso Nazionale AMCLI, Rimini 8-11 november 2011

11. G. Pisani, S. Pupella, K.Cristiano, **F. Marino**, M. Simeoni, F. Luciani, G. Scuderi, V. Sambri3, G.Rossini3, P.Gaibani3, A.Pierro, M. Wirz, G. Grazzini (2012) "*Detection of West Nilevirus RNA (lineages 1 and 2) in an external quality assessment programme forlaboratories screening blood and blood components for West Nile virus bynucleic acid amplification testing".* Blood Transfus. October 2012 ; 10(4): 515–520.

12. Sally A. Baylis, Johannes Blümel, Saeko Mizusawa, Keiji Matsubayashi,Hidekatsu Sakata, Yoshiaki Okada, C. Micha Nübling, Kay-Martin O. Hanschmann,and the HEV Collaborative Study Group *World Health Organization InternationalStandard to Harmonize Assays for Detection of Hepatitis E Virus RNA*. Emerging Infectious Diseases www.cdc.gov/eid • Vol. 19, No. 5, May 2013

13. Abstract: **"***Production abd QualityControl of Animal Immunoglobulins and immune Sera for Human Use"***-** Maria WIRZ,Francesca LUCIANI, **Francesco MARINO**;Congresso Internazionale " Quality Control Tests for Human Vaccines andSera TR 09 IB FI 01 " – Cappadocia 24-25 October 2013

14. Abstract: **"***HUMAN IMMUNOGLOBULINPREPARATION FOR THERAPEUTIC USE: AN OVERVIEW ON QUALITY AND SAFETY"* **-** Francesca LUCIANI, **Francesco MARINO**, Maria WIRZ; Congresso Internazionale " Quality Control Tests for HumanVaccines and Sera TR 09 IB FI 01 " – Cappadocia 24-25 Ottobre 2013

15. Abstract: *"Specific human immunoglobulin preparations:quality control issues"* **- Francesco MARINO**,Francesca LUCIANI, Maria WIRZ; Congresso Internazionale " QualityControl Tests for Human Vaccines and Sera TR 09 IB FI 01 " – Cappadocia 24-25 October 2013

16. Abstract:"*Confronto interlaboratorio europeo per la Valutazione delle Performance Analitiche dei Metodi NAT per il Rilevamento del WNV RNA nel Plasma". Pisani G., **Marino F.**,Simeoni M., Fabi S., Cristiano K., et al.*- SIMTI 2014

17. Abstract:"*Valutazione delle Performance Analitiche dei Metodi immunometrici per il Rilevamento di HBsAg nel Plasma". Pisani G., **Marino F.**, Simeoni M., Fabi S.,Cristiano K., et al.*- SIMTI 2014

18. G. Pisani, K. Cristiano, S. Fabi, M. Simeoni, **F. Marino** & A. Gaggioli "*A significantly lower potency observed for the 3rd WHO International Standard for Parvovirus B19V DNA with the cobas TaqScreen DPX test*"- Vox Sanguinis (May 2016) 111, 115–119

GMP Inspection

1. 24 -27/02/2014 INJECTALIASPA (Observer)
2. 10 -13/06/2014 Dynacreen Laboratorio Farmaceutico SRL (Observer)
3. 22 -25/07/2014 Anallergo SPA (Observer)
4. 14 -16/10/2014 Bouty SPA (Observer)
5. 13 -16/01/2015 Istituto di RicercheBiomediche "Antoine Marxer" RBM SpA (Observer)
6. 09 -13/02/2015 BSP Pharmaceuticals (Observer)
7. 30/03-02/04/2015 Genetic (Observer)
8. 20-23/04/2015 Altergon (Observer)
9. 11-15/05/2015 Beltapharm (Observer)
10. 16-18/06/2015 Istituto De Angeli (Observer)
11. 13-17/07/2015 I.BIR.N (Observer)
12. 07-11/09/2015 TheraMetricsCSS (Observer)
13. 12-14/10/2015 BAYERHEALTHCARE Manufacturing SRL (Inspector junior)
14. 23-26/11/2015 Esapharma SRL (Inspector junior)
15. 14-17/12/2015 Zeta Farmaceutici SPA (Inspector junior)
16. 25-28/01/2016 Istituto Biochimico Nazionale Savio (Inspector junior)
17. 17-19/02/2016 RESEARCH TOXICOLOGY CENTRE S.P.A (Team Leader)
18. 8-10/03/2016 Allergy (Inspector junior)
19. 5-7/04/2016 Phardis srl (Team Leader)
20. 18-20/05/2016 IZSLER (Team Leader)
21. 20-24/06/2016 Laboratorio farmaceutico SIT (Inspector junior)
22. 05-08/07/2016 SIIT (Inspector junior)

23. 27-30/09/2016 EUROMED ex Therametericcs (Inspector junior)
24. 25-28/10/2016 BioChemilab (Team Leader)
25. 25-28/01/2016 ADVENT (Inspector junior)
26. 13-17/02/2017 Chiesi Centro Ricerche (Inspector junior)
27. 26-27/04/2017 Marconi Freddeuropa (Team Leader))
28. 30/05/2017-01/06/217 Kedrion (Inspector junior)
29. 19-22/06/2017 Sigmar (Inspector junior)
30. 18-21/07/2017 New.Fa.Dem (Inspector junior)
31. 25-27/10/2017 Grifols Italia (Inspector junior)
32. 27-30/11/2017 FIRMA (Inspector junior)
33. 19-21/02/201/8 SOL SPA (Inspector junior)