



Curriculum Vitae

Personal information **Andrea Gaggioli**

Work experience

1. Employer: Istituto Superiore di Sanità – Rome _ National Centre for the Control and Evaluation of Medicines (CNCF)
 - Start date: 012018
 - End date:
 - Position: Senior Researcher (from year 2024)
 - Activities: Responsible of Biostatistics Section in the Biologicals and Biotechnologicals Unit of the National Centre for the Control and Evaluation of Medicines (CNCF). Statistical analysis and support for topics and issues related to: Control activities on medicines for human use carried out according to ISO 17025 (laboratory testing for Blood Products and Vaccines). Biologicals control and evaluation, Participation to the batch release and plasma pool testing activities, in compliance with the PhEUR and Italian government directives for blood products and vaccines. Analysis of intra and inter laboratory data: Statistical evaluation of bioassays, chemico-physical tests, and PTS/EQA. Statistical Quality Control (External and Internal/SPC). Dossier evaluation for medicines for human use according to ISO 9000: Quality assessment for centralized, decentralized, mutual recognition procedure and scientific advices, regarding biological, biotechnologicals drugs, CAR_T
 - Country: Italy
2. Employer: Istituto Superiore di Sanità – Rome _ National Center for Immunobiologicals Research and Evaluation
 - Start date: 082005
 - End date: 122017
 - Position: Researcher
 - Activities: Statistical analysis for the Control and Evaluation of Biologicals and Biotech. Data from biological assays (viral and bacterial vaccines, biological products). Research activity concerning accreditation and quality assurance. Validation of analytical Methods and softwares. Participation to the Batch Release activity for Human Immunoglobulins and Vaccines. Statistical Quality Control (External and Internal/SPC). Statistical evaluation of PTS and EQA. Quality Assessor for the National Agency (Biologicals and Biotechnology Products): Centralized Procedures, Mutual Recognition, Scientific Advices.
 - Country: Italy
3. Employer: Istituto Superiore di Sanità (ISS) _ National Centre for Epidemiology Surveillance and Health Promotion (CNESPS)
 - Start date: 022002
 - End date: 072005
 - Position: Researcher
 - Activities: Statistical analysis of data from epidemiological Projects on cardiovascular diseases
 - Country: Italy

Education and training

1. Subject: University of Rome "La Sapienza"
 - Start date: 091994
 - End date: 052001
 - Qualification: Master Degree in Statistics and Economics
 - Organisation: La Sapienza
 - Country: Italy

Additional information

Publications

1. S.Giampaoli, M.F.Vescio, A.Gaggioli, D.Vanuzzo: "Prevalence of the Arterial Hypertension in the Italian Population", Journal: "Notiziario dell'Istituto Superiore di Sanità", Vol. 15_N°9, September 2002.
2. ITALIAN ATLAS OF CARDIOVASCULAR DISEASES, 1st Edition 2003. Journal: Italian Heart Journal, May 2003 Vol.4 / Suppl. 4
3. ITALIAN ATLAS OF CARDIOVASCULAR DISEASES, 2nd Edition 2004. Journal: Italian Heart Journal, April 2004 Vol.5 / Suppl. 3
4. L. Pilotto, A. Gaggioli, C. Lo Noce, F. Dima, L. Palmieri, M. Uguccioni, S. Pedè, S. Giampaoli, D. Vanuzzo, on behalf of the Cardiovascular Epidemiological Observatory: "Diabetes in Italy: a Public Health problem". Journal: Italian Heart Journal, Suppl., June 2004, Vol. 5: 480_486.
5. Vanuzzo D, Pilotto L, Uguccioni M, Pedè S, Valagussa F, Gaggioli A, Palmieri L, Dima F, Lo Noce C, Seccareccia F, Giampaoli S. "Cardiovascular Epidemiology: Trend of Risk Factors in Italy. Italian heart journal 2004;5(Suppl 8):19S_27S.
6. Ricci M.L., Fontana S., Bella A., Gaggioli A., Cascella R., Cassone A., Scaturro M., Microbiologists of the Regional Agency for Environmental Protection of Novara: "A preliminary assessment of the occupational risk of acquiring Legionnaires' disease for people working in telephone manholes, a new workplace environment for Legionella

growth". American Journal of Infection Control 2010 Sep;38(7):540_5.

7. Pisani G, Cristiano K, Marino F, Luciani F, Bisso GM, Gaggioli A, Mele C, Pupella S, Grazzini G, Wirz M.: "External quality assessment programmes for detection of HCV RNA, HIV RNA and HBV DNA in plasma: improved proficiency of the participants observed over a 2_year period". Vox Sanguinis 2010 Nov; 99(4):319_24.
8. Pisani G, Pupella S, Marino F, Gaggioli A, Sambri V, Rossini G, Wirz M, Grazzini G and Interlaboratory Study Group: "Interlaboratory study to evaluate the performance of laboratories involved in West Nile virus RNA screening of blood and blood components by nucleic amplification testing in Italy". Blood Transfusion 2011;9(4):425_429.
9. Christina von Hunolstein, Luisa Ralli, Antonella Pinto, Paul Stickings, Androulla Efstratiou, Ida Czumbel, EDSN EQA Participants and Andrea Gaggioli. Relevance and Criticality in an External Quality Assessment for the Determination of Diphtheria Antitoxin. Journal of Immunology & Clinical Research, 2_1022_2014
10. Ruggeri FM, Bonomo P, Ianiro G, Battistone A, Delogu R, Germinario C, Chironna M, Triassi M, Campagnuolo R, Cicala A, Giammanco GM, Castiglia P, Serra C, Gaggioli A, Fiore L. Rotavirus genotypes in sewage treatment plants and in children hospitalized with acute diarrhea in Italy, 2010 and 2011. Applied and environmental microbiology 2015;81(1):241_249
11. Murtas S*, Gaggioli A*, Von Hunolstein C. Quantifying uncertainty in determination of polysaccharides in glycoconjugate vaccines based on in_house validation data. Accreditation and quality assurance 2012;17(2):177_182.
12. Francesca Luciani, Sara Galluzzo, Andrea Gaggioli, Nanna Aaby Kruse, Pascal Venneugues, Christian K Schneider, Carlo Pini, and Daniela Melchiorri. Implementing quality by design for biotech products: Are regulators on track? mAbs 7:3, 451455; May/June 2015; © 2015 Taylor and Francis Group, LLC
13. 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 2016, May (5). 111(2):115_119
14. Etna, M. P., Giacomini, E., Rizzo, F., Severa, M., Ricci, D., Shaid, S., Lambrigts, D., Valentini, S., Galli Stampino, L., Alleri, L., Gaggioli, A., von Hunolstein, C., Spreitzer, I. and Coccia, E. M. (2020) "Optimization of the monocyte activation test for evaluating pyrogenicity of tick_borne encephalitis virus vaccine", ALTEX _ Alternatives to animal experimentation, 37(4), pp. 532_544. doi: 10.14573/altex.2002252
15. Nappi F., Luciani F., Gaggioli A., Pini C. "Assessment of Biosimilarity by comparison of Originator and Biosimilar: Quality parameters analysis". SIMeF Journal; N°11 – June 2020.
16. Roskopf U., von Hunolstein C., Gaggioli A. – "Study report: Proficiency testing study on a WHO/TAL_trained methodology High Performance Anion Exchange Chromatography with Pulsed Amperometric Detection (HPAEC_PAD) for the determination of the total and free saccharide content in Haemophilus influenzae type b (Hib) liquid combined vaccines". WHO Drug Information, Vol 34, No. 4, 2020
17. Etna MP, Signorazzi A, Ricci D, Severa M, Rizzo F, Giacomini E, Gaggioli A, Bekeredjian_Ding I, Huckriede A, Coccia EM. "Human plasmacytoid dendritic cells at the crossroad of type I interferon_regulated B cell differentiation and antiviral response to tickborne encephalitis virus" PLoS Pathog 17(4) 2021: e1009505. <https://doi.org/10.1371/journal.ppat.1009505>
18. G. Pisani, K. Cristiano, M. Simeoni, A. Martina, I. Pati, A. Carocci, A. Gaggioli, F. Marino, D. Adriani, S. Pupella, F. Candura, V. De Angelis. _ Detection of antibodies against SARS_CoV_2 both in plasma pools for fractionation and in commercial intravenous immunoglobulins produced from plasma collected in Italy during the pandemic. Blood Transfus 2021; DOI 10.2450/2021.0055_21. Published online: 27/05/2021
19. Esposito V.; Carocci A.; Luciani F.; Battistone A.; Gaggioli A.; Marino M. - "Validation and application of a SEC-HPLC method for the determination of total protein in therapeutic immunoglobulins as an alternative to the European Pharmacopoeia methods. Pharmaceutica Bio & scientific notes. Volume 2023, Pages 69-81, 2023

Projects

Quality Control Tests for Human Vaccines and Sera, Partner Country: Turkey Twinning number: TR 09 IB FI 01 _ IPA decentralised National programmes CRIS Number: TR2009/0301.01

Memberships

Member of the competent authority

Other Relevant Information