

Curriculum Vitae

Personal information **Eugenia Cogliandro**

Work experience

1. Employer: Eugenia Cogliandro
 - Start date: 112004
 - End date: -
 - Position: Scientific administrator/quality assessor (Dirigente chimico) at the Italian Medicines Agency_AIFA
 - Activities: _Since October 2010 to date: coordinator of activities related to the quality assessment of national, MR and DC procedures and other quality related issues with impact on registration dossiers, as a liaison between quality assessors and GMP inspectors (e.g. GMP issues or quality defects, CEP withdrawal/suspension, annual control program on national products by OMCL) _Since October 2016 to date: Deputy of the Head of Medicinal Products Authorisation Department _Since August 2012 to June 2019: coordinator of national Scientific Advice procedures _Since September 2010 to date: support activity in quality assurance system, internal audits, POS drafting, BEMA visit preparation (BEMA cycles II, III and V), JAP visit preparation (2015) _Since 2004 to date: assessor for the evaluation of the quality part of the registration dossiers submitted under the Mutual Recognition, Decentralised and Centralised Procedures with Italy acting as CMS, RMS or Rapporteur/Co_rapporteur, referral, Scientific Advice and peer review _2004_2011: project manager for European applications under the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) with Italy acting as CMS or RMS 2004_2010: reviewer of the texts (SPC, PIL, Labels) authorised through MRP/DCP
 - Country: Italy
2. Employer: Eugenia Cogliandro
 - Start date: 051999
 - End date: 102004
 - Position: Scientific Administrator/Quality Assessor at the Italian Ministry of Health, Directorate General for Drug Evaluation and Pharmacovigilance
 - Activities: 1999_2004: assessor for the evaluation of the quality part of the registration dossiers submitted under the Mutual Recognition and Centralised Procedures _1999_2004 project manager for European Applications under the Mutual Recognition Procedure (MRP) 1999_2004: regulatory affairs expert of the drug registration process throughout the current legislation (Italian, European) _1999_2004: reviewer of the texts (SPC, PIL, Labels) authorised through MRP
 - Country: Italy
3. Employer: Eugenia Cogliandro
 - Start date: 031995
 - End date: 041999
 - Position: scholarship holder at CNR (National Research Council)
 - Activities: 01.01.1998 _ 31.12.1998 CNR research program "Development of Capillary Electrophoretic and micro_HPLC Techniques for determination of proteins, peptides, glycoconjugates and other biopolymers" 01.04.1996 _ 31.03.1997 CNR research program "Development of innovator high resolution micro analytical methods for the analysis of complex matrices" 01.03.1995 _ 15.02.1996 CNR research program " High resolution chromatographic and electrophoretic techniques_Methods for separation and determination of substances with biological activity and synthetic chemical products"
 - Country: Italy
4. Employer: Eugenia Cogliandro
 - Start date: 011993
 - End date: 121994
 - Position: scholarship holder at Messina University
 - Activities: Research activity concerning isolation (LC), separation (HPLC) and characterisation (NMR, MS) of oxygen heterocyclic compounds of citrus essential oils.
 - Country: Italy

Education and training

1. Subject:
 - Start date: 092003
 - End date: 042013
 - Qualification: Teacher
 - Organisation: _ Lessons Learnt Exercise on Sartan Contamination_Prevention section and Ph. Eur Control of nitrosamines, training for inspectors, AIFA 29 novembre 2019 _ Study Visit Serbia_Kazakhstan: "Medicinal Products Authorization Department: Offices and activities_National, Mutual Recognition and Decentralised Procedures " e "Module 3 Chemicals: How to perform the assessment and key requirements", AIFA July 2018 _Master II level in Pharmaceutical Techniques and Regulatory Activities (TFAR), Pavia University, 2018 _Workshop: Modern analytical techniques in Pharmaceutical Industry A tool to support pharmaceutical quality and to ease regulatory process 21st October 2016, Pavia University _Master "Regulatory sciences" AIFA/La Sapienza Roma University, 2012/13, 2013/14 and 2014/15 _Master "Preclinical and Clinical Development of Drugs", Cattolica University, Roma, 2007/08, 2008/09, 2009/10, 2012/13, 2014/15, 2015/16 _19th Summer School on Pharmaceutical Analysis _ Advanced analytical Methodologies in Chemical Drug Manufacturing, Milan University, Rimini Campus, September 2014 _Advanced course "Medicinal products management_regulatory

aspects", Milan University, 2011 and 2012 _Master "Management of Clinical Trials" Modena and Reggio Emilia University, 2006/07 e 2007/08 _European School for Scientific and Regulatory Assessment of New Medicines, Roma University "Tor Vergata", 2007 _Master "Regulatory Affairs of drugs" Chieti University, 2003/04

- Country: Italy
- 2. Subject: Messina University
 - Start date: 091993
 - End date: 121996
 - Qualification: Specialist
 - Organisation: Specialisation in Pharmacognosy 50/50 cum laude
 - Country: Italy
- 3. Subject: Messina University
 - Start date: 091987
 - End date: 121992
 - Qualification: Degree
 - Organisation: Degree in Pharmaceutical Chemistry and Technology 110/110 cum laude
 - Country: Italy

Additional information

Publications

International journals Danilo Corradini, Eugenia Cogliandro, Luca D'Alessandro, Isabella Nicoletti. Influence of electrolyte composition on the electroosmotic flow and electrophoretic mobility of proteins and peptides, *Journal of Chromatography A*, 1013 (2003) 221–232 □ Danilo Corradini, Eugenia Cogliandro, Isabella Nicoletti. Improved peptide mapping by capillary zone electrophoresis using triethylenetetramine phosphate buffer as the electrolyte solution", *Journal of liquid chromatography & related technologies*, 2785_2800, vol. 24 (2001) □ Isabella Nicoletti, Eugenia Cogliandro, Claudio Corradini, Danilo Corradini, Laura Pizzoferrato. Determination of furosine in hydrolyzate of processed milk by HPLC using a narrow bore column and diode_array detector, *Journal of liquid chromatography & related technologies*, vol. 23 (5), 717_726 (2000) □ Isabella Nicoletti, Claudio Corradini, Eugenia Cogliandro, Antonella Cavazza. Determination of alpha_hydroxy acids in cosmetic products by high_performance liquid chromatography with a narrow_bore column, *International Journal of Cosmetic Science*, 265_274 (1999) □ Paola Dugo, Luigi Mondello, Eugenia Cogliandro, Antonella Cavazza, and Giovanni Dugo. On the genuiness of citrus essential oils. Part LIII. Determination of the composition of the oxygen heterocyclic fraction of lemon essential oils (Citrus limon (L.) Burm. f.) by normal_phase high performance liquid chromatography, *Flavour. Frag. J.* 13, 329_334 (1998) □ Laura Pizzoferrato, Pamela Manzi, Vittorio Vivanti, Isabella Nicoletti, Claudio Corradini ed Eugenia Cogliandro (1998) Maillard Reaction in Milk_Based Foods: Nutritional Consequences, *Journal of Food Protection*, Vol. 61, No. 2, pp. 235_239 (February 1998) □ Claudio Corradini, Giovanni Canali, Eugenia Cogliandro, Isabella Nicoletti. Separation of alditols of interest in food products by high_performance anion_exchange chromatography with pulsed amperometric detection, *Journal of Chromatography A*, vol 791, 343–349 (1997) □ Isabella Nicoletti, Eugenia Cogliandro, Claudio Corradini, Danilo Corradini Analysis of _N_2_Furoylmethyl_L_Lysine (Furosine) in concentrated milk by reversed phase chromatography with a microbore column, *J. Liq. Chrom. & Rel. Technol.* 20 (5), 719_729 (1997) □ Isabella Nicoletti, Claudio Corradini, Eugenia Cogliandro, Danilo Corradini Identification and dosage of 2_Furaldehyde and 5_Hydroxymethyl_2_Furaldehyde in beverage by reversed phase chromatography with a microbore column, *J. Liq. Chrom. & Rel. Technol.* 19 (8), 1241_1254 (1996) □ Paola Dugo, Luigi Mondello, Eugenia Cogliandro, Antonella Verzera, and Giovanni Dugo. On the Genuiness of Citrus Essential Oils. 51. Oxygen Heterocyclic Compounds of Bitter Orange Oil (Citrus aurantium L.), *J. Agric. Food Chem.* 44(2) 544_549 (1996) □ Paola Dugo, Luigi Mondello, Eugenia Cogliandro, Ildefonso Stagno d'Alcontres, and Antonella Cotroneo. On the Genuiness of Citrus Essential Oils. Part XLVI. Polymethoxylated Flavones of the Non Volatile Residue of Italian Sweet Orange and Mandarin Essential Oils, *Flavour Fragr. J.* 9, 105_111 (1994) National Journals □ E. Cogliandro, M. Nicotra: I controlli e le ispezioni a garanzia dei requisiti di qualità, sicurezza ed efficacia dei farmaci equivalent _ La qualità delle materie prime e dei prodotti finiti, *Bollettino d'Informazione sui Farmaci (BIF)*, XV N.3 2008 □ Claudio Corradini, Eugenia Cogliandro, Isabella Nicoletti. Detection and determination of furosine by HPLC with a diode array detector (HPLC_DAD), *Laboratorio 2000*, 124_126 (1997) □ Isabella Nicoletti, Eugenia Cogliandro, Claudio Corradini. Alpha_Hydroxy acids in cosmetic formulations, *Laboratorio 2000*, 50_52 (1999) Proceeding: □ Claudio Corradini, Giovanni Canali, Antonella Cavazza, Eugenia Cogliandro, Isabella Nicoletti. Determination of honey authenticity and its botanical origin by micellar electrokinetic chromatography (MEKC) and HPLC, vol. Authenticity and Adulteration of Food _ The analytical approach_ edited by R. Amadò, R. Battaglia _ *Euro Food Chem IX*, 664_670 Interlaken (1997) □ Laura Pizzoferrato, Pamela Manzi, Vittorio Vivanti, Isabella Nicoletti, Claudio Corradini, Eugenia Cogliandro. Indirect determination of e_deoxyketosyl_lysine in milk based foods, *Chemical Reactions in Food III*, edited by J. Velisek and J. Davidek, Prague, 154_158 (1996) □ Claudio Corradini, Antonella Cavazza, Giovanni Canali, Eugenia Cogliandro, Isabella Nicoletti. Elettroforesi capillare (CE): cenni teorici e sua applicazione in campo alimentare, A.N.CHI.D. "Research and chemical checks as a contribution to the fight against fraud within the EU, Venezia, 351_360 (1996) □ Claudio Corradini, Giovanni Canali, Eugenia Cogliandro, Isabella Nicoletti. Determination of sugars and sugar alcohols in dietetic sweeteners and food by high_performance anion_exchange chromatography (HPAEC) coupled with pulsed amperometric detection (PAD), vol.2 Current Status and Future Trends in Analytical Chemistry _ edited G. Sontag and W. Pfannhauser, Austrian Chemical Society, Vienna, 307_310 (1995) □ P. Dugo, L. Mondello, E. Cogliandro, A. Verzera, G. Dugo, "I composti a nucleo eterociclico contenente ossigeno degli oli essenziali agrumari", 2° Congresso nazionale di Chimica degli Alimenti, 779_783, Messina (1995) □ P. Dugo, L. Mondello, E. Cogliandro, A. Verzera, A. Cavazza, G. Dugo, "I composti a nucleo eterociclico contenente ossigeno dell'olio essenziale di arancia amara", 2° Congresso nazionale di Chimica degli Alimenti, 773_777, Messina (1995) □ L. Mondello, P. Dugo, E. Cogliandro, G. Dugo, "Caratterizzazione dell'olio essenziale di pummelo mediante GC_MS, HPLC e indici chimico_fisici, 2° Congresso nazionale di Chimica degli Alimenti, 785_789, Messina (1995) □ Claudio Corradini, Eugenia Cogliandro, Danilo Corradini Isabella Nicoletti "Cromatografia Elettrocinetica Micellare Capillare (MECC) e Cromatografia Liquida ad Alta Risoluzione (HPLC) con colonne microbore: due tecniche a confronto per la determinazione rapida della 2_furaldeide e del 5_idrossimetil 2_furaldeide negli alimenti, 2° Congresso nazionale di Chimica degli Alimenti, 25_36, Messina (1995)

Projects

Memberships

_ Since June 2022: 1st vice_chair of the of the European Pharmacopoeia Commission, EDQM, Strasbourg _ Since 2005 to date: Italian representative in the CHMP/CVMP Quality Working Party (QWP), EMA, London _ Since 2009 to date: Italian delegate of the European Pharmacopoeia Commission, EDQM, Strasbourg _ 2008 _ 2013: Italian representative in the CMDh subgroup on variation regulation, EMEA, London _ 2007_2010: Italian representative in the European Commission group "Notice to Applicant", Brussels _ 2004_2005: Alternate Italian representative at MRFG group, EMEA, London _ 2001_2004: Alternate Italian representative in the CHMP/CVMP Quality Working Party (QWP), EMA, London

Other Relevant Information

- National and international courses and conferences: n.9 as speaker n.35 co_author (n.16 oral presentations, n.19 posters)

- **Expertise:** Quality assessment of chemical products, in particular of active substances (e.g. mutagenic impurities/nitrosamines). Regulatory topics, in particular on active substances (CEP, ASMF, QP declaration) and variations. Analytical chemistry: HPLC, Capillary Electrophoretic and micro-HPLC Techniques for determination of proteins, peptides, glycoconjugates and other biopolymers. European Pharmacopoeia related topics.