

PERSONAL INFORMATION

Eugenia Cogliandro

WORK EXPERIENCE

November 2004–Present

Scientific administrator/quality assessor (Dirigente chimico) at the Italian Medicines Agency-AIFA

Eugenia Cogliandro (Italy)

-Since October 2010 to date: coordinator of quality assessors involved in national, MRP and DCP procedures and other quality related issues (e.g. CEP withdrawal/suspension, GMP issues or quality defects with impact on registration dossiers)

-Since August 2012 to date: 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 and III), JAP visit preparation (2015), and - from August 2015 - BEMA assessor

-Since 2004 to date: assessor for the evaluation of the chemical-pharmaceutical 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

May 1999–October 2004

Scientific Administrator/Quality Assessor at the Italian Ministry of Health, Directorate General for Drug Evaluation and Pharmacovigilance

Eugenia Cogliandro (Italy)

--1999-2004: assessor for the evaluation of the chemical-pharmaceutical 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

March 1995–April 1999

scholarship holder at CNR (National Research Council)

Eugenia Cogliandro (Italy)

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"

January 1993–December 1994

scholarship holder at Messina University

Eugenia Cogliandro (Italy)

Research activity concerning isolation (LC), separation (HPLC) and characterisation (NMR, MS) of oxygen heterocyclic compounds of citrus essential oils.

EDUCATION AND TRAINING

September 2003–April 2013

Teacher

(Italy)

- 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

 September 1993–December
1996

Specialist

Messina University (Italy)

 Specialisation in Pharmacognosy
50/50 cum laude

 September 1987–December
1992

Degree

Messina University (Italy)

 Degree in Pharmaceutical Chemistry and Technology
110/110 cum laude

ADDITIONAL INFORMATION

Expertise

Regulatory affairs, quality assessment.
Analytical chemistry: HPLC,
Capillary Electrophoretic and micro-HPLC Techniques for determination of proteins, peptides, glycoconjugates and other biopolymers

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 genuineness 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 Genuineness 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 Genuineness 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 olii 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 2005 to date: Italian representative in the CHMP/CVMP Quality Working Party (QWP), EMA, London
- Since 2009 to December 2016: Italian delegate of the European Pharmacopoeia Commission, 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)