Curriculum Vitae

Personal information

Maria Grazia Evandri

Work experience

1. European Medicines Agency (EMA)
   - Start date: Feb 2022
   - End date:
   - Position: Italian alternate at the Committee for Medicinal Products for Human Use (CHMP)
   - Activities: Responsible for making scientific opinions on authorisation of medicines in the European Union.
   - Country: Netherlands
2. Wold Health Organisation (WHO)
   - Start date: Aug 2021
   - End date: Dec 2025
   - Position: Pre_qualification consultant assessor
   - Activities: Non_clinical assessor of safety aspects mainly related to impurity of medicinal products supplied by procurement agencies.
   - Country: Italy
3. Italian Medicines Agency (AIFA) Rome - Centralised Procedures Office
   - Start date: Feb 2026
   - End date:
   - Position: Head
   - Activities: Scientific and regulatory management of Italian (Co-)Rapporteurships and other centralised procedures
   - Country: Italy
4. Italian Medicines Agency (AIFA) Rome _ Pharmaceutical innovation and strategy sector
   - Start date: Apr 2017
   - End date: Feb 2026
   - Position: Pharmacist, coordinator
   - Activities: Support to the Head of sector and Italian CHMP member in non_clinical issues, product information consistency and regulatory affairs for centralised medicinal products. Non_clinical assessor for centralised procedures (chemical, biological and ancillary blood derivatives medicinal products) including marketing authorisation applications, national and EMA scientific advice (including rapid scientific advice on COVID_19 related products), PRIME, referrals and post_approval procedures, playing a leading role in many Italian (Co_)Rapporteurship/Peer reviewer scientific evaluations. Since May 2021, member of the EC 'ad hoc working group to focus on pharmaceuticals in the environment': in this context I contributed to drafting the concept paper for the revision of pharmaceutical legislation aimed at strengthening the environmental risk assessment (ERA) requirements and conditions of use for medicines. Since 2018 Italian member of the EMA Safety Working Party (SWP) (additional expert since 2014). In this context: _ member of the nitrosamines SWP expert group (NSEG): contribution to impurity acceptable intake assessment following request from CHMP and CMDh, and to drafting of guidance documents; _ member of the non_clinical curriculum steering group: contribution to the development of training material for EU non_clinical assessors, _ member of the drafting group for the guideline on the non_clinical requirements for radiopharmaceuticals, Since 2017, consultants for the 'Preliminary Assessment of REgulatory Relevance' (PARERE) a network of national regulators that provides EU Reference Laboratory for alternatives to animal testing, views on test methods and testing strategies applied to pharmaceuticals, in line with the Refine, Reduce, Replace (3Rs) principles. From 2005 to 2018 Italian member of the EMA Quality Review of Documents Working Group. Since 2005 member of the network of EMA experts in non_clinical area.
   - Country: Italy
5. Italian Medicines Agency (AIFA) Rome
   - Start date: 072008
   - End date: 032017
   - Position: Pharmacist, permanent job
   - Activities: Non_clinical assessor (chemical and biological products) for centralised marketing authorisation applications, post_approval and national and EMA scientific advice procedures. Clinical safety assessor for centralised post_approval procedures. Expert in regulatory affairs of centralised procedures. Linguistic reviewer for centralised product information. Contact point for EMA expert database up to 2011.
   - Country: Italy
6. Italian Medicines Agency (AIFA) Rome _ European Assessment Office
   - Start date: 012005
   - End date: 062008
   - Position: Pharmacist, temporary job
   - Activities: Non_clinical assessor (chemical products) for centralised marketing authorisation applications and national scientific advice procedures. Linguistic reviewer for centralised product information. Contact point for EMA expert database and national expert database.
   - Country: Italy
7. University "La Sapienza" Rome Faculty of Pharmacy
   - Start date: 102004

- End date: 022005
- Position: Contract professor
- Activities: Pharmacognosy. Herbal drugs: morphological, microscopical and chemical analysis; quali_quantitative characterisation; biological activity and mechanism of action; therapeutic use.
- Country: Italy

8. University "La Sapienza" Rome Faculty of Pharmacy

- Start date: 102004
- End date: 022005
- Position: Contract professor
- Activities: Principles of environmental toxicology and its impact to human health (e.g. endocrine disruptors).
- Country: Italy

9. Italian Medicines Agency (AIFA) Rome – International Relations Office

- Start date: 092004
- End date: 122004
- Position: Pharmacist, consultant
- Activities: Non_clinical assessor for centralised marketing authorisation applications (chemical products). Contact point for EMA expert database and national expert database.
- Country: Italy

10. University "La Sapienza" Rome Faculty of Pharmacy

- Start date: 012004
- End date: 122004
- Position: Consultant
- Activities: Monitoring of adverse events from herbal medicinal products.
- Country: Italy

11. Research Toxicology Centre (RTC) Pomezia Rome

- Start date: 062001
- End date: 012002
- Position: Fellowship
- Activities: Environmental risk assessment of shallow and deep wastewaters in Lazio region of Italy. Main assays: genotoxicity (Ames test, micronucleus assay, Unscheduled DNA assay); toxicity test (Daphnia magna, Selenastrum capricornutum).
- Country: Italy

12. University "La Sapienza" Rome Faculty of Pharmacy

- Start date: 012001
- End date: 122001
- Position: Fellowship
- Activities: Ecotoxicological assessment of leacheables from plastic polymers used in chemical and food industries. Main assays: genotoxicity (Allium cepa test, micronucleus assay); toxicity test (Daphnia magna, Selenastrum capricornutum), endocrine disruptor activity (Saccharomyces cerevisiae).
- Country: Italy

13. University "La Sapienza" Rome Faculty of Pharmacy

- Start date: 031997
- End date: 121997
- Position: Fellowship
- Activities: Quality control of herbal drugs. Main field: morphological, microscopical and chemical analysis (quail_quantitative characterisation of active ingredients, in vitro and in vivo biological activity).
- Country: Italy

Education and training

1. Subject: University "LUISS Guido Carli" Rome
   - Start date: 122009
   - End date: 122010
   - Qualification: Executive Master in Healthcare and Pharmaceutical Administration
   - Organisation: Health systems in Europe with focus on Italian one; pharmaco_economy, health technology assessment, hospital performances, etc.
   - Country: Italy
2. Subject: University "Tor Vergata" Rome
   - Start date: 112007
   - End date: 112008
   - Qualification: Master in Scientific and Regulatory Assessment of New Medicines
   - Organisation: Hands on in the marketing authorisation dossier: scientific and regulatory approach.
   - Country: Italy
3. Subject: University "La Sapienza" Rome Faculty of Pharmacy
   - Start date: 112001
   - End date: 072004
   - Qualification: Residency in Clinical Pharmacy
   - Organisation: Pharmacology, toxicology, biostatistics/epidemiology, metanalysis, clinical trial designs (prospective and retrospective), pharmaceutical legislation, management of hospital pharmacy/local health services.
   - Country: Italy
4. Subject: University "La Sapienza" Rome Faculty of Pharmacy
   - Start date: 012002
   - End date: 122003
   - Qualification: Post_Doc in Pharmacology
   - Organisation: Environmental risk assessment of waters and wastewaters from different sources; screening of endocrine disruptor activity using a yeast model (Saccharomyces cerevisiae) expressing human estrogen receptor.
   - Country: Italy
5. Subject: University "La Sapienza" Rome Faculty of Pharmacy
   - Start date: 111998
   - End date: 112000
   - Qualification: Doctor of Philosophy (PhD) in Pharmacology, Pharmacognosy and Toxicology
   - Organisation: In vitro and in vivo pharmaco_toxicological characterisation of: herbal extracts, wastewaters, food contaminants and flame retardants. Screening of: endocrine disruptor activity using a

yeast model (Saccharomyces cerevisiae) expressing human estrogen receptor, mutagenesis, chromosomal aberration, general toxicity.
- Country: Italy

6. Subject: University "La Sapienza" Rome Faculty of Pharmacy
   - Start date: 122002
   - End date: 122002
   - Qualification: License/qualification to practice as a pharmacist (licence n. 12085)
   - Organisation: Applied pharmaceutical chemistry, pharmacology, toxicology, pharmaceutical legislation.
   - Country: Italy
7. Subject: University "La Sapienza" Rome Faculty of Pharmacy
   - Start date: 111991
   - End date: 111996
   - Qualification: Degree in Pharmacy
   - Organisation: Pharmaceutical chemistry, physics, pharmacology, anatomy, toxicology, pharmacognosy, biology, physiology, pharmaceutical legislation. Theory and laboratory practice.
   - Country: Italy
8. Subject: Liceo Scientifico Statale "Nomentano" Rome
   - Start date: 091986
   - End date: 071991
   - Qualification: High school Diploma
   - Organisation: Humanistic and scientific subjects with focus on mathematics, physics, biology, chemistry, geography.
   - Country: Italy

Additional information

Publications

Peer_reviewed publications (Hirsch_INDEX: 12; Orcid ID: 0000_0003_0019_1233):

1. Caroline T.A. Moermond, Cecilia Berg, Ulrika Bergstrom, Lucie Bielská, Maria Grazia Evandri, Marco Franceschin, Daniela Gildemeister, Mark H.M.M. Montforts (2023) Proposal for regulatory risk mitigation measures for human pharmaceutical residues in the environmen. Regulatory Toxicology and Pharmacology. *in press*

2. Daniela Gildemeister, Caroline T.A. Moermond, Cecilia Berg, Ulrika Bergstrom, Lucie Bielsk, Maria Grazia Evandri, Marco Franceschin, Boris Kolar, Mark H.M.M. Montforts, Christine Vaculik (2023) Improving the regulatory environmental risk assessment of human
pharmaceuticals: Required changes in the new legislation. *in press*

3. Luca Romanelli, Maria Grazia Evandri (2018) Permitted Daily Exposure for Diisopropyl Ether as a Residual Solvent in Pharmaceuticals. Toxicological Research, 34, 2: 1_15.

4. F. Maranghi, R. Tassinari, D. Marcoccia, I. Altieri, T. Catone, G. De Angelis, E.Testai, S. Mastrangelo, M.G. Evandri, P. Bolle, S. Lorenzetti (2010) The food contaminant semicarbazide acts as an Endocrine Disrupter: evidence from an integrated in vivo/in vitro approach. Chemico_Biological Interactions, 183: 40_48.

5. Mazzanti G., Battinelli L., Daniele C., Costantini S., Ciaralli L., Evandri M.G. (2008) Purity control of some Chinese crude herbal drugs marketed in Italy. Food and Chemical Toxicology, 46: 3043_3047.

6. Di Sotto A., Evandri M.G., Mazzanti G. (2008) Antimutagenic and mutagenic activities of some terpenes in the bacterial riverse mutation assay. Mutation Research, Apr. 22, 653 (1_2): 129_132.

7. P. Bolle, S. Mastrangelo, F. Perrone, M.G. Evandri (2007) Estrogen_like effect of a Cimicifuga racemosa extract sub_fraction as assessed by in vivo, ex vivo and in vitro assays. Journal of Steroid Biochemistry and Molecular Biology, 107: 262_269.

8. S. Mastrangelo, M.G. Evandri, M. Tomassetti, P. Bolle (2005). Quercetin reduces chromosome aberrations induced by atrazine in the Allium cepa test. Environmental and Molecular Mutagenesis, 47: 254_259.

9. Evandri M.G., Battinelli L., Daniele C., Mastrangelo S., Bolle P., Mazzanti G. (2005). The antimutagenic activity of Lavandula angustifolia (lavender) essential oil in the bacterial reverse mutation assay. Food and Chemical Toxicology, 43 (9): 1381_1387.

10. P. Bolle, S. Mastrangelo, P. Tucci, M.G. Evandri (2004) Clastogenicity of atrazine assessed with the Allium cepa test. Environmental and Molecular Mutagenesis, 43 (2): 137_141.

11. M.G. Evandri, L.G. Costa, P. Bolle (2003) Evaluation of brominated diphenyl ether_99 with Raphidocelis subcapitata and Daphnia magna. Environmental Toxicology and Chemistry, 22 (9): 2167_2172.

12. M.G. Evandri, S. Mastrangelo, L.G. Costa, P. Bolle (2003) In vitro assessment of mutagenicitry and clastogenicity of a pentabrominated diphenyl ether (BDE_99) flame retardant. Environmental and Molecular Mutagenesis, 42 (2): 85_90.

13. P. Bolle, M.G. Evandri, L. Saso (2002) The controversial efficacy of vitamin E for human male infertility. Contraception, 65, (4): 313_315.

14. P. Tucci, M.G. Evandri, P. Bolle (2002) Tachykinin_independent activity on in vitro lamb detrusor. Journal of Pharmacy and Pharmacology, 54: 1_5.

15. C. Bartocci, M.G. Evandri, P. Tucci, P. Bolle (2001) Interactions between D_9THC and capsaicin on isolated lamb bladder detrusor. Il Farmaco, 56, (5_7): 349_351.

16. L. Battinelli, B. Tita, M.G. Evandri, G. Mazzanti (2001) Antimicrobial activity of Epilobium spp. extracts. Il Farmaco, 56, (5_7): 345_348.

17. M.G. Evandri, P. Bolle (2001) Pharmaco_toxicological screening of commercially available Italian natural mineral waters. Il Farmaco, 56, (5_7): 475_482.

18. Evandri M.G., Tucci P., Bolle P. (2000) Toxicological evaluation of commercial mineral water bottled in polyethylene terephthalate: a cytogenetic approach with Allium cepa. Food Additives and Contaminants, 17, (12): 1037_1045.

Publications in national journals:

1. M.G. Evandri (2007) La leggibilità del foglio illustrativo dei medicinali. Notiziario Chimico Farmaceutico, Marzo: 114_116.

2. Domenica Costantino, Brunella Piro, Rita Salotti, Alessia Buggè, Barbara Cerilli, Maria Grazia Evandri, Simona Galeassi, Antonio Annetta, Laura Veo (2005) L'uso dei fitoterapici in Italia: indagine collaborativa SIFO_Federfarma in due regioni Italiane. Giornale Italiano di Farmacia Clinica, 19 (1): 33_44.

3. Evandri M.G. et al. In: Costantini S., Mazzanti G., Menniti_Ippolito F. (2004). Medicine tradizionali ayurvedica e cinese: qualità e sicurezza di alcune preparazioni. Rapporti ISTISAN 04/33. 4. G. Mazzanti, M.G. Evandri, L. Battinelli (1998) Saggi farmacognostici su campioni commerciali di fiori e foglie di Malva sylvestris L.. Bollettino Chimico Farmaceutico, 137, (8):

337_340.

Chapter in books:

1. Evandri M.G. co_author “Lessons learnt from presence of N_nitrosamine impurities in sartan medicines” 26 June 2019 EMA
https://www.ema.europa.eu/documents/report/lessons_learnt_presence_n_nitrosamine_impurities_sartan_medicines_en.pdf

2. M.G. Evandri co_author “L’uso dei farmaci in Italia”, Rapporto nazionale 2015 OSMED AIFA
https://www.aifa.gov.it/_/l_uso_dei_farmaci_in_italia_rapporto_osmed_20_6.

3. G. Bonanni, M.G. Evandri (2002) Levodropropizina e dropropizina nel trattamento della tosse. In: Farmacia 2002, Tecniche Nuove Milano: 19_24.

Projects

Memberships

Since 2016, member of the management board of "Enrico and Enrica Sovena" Foundation https://www.fondazionesovena.it/, a non_profit Italian organisation whose mission is to economically support young researchers in medical science. Lecture speaker: _“Non_clinica studies: from animal to organ on a chip” Master di II livello in Discipline Regolatorie e Market Access – 15 anni di Discipline regolatorie e Market Access, Novara 15 October 2022. _ "Centralised procedure for medicinal products approval", EUPATI Corso per paziente esperto, Rome, 6 June 2022 and 12 June 2021. _ "Non_clinical data assessment, product information" II level Master degree at University of Piemonte Orientale, 16 April 2021. _ "Regulatory system: from Europe to Italy",EUPATI Corso per paziente esperto, Rome 28 Septemer 2019. _ "Conditional approval and PRIME: consolidated experience and future perspectives" Symposium Associazione farmaceutici industria, Rimini 8 June 2017. _ "Labelling, foglio illustrativo paziente e QRD templates" Temas_Forum Hotel Holiday Inn Parco dei Medici, Rome, 4 July 2013. _ "Herbal drugs: efficacy and safety" Clinical Pharmacy Faculty of Pharmacy University "La Sapienza", Rome, 16 March 2009. _ "Focus on Medicines Product Information" Temas_Forum Hotel Holiday Inn Parco dei Medici, Rome, 30 September 2008. _ "Adverse drug reaction for herbal drugs" Clinical Pharmacy Faculty of Pharmacy University "La Sapienza", Rome, 26 March and 27 April 2007. _ "Approval of medicinal products for human use: EMA and AIFA roles" Faculty of Pharmacy University "La Sapienza", Rome, 17 April 2006. _ "PIL User Testing; legislative aspects, test validation and application" Temas_Forum Hotel Holiday Inn Parco dei Medici, Rome, 18 October 2006. _ "Approval of medicinal products for human use: EMA and AIFA roles" Faculty of Pharmacy University "La Sapienza", Rome 15 December 2005. _ "Adverse drug reaction for herbal drugs" Istituto di Alta Formazione Sanitaria Rome, 27 April 2004.

Other Relevant Information

Participation in: _EMA training for assessors (oncology) London, 14 _ 25 March 2011. _EMA Product Information Leaflet_User testing, London, 28_29 June 2010. _Workshop for European assessors of clinical data on vaccine, Frascati, Rome 13_14 May 2010. _EMA Pharmacovigilance Assessors' Training, London 25_26 June 2009. _EMA Introduction to MedDRA data analysis and SMQs for physicians, London 21 April 2009. _EMA Assessors Training on the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling, London 15 September 2008. _EMA Training meeting for Experts contact point, London 28 March 2006. _EMA New Assessor training, London 21_22 February 2005. Member in examination commission for Pharmacognosy course at Faculty of Pharmacy University "La Sapienza" Rome: 2000_2006. Referee for several international journals First Certificate of English, grade C, June 2001.