

PERSONAL INFORMATION

Maria Grazia Evandri

WORK EXPERIENCE

April 2017- Present

Permanent job as Pharmacist

Agenzia Italiana del Farmaco (AIFA) Rome - Pharmaceutical innovation and strategy sector (Italy)

Coordinator of regulatory aspects of centralised medicinal products, non-clinical assessor for centralised marketing authorisation applications and scientific advice procedures (main field: in vitro and in vivo pharmacology, toxicology, environmental risk assessment for chemical and biotech products).

Linguistic reviewer for centralised product information.

July 2008-March 2017

Permanent job as Pharmacist

Agenzia Italiana del Farmaco (AIFA) Rome (Italy)

Non-clinical assessor for centralised marketing authorisation applications and scientific advice procedures. Main field: in vitro and in vivo pharmacology, toxicology, environmental risk assessment for chemical and biotech products.

Clinical safety assessor for centralised post-approval procedures. Expert in regulatory aspects of centralised procedures. Linguistic reviewer for centralised product information.

January 2005-June 2008

Temporary job as Pharmacist

Agenzia Italiana del Farmaco (AIFA) Rome - European Assessment Office (Italy)

Non-clinical assessor for centralised marketing authorisation applications and national scientific advice procedures. Main field: in vitro and in vivo pharmacology, toxicology, environmental risk assessment for chemical and biotech products.

Linguistic reviewer for centralised product information. Contact point for EMA experts database and national experts database.

September 2004-December 2004

Consultant as Pharmacist scientific administrator

Agenzia Italiana del Farmaco (AIFA) Rome International Relations Office (Italy)

Non-clinical assessor for centralised marketing authorisation applications. Main field: in vitro and in vivo pharmacology, toxicology for chemical products. Contact point for EMA experts database and national experts database.

October 2004-February 2005

Contract professor for university course in science and technology of herbal drugs

University La Sapienza Rome Faculty of Pharmacy (Italy)

Pharmacognosy. Herbal drugs: morphological, microscopical and chemical analysis; quali-quantitative characterisation; biological activity and mechanism of action; therapeutic use.

October 2004-February 2005

Contract professor for university course in environmental toxicology

University La Sapienza Rome Faculty of Pharmacy (Italy)

Principles of pharmacology and toxicology.

January 2004-December 2004

Consultant

University La Sapienza Rome Faculty of Pharmacy (Italy)

Monitoring of adverse events from herbal medicinal products.

January 2001-December 2001

Fellowship

University La Sapienza Rome Faculty of Pharmacy (Italy)

Ecotoxicological assessment of leacheables from plastic polymers used in chemical and food industries. Main assays: in vitro genotoxicity (Allium cepa test, micronuclei assay); toxicity test (Daphnia magna, Selenastrum capricornutum), endocrine disruptor activity (Saccharomyces cerevisiae).

June 2001-January 2002

Fellowship

Research Toxicology Centre (RTC) Pomezia Rome (Italy)

Environmental risk assessment of shallow and deep wastewaters in Lazio region of Italy. Main assays: in vitro genotoxicity (Ames test, lymphocytes assay, Unscheduled DNA assay); toxicity test (Daphnia magna, Selenastrum capricornutum).

March 1997-December 1997

Fellowship

University La Sapienza Rome Faculty of Pharmacy (Italy)

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).

EDUCATION AND TRAINING

December 2009-December 2010

Executive Master in Healthcare and Pharmaceutical Administration

University LUISS Guido Carli Rome (Italy)

Health systems in Europe with focus on Italian one; pharmacoeconomy, health technology assessment, hospital performances, etc.

November 2007-November 2008

Master in Scientific and Regulatory Assessment of New Medicines

University Tor Vergata Rome (Italy)

Scientific assessment of medicinal product marketing authorisation applications.

November 2001-July 2004

Residency in Clinical Pharmacy

University La Sapienza Rome Faculty of Pharmacy (Italy)

Pharmacology, toxicology, biostatistics, metanalysis, clinical trial design (prospective and retrospective), pharmaceutical legislation, management of hospital pharmacy/local health services.

January 2002-December 2003

Post-Doc in Pharmacology

University La Sapienza Rome Faculty of Pharmacy (Italy)

Environmental risk assessment of waters and wastewaters from different origins; screening of endocrine disruptor activity using a yeast model (*Saccharomyces cerevisiae*) expressing human estrogen receptor.

November 1998-November 2000

Doctor of Philosophy (PhD) in Pharmacology, Pharmacognosy and Toxicology

University La Sapienza Rome Faculty of Pharmacy (Italy)

In vitro and in vivo pharmaco-toxicological characterisation of: herbal extracts, wastewaters, food contaminants, flame retardants. Screening of: endocrine disruptor activity using a yeast model (*Saccharomyces cerevisiae*) expressing human estrogen receptor, mutagenesis, chromosomal aberration, general toxicity.

December 2002-December 2002

License/qualification to practice as a pharmacist (licence n. 12085)

University La Sapienza Rome Faculty of Pharmacy (Italy)

Applied pharmaceutical chemistry, pharmacology, toxicology, pharmaceutical legislation.

November 1991-November 1996

Degree in Pharmacy

University La Sapienza Rome Faculty of Pharmacy (Italy)

Pharmaceutical chemistry, physics, pharmacology, anatomy, toxicology, pharmacognosy, biology, physiology, pharmaceutical legislation. Theory and laboratory practice.

September 1986-July 1991

High school Diploma

Liceo Scientifico Statale Nomentano Rome (Italy)

Humanistic and scientific subjects with focus on mathematics, physics, biology, chemistry, geography.

ADDITIONAL INFORMATION

Expertise

European Medicines Agency (EMA) Safety Working Party; since 2014 as additional expert, since 2018 nominated Italian member.

Since 2018, I have been involved in the assessment of acceptable intakes of nitrosamine impurities in medicinal products.

Since 2005 nominated as EMA non-clinical expert (main field: in vitro and in vivo pharmacology, toxicology, environmental risk assessment, for chemical and biotech products).

From 2005 to 2019, Italian member of the EMA Quality Review of Documents Working Party.

Linguistic reviewer of centralised product information and assessor for package leaflet readability testing.

Publications

Peer-reviewed publications:

1. Luca Romanelli, Maria Grazia Evandri (2018) Permitted Daily Exposure for Diisopropyl Ether as a Residual Solvent in Pharmaceuticals. *Toxicological Research*, 34, 2: 1-15.
2. F. Maranghi, R. Tassinari, D. Marcocchia, 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.
3. 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.
4. Di Sotto A., Evandri M.G., Mazzanti G. (2008) Antimutagenic and mutagenic activities of some terpenes in the bacterial reverse mutation assay. *Mutation Research*, Apr. 22, 653 (1-2): 129-132.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. M.G. Evandri, S. Mastrangelo, L.G. Costa, P. Bolle (2003) In vitro assessment of mutagenicity and clastogenicity of a pentabrominated diphenyl ether (BDE-99) flame retardant. *Environmental and Molecular Mutagenesis*, 42 (2): 85-90.
11. P. Bolle, M.G. Evandri, L. Saso (2002) The controversial efficacy of vitamin E for human male infertility. *Contraception*, 65, (4): 313-315.
12. P. Tucci, M.G. Evandri, P. Bolle (2002) Tachykinin-independent activity on in vitro lamb detrusor. *Journal of Pharmacy and Pharmacology*, 54: 1-5.
13. 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.
14. L. Battinelli, B. Tita, M.G. Evandri, G. Mazzanti (2001) Antimicrobial activity of *Epilobium* spp. extracts. *Il Farmaco*, 56, (5-7): 345-348.
15. M.G. Evandri, P. Bolle (2001) Pharmaco-toxicological screening of commercially available Italian natural mineral waters. *Il Farmaco*, 56, (5-7): 475-482.
16. 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 Bugge, 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 (in italiano).
3. Evandri M.G. et al. In: Costantini S., Mazzanti G., Menniti-Ippolito F. (2004).

Medicine tradizionali ayurvedica e cinese: qualita e sicurezza di alcune preparazioni. Rapporti ISTISAN 04/33 (in italiano).

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 (in Italiano).

Chapter in books:

1 G. Bonanni, M.G. Evandri (2002) Levodropropizina e dropropizina nel trattamento della tosse. In: Farmacia 2002, Tecniche Nuove Milano: 19-24 (in Italiano).

Projects

Memberships

Since 2016, I am in the management board of "Enrico and Enrica Sovena" Foundation, a non-profit Italian organisation whose mission is to fund young researchers in medical science fields.

Other Relevant Information

Since June 2013, Italian contact point for AIFA-WHO pre-qualification for centralised vaccines .

Italian contact point for EMA experts database since 2005 to 2011.

In 2019 Q3, I was involved in the CHMP revision of guidance for substance based medical device consultation as per Regulation 2017/745.

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 international journals:

Environmental Research

Environmental and Molecular Mutagenesis

Food and Chemical Toxicology

Journal of Food Biochemistry

Natural Product Communication

Cell Proliferation

Phytotherapy Research

Journal of Pharmacological Sciences

Lecture speaker:

- "Centralised procedure for medicinal products approval", EUPATI Corso per paziente esperto, Rome, 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 September 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.

First Certificate of English, grade C, June 2001.