



## Curriculum Vitae

### Personal information **Cristiano Colalto**

#### Work experience

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From March 2022 to Present – Quality and non-clinical assessor, AIFA – Agenzia Italiana del Farmaco (Italy), Marketing Authorization Office

Activities include the quality and non-clinical assessment of national procedures, DCPs and MRs for marketing authorisation applications.

Responsibilities include the evaluation of genotoxicity and safety pharmacology in accordance with ICH guidelines, the in silico assessment of impurity profiles using Lhasa Nexus (DEREK & SARAH tools), and the analysis of extractables and leachables (E&L) reports within the context of container-closure system safety. Additional duties comprise the evaluation of Environmental Risk Assessment (ERA) reports in line with the guideline EMEA/CHMP/SWP/4447/00 Rev. 1 – Corr., including the assessment of OECD-compliant studies relevant to environmental fate and ecotoxicity. In addition, responsibilities include the evaluation of local tolerability studies based on OECD tests, where applicable in topical formulations and eye drops, to support product safety.

From April 2019 to February 2022 – External Collaborator, AIFA – Agenzia Italiana del Farmaco (Italy)

Activity of quality and safety assessment of homoeopathic medicinal products in the national procedure, including the review of quality documentation, the evaluation of non-clinical evidence, and the assessment of genotoxicity and safety pharmacology in accordance with HMPWG and ICH principles.

From January 2006 to March 2019: Community Pharmacist AGEC -Azienda gestione Edifici Comunali (Italy).

Responsible for dispensing of prescription and over-the-counter medicines to the public. reviewing prescriptions from doctors to ensure accuracy and suitability for the patient, including the dosage, ingredients required, and correctly and safely labelled, preparing galenic, official and magistral medicines.

#### Education and training

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From January 2020 to January 2021: II Level Master Degree in "Legal competences in healthcare" at Università Cattolica del Sacro Cuore (Rome, Italy)

Training included regulatory frameworks for pharmaceuticals and medical devices, healthcare law, administrative procedures in the health sector, legal aspects of marketing authorisations, compliance with national and EU legislation, management of regulatory documentation, public-sector contracting rules, medico-legal principles, and the application of legal reasoning in regulatory and healthcare settings.

From October 2006 to November 2010: Post-degree 4-yrs Specialization in Pharmacology at the School of Specialization in Pharmacology, University of Milan (Italy)

Curriculum included advanced general and clinical pharmacology, toxicology, pharmacokinetics and pharmacodynamics, mechanisms of drug action, non-clinical study design and interpretation, biostatistics, preclinical safety assessment, drug development methodology, regulatory sciences and pharmacovigilance principles.

From September 2000 to October 2005: 5yrs Degree in Pharmacy at the University of Padua (Italy)

#### Additional information

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##### Publications

Colalto C, Festa C, Alexanian A, Pireddu MM, Gabriele G, Parlato M. From stockpiles to preparedness: antidotes in CBRN emergencies. *Health Policy*. 2026 *On referee*

Colalto C. Aspects of complexity in quality and safety assessment of peptide therapeutics and peptide-related impurities. A regulatory perspective. *Regul Toxicol Pharmacol*. 2024 Nov;153:105699.

Colalto C. Safety assessment of Homeopathic medicines: The Adonis vernalis paradox and the "analysis trap" of using different pharmacopeia. *J Appl Toxicol* 40 (2020); 1454-66.

Colalto C. Volatile molecules for COVID-19: A possible pharmacological strategy? *Drug Dev Res*. 81 (2020); 950-968.

Colalto C. BOOK chapter: Droghe Immunostimolanti - Book: "Farmacognosia e Fitoterapia: basi scientifiche e aspetti applicative" a cura di Gabriela Mazzanti, Mario Dell'Agli, Angelo Izzo. Editor: PICCIN NUOVA LIBRARIA SPA. ISBN: 882993058X

Colalto C. BOOK chapter: Droghe Vegetali e disturbi delle vie Aeree Superiori - Book: "Farmacognosia e Fitoterapia: basi scientifiche e aspetti applicative" a cura di Gabriela Mazzanti, Mario Dell'Agli, Angelo Izzo. Editor: PICCIN NUOVA LIBRARIA SPA. ISBN: 882993058X

Borrelli F, Colalto C, Delfino DV, Iriti M, Izzo AA. Herbal dietary supplements for erectile dysfunction: a systematic review and metaanalysis. *Drugs* 78 (2018); 643-73.

Colalto C: What phytotherapy needs: evidence-based guidelines for better clinical practice. *Phytotherapy Res*. 32 (2018); 413-25.

Colalto C: 38° National congress Societa Italiana di Farmacologia, 25-28 Ottobre 2017, Rimini: POSTER: "Need for evidence-based guidelines for improving phytotherapy in clinical practice."

Colalto C. 38° Congresso Nazionale Societa Italiana di Farmacologia, 25-28 Ottobre 2017, Rimini: COMUNICAZIONE

ORALE "Herbal dietary 08/03/2023 European Medicines Agency Page 1/2 supplements for erectile dysfunction: a systematic review and metaanalysis." Authors: Borrelli F, Colalto C, Delfino DV, Iriti M, Izzo AA.

Working Group on Pharmacognosy: Guidelines for the use of plant-based products. 2 ottobre 2013 available at [https://www.sifweb.org/documenti/guideline\\_2013-10-02](https://www.sifweb.org/documenti/guideline_2013-10-02)

Colalto C: Unpredictable adverse reactions to herbal products. *J Drug Metab Toxicol* 3 (2012); 2-3.

Colalto C: Valutazione dei rischi connessi all'utilizzo di prodotti farmaceutici e para- farmaceutici contenenti piante medicinali. *Pratica Medica e Aspetti Legali* 6 (2012);31-37.

Colalto C: Response to the letter "Drug interactions with St. John's wort products". *Pharmacol Res.* 63 (2011);257-58.

Colalto C: Herbal interaction on absorption of drugs: mechanisms of action and clinical risk assessment. *Pharmacol Res.* 62 (2010); 207-227.

Passilongo PR, Colalto C, Segala N: Il giorno dopo e troppo tardi. Il farmacista educatore sanitario: prevenzione dell'AIDS a scuola. *Dialogo Sui Farmaci* 1 (2010); 19-21.

Dell'Aica I, Niero R, Piazza F, Cabrelle A, Sartor L, Colalto C, Brunetta E, Lorusso G, Benelli R, Albini A, Calabrese F, Agostini C, Garbisa S; Hyperforin blocks neutrophil activation of MMP-9, motility and recruitment, and restrains inflammation-triggered angiogenesis and lung fibrosis. *J Pharmacol Exp Ther* 321 (2007); 492-500.

## Projects

Activity of referee for scientific journals, for example: *Annals of internal Medicine*.

6.000 euro scholarship obtained from the ITALIAN PHARMACEUTICAL COUNCIL (FOFI) for participation of Master degree course: ""Skills in Healthcare Legal Services", ALTEMS - University Cattolica del Sacro Cuore in years 2020/2021

## Memberships

Member of Italian Pharmacological Society (SIF) since 2011 and Italian Toxicological Society (SITOX) since 2021. Member of some Working groups in this societies: -Phytotherapy and Pharmacognosy- working group (SIF), -Safety on botanical products- working group (SITOX),- Food Safety- working group (SITOX), -Clinical toxicology- working group (SITOX).

Since 2004, member of Military Corp of Italian red Cross as Pharmacist involved in National antidote stockpile organization.

Member of Homeopathic Society of Verone, Vicolo Dietro Santissimi Apostoli, 4, 37121 Verona VR, an Italian school of Homeopathic medicine.

## Other Relevant Information

I have collaborated with the CMDh member and with the Non-clinical Working Party (NC-WP) representative of AIFA on targeted regulatory investigation and analysis projects. I am a member of the Methodology Working Party and participate in the AI Working Group. I am also engaged in initiatives related to equity in environment and health, environmental justice, and citizen science, and I have been the author of a report addressing PFAS pollution issues in the Veneto region (my home region) in northern Italy.