



## Curriculum Vitae

### Personal information **Monica Bartolomei**

#### Work experience

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1. Employer: Istituto Superiore di Sanità, National Centre for the Control and evaluation of Medicines, Chemical Drugs Unit
  - Start date: 122022
  - End date:
  - Position: Research Director
  - Activities: Coordinator of post\_marketing surveillance activities especially related to pharmaceutical defects or foreign matters or lack of efficacy (since 2018). Coordinator of anti\_falsification activities (since 2018) Coordinator of evaluation activities related to quality of non\_immunological veterinary medicines (Agreement ISS\_Ministry of Health, since 2021)
  - Country: Italy
2. Employer: Istituto Superiore di Sanità
  - Start date: 012007
  - End date: 122022
  - Position: Senior Researcher
  - Activities: Control activities in the field of chemical medicines: \_ Post\_marketing surveillance studies \_ OMCL\_network related activities \_ falsified medicines Evaluation activities in the field of chemical medicines Assessor of Investigational Medicinal Product Dossiers (Quality part) for Phase I Clinical Trials (since 2012). Assessor of quality part (Module 3 or Part II) of CTD in National and European marketing authorization procedures of human and veterinary medicines. Expert of the Italian Working Party on Radiopharmaceuticals since 2009. Assessor of quality part (Module 3 or Part II) of CTD in national marketing authorisation procedures of radiopharmaceuticals. Coordinator of activities related to quality of cosmetics (from 03/2010 to 08/2010) Member of Italian Working Group COVID\_19 "Drugs" (11/03/2020\_29/04/2020) and "Drugs and Clinical Trials" (since 29/04/2020, Decreto n.63/2020) Research activity related to falsified medicines and "medicines in disguise": food supplements, cosmetics, medical devices, other health products containing undeclared APIs.
  - Country: Italy
3. Employer: Istituto Superiore di Sanità \_ Department of Therapeutic Research and Medicines Evaluation – Quality of Chemical Drugs Unit
  - Start date: 012003
  - End date: 012007
  - Position: Researcher
  - Activities: Control and evaluation activities in the field of chemical medicines OMCL\_network related activities. Assessor of quality part (Module 3 or Part II) of CTD in National and European marketing authorization procedures of human and veterinary medicines. Evaluation of Quality part of biocide disinfectants (Presidi Medico Chirurgici) Research activity: quality of generic medicines and counterfeit and illegal medicines
  - Country: Italy
4. Employer: Istituto Superiore di Sanità – Laboratory of Pharmaceutical Chemistry. Physical\_organic Chemistry Unit
  - Start date: 032002
  - End date: 012003
  - Position: Head of Physical\_organic Chemistry Unit ad interim
  - Activities: Research activities: physico\_chemical characterization of drugs; solid\_state studies on API. Quality of generic medicines. OMCLs network related activities. Evaluation of Quality part of biocide disinfectants (Presidi Medico Chirurgici)
  - Country: Italy
5. Employer: Istituto Superiore di Sanità – Laboratory of Pharmaceutical Chemistry. Physical\_organic Chemistry Unit
  - Start date: 041992
  - End date: 032002
  - Position: Researcher
  - Activities: Research activities: physico\_chemical characterisation of API, solid\_state studies on active substance by spectroscopic and thermal analysis, polymorphism.
  - Country: Italy
6. Employer: Farmacia Santi, ex Chieffo, via Capo Le Case 47, Rome
  - Start date: 041989
  - End date: 041992
  - Position: Pharmacist
  - Activities:
  - Country: Italy

#### Education and training

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1. Subject: University "La Sapienza" Rome \_ Italy
  - Start date: 1988
  - End date:
  - Qualification: University degree in Pharmacy
  - Organisation:
  - Country: Italy

## Additional information

### Publications

1) M. C. Gaudiano, P. Bertocchi, D. De Orsi, L. Manna, E. Antoniella, A. L. Rodomonte, A. Sorbo, F. Aureli, M. Bartolomei. A case of medicine in disguise: motion sickness patches sold as medical devices containing active pharmaceutical substances. *Ann Ist Super Sanità*, 58, 4 (2022) 254\_263. 2) M. Raimondo, A. Borioni, M. Bartolomei, A. Mosca, G. Gostoli Classification of the Ibuprofen Active Pharmaceutical Ingredients by chemical patterns combining HPLC, <sup>1</sup>H-NMR spectroscopy and Chemometrics: Traceability of legal medicines. *Annali Istituto Superiore di Sanità*, 56, 4 (2020) 403\_408. 3) L. Manna, M.C. Gaudiano, M. Bartolomei, L. Valvo, P. Bertocchi, E. Antoniella and A. Rodomonte. A special case of medicine in disguise: Tattoo inks containing anaesthetics. *Talanta* (2019) 198:337\_343. 4) Gaudiano M.C., Manna L., Bartolomei M., Rodomonte A.L., Bertocchi P., Antoniella E., Romanini L., Alimonti S., Rufini L. and Valvo L. Health risks related to illegal and on\_line sale of drugs and food supplements: results of a survey on marketed products in Italy from 2011 to 2013". *Annali Istituto Superiore di Sanità* 52,1 (2016) 128\_132. 5) Mustazza C, Borioni A, Rodomonte A, Bartolomei M, Antoniella E, Di Martino P, Valvo L, Sestili I, Costantini E, Gaudiano MC. Characterization of Sildenafil analogs by MS/MS and NMR: a guidance for detection and structure elucidation of phosphodiesterase\_5 inhibitors. *Journal of pharmaceutical and biomedical analysis* (2014); 96:170\_186. 6) M.C. Gaudiano, L. Manna, M. Bartolomei, P. Bertocchi, A.L. Rodomonte, B. Gallinella, E. Antoniella, N. Muleri, G. Civitelli, S. Alimonti, L. Romanini, L. Rufini and L. Valvo. A Survey on Illegal and Counterfeit Medicines for the Treatment of Erectile Dysfunctions in Italy. *J. Sexual Medicine* (2012) 9, 2130\_2137. 7) M.C. Gaudiano, D. Lucente, E. Antoniella, P. Bertocchi, N. Muleri, L. Manna, M. Bartolomei, S. Alimonti, L. Valvo, A.L. Rodomonte. For export only" medicines come back to Europe: a RP- LC method for the screening of six glucocorticoids in illegal and counterfeit anti\_inflammatory and lightening creams. *J. Pharm. Biomed. An.* 53 (2010) 158\_164. 8) A.L. Rodomonte, M.C. Gaudiano, E. Antoniella, D. Lucente, V. Crusco, M. Bartolomei, P. Bertocchi, L. Manna, L. Valvo, F. Alhauque, N. Muleri Counterfeit drugs detection by measurement of tablets and secondary packaging colour. *Short communication J. Pharm. Biomed. An.* 53 (2010) 215\_220. 9) A. Rodomonte, E. Antoniella, P. Bertocchi, M. C. Gaudiano, L. Manna and M. Bartolomei Different crystal morphologies arising from different preparation methods of a same polymorphic form may result in different properties of the final materials. The case of diclofenac sodium trihydrate. *J. Pharm. and Biomed. An.*, 48 (2008) 477\_481. 10) M.C. Gaudiano, A. Di Maggio, E. Antoniella, L. Valvo, P. Bertocchi, L. Manna, M. Bartolomei, S. Alimonti, A. L. Rodomonte. An LC method for the simultaneous screening of some common counterfeit and substandard antibiotics. Validation and uncertainty estimation. *J. Pharm. Biomed. Anal.*, 48 (2008) 303\_309. 11) M. Bartolomei, A. Rodomonte, E. Antoniella, G. Minelli and P. Bertocchi. Hydrate modifications of the non steroidal anti\_inflammatory drug diclofenac sodium: solid-state characterisation of a trihydrate form. *J. Pharm. Biomed. Anal.*, 45 (2007) 443\_449. 12) A. Rodomonte, A. Montinaro e M. Bartolomei Uncertainty evaluation in the chloroquine phosphate potentiometric titration: Application of three different approaches. *J. Pharm. Biomed. Anal.* 42 (2006) 56\_63. 13) M. Bartolomei, P. Bertocchi, E. Antoniella, A. Rodomonte. Physico\_chemical characterisation and intrinsic dissolution studies of a new form of diclofenac sodium: comparison with anhydrous form. *J. Pharm. Biomed. Anal.* 40 (2006) 1105\_1113. 14) M. Cotta Ramusino, M. Bartolomei, L. Romanini, L. Rufini. Preparati a base di erbe officinali: la normativa italiana. *Notiziario ISS \_ Vol.15 - n.1* (gennaio 2002). 15) M. Bartolomei Solid state studies on the hemihydrate and anhydrous forms of flunisolide. *J. Pharm. and Biomed. Analysis* 24 (2000) 81\_93. 16) M. Bartolomei, P. Bertocchi, M. Cotta Ramusino, L. Valvo, E. Santucci. Physicochemical characterization of the modifications of (R,S) propranolol hydrochloride: solubility and dissolution studies. *J. Pharm. and Biomed. Analysis* 21 (1999) 299\_309. 17) L. Montanari, M. Costantini, E. Ciranni Signoretti, L. Valvo, M. Santucci, M. Bartolomei, P. Fattibene, S. Onori, A. Faucitano, B. Conti, I. Genta. Gamma irradiation effects on poly (d,l\_lactide\_co\_glycolide) microspheres. *Journal of Controlled Release* 56 (1998) 219\_229. 18) M. Cotta Ramusino, M. Bartolomei, B. Gallinella. <sup>1</sup>H NMR, UV and Circular Dichroism Study of inclusion complex formation between 5\_lipoxygenase inhibitor zileuton and beta\_and gamma\_cyclodextrins. *Journal of Inclusion Phenomena and Molecular Recognition in Chemistry* 32 (1998) 485\_498. 19) M. Bartolomei, P. Bertocchi, M. Cotta Ramusino, E. Ciranni Signoretti. Thermal studies on the polymorphic modifications of (R,S) propranolol hydrochloride. *Thermochimica Acta* 321 (1998) 43\_52. 20) M. Bartolomei, M. Cotta Ramusino, P. Ghetti. Solid\_state investigation of fluocinolone acetonide. *Journal of Pharm. and Biom. Analysis* 15 (1997) 1813\_1820. 21) M. Cotta Ramusino, M. Bartolomei, L. Rufini. <sup>1</sup>H NMR and UV spectroscopic study of inclusion complex formation between pyridoxine and beta\_and gamma\_cyclodextrins. *Journal of Inclusion Phenomena and Molecular Recognition in Chemistry* 25 (1996) 113\_116. 22) M. Bartolomei, M. Cignitti, M. Cotta Ramusino, G. La Manna. Ab initio study of the tautomeric forms of some quinolinediones. *Journal of Molecular Structure (Theochem.)* 330 (1995) 431\_435. 23) M. Bartolomei, M. Cignitti, M. Cotta Ramusino, M. T. Iela. Solid\_phase thermal decomposition of benomyl. *Pesticide Science* 41 (1994) 91\_95. Technical Report: 1) L. Valvo, M. Bartolomei, M.C. Gaudiano, I. Sestili, L. Manna, E. Antoniella, A. Rodomonte, P. Bertocchi, C. Pini. Risks related to the online purchase of medicines for prevention and therapy of COVID\_19 and to the dissemination of fake news on social networks. *Rapporto ISS COVID\_19, n.15/2020*. 2) M. Bartolomei, M.C. Gaudiano, L. Manna, C. Caldaroni, L. Romanini, P. Bertocchi, D. De Orsi, S. Alimonti, L. Rufini, L. Valvo. Integratori alimentari contraffatti nel mercato europeo ASKLEPIOS. *Rapporti ISTISAN 19/10* (2019) 3) M.C. Gaudiano, L. Manna, P. Bertocchi, M. Bartolomei, A. Rodomonte, S. Alimonti, L. Romanini, L. Rufini, N. Muleri, B. Gallinella, M. Mirra, S. Lucattini, M. Di Gregorio, L. Fucili, L. Valvo. Lotta alla contraffazione farmaceutica: le attività dell'Istituto Superiore di Sanità. *Rapporti ISTISAN 10/20* (2010) 4) L. Valvo, M. Bartolomei, P. Bertocchi, M.C. Gaudiano, L. Manna "L'Istituto Superiore di Sanità (ISS) e le attività inerenti la contraffazione farmaceutica" capitolo 5.8 p.120\_125 del Volume "Farmaci Contraffatti"/"Counterfeit Medicines" EDQM/AIFA, 2010. 5) M.C. Gaudiano, M. Bartolomei, I. Sestili "Procedure di mutuo riconoscimento: problematiche di qualita' dei farmaci per uso umano nei dossier di autorizzazione all'immissione in commercio". *Rapporti ISTISAN 06/15* (2006). 6) A. Rodomonte, M. Bartolomei Stima dell'incertezza di misura nell'attività di controllo chimico dei farmaci *Rapporti ISTISAN*, 03/18 (2003). 7) M. Cotta Ramusino, M. Bartolomei, L. Romanini. Network europeo dei laboratori ufficiali di controllo dei farmaci. Il ruolo del Laboratorio di Chimica del Farmaco dell'Istituto Superiore di Sanità. *Rapporti ISTISAN*, 02/13 (2002) 8) M. Cotta Ramusino, M. Bartolomei, A. Bianchi, L. Romanini, L. Rufini. Classificazione dei preparati a base di erbe officinali e regolamentazione dell'importazione nel mercato dell'Unione Europea. *Rapporti ISTISAN*, 01/35 (2001). (riprodotto sul mensile "Farma Mese") 9) L. Montanari, M. Costantini, E. Ciranni, L. Valvo, M. Santucci, M. Bartolomei, P. Fattibene, S. Onori, B. Conti, I. Genta. Processi di sterilizzazione e loro influenza sulle proprietà del principio attivo. *Rapporti ISTISAN*, 98/13, 45 (1998). 10) L. Gagliardi, L. Turchetto, M. Bartolomei, P. Sangermano, R. Netti, L. Spadafina, L. Iannuzzi. Rapporto sui cosmetici n.3. Analisi chimico\_microbiologiche su una classe di cosmetici: i rossetti. *Bollettino Chimici Igienisti*, 42 (1991) 651. 11) L. Gagliardi, L. Turchetto, M. Bartolomei, M. Ambroso, P. Sangermano, R. Netti. Identificazione dei coloranti in alcuni prodotti cosmetici. *Bollettino dei Chimici Igienisti* 41 (1990) 537\_553. 12) L. Gagliardi, L. Turchetto, A. Amato, M. Bartolomei, R. Netti, L. Bellucci, L. Spadafina, L. Iannuzzi. Rapporto sui cosmetici n. 2. Analisi chimico\_microbiologiche su una classe di cosmetici: i deodoranti e antitraspiranti. *Bollettino dei Chimici Igienisti* 41 (1990) 423\_439. 13) L. Gagliardi, L. Turchetto, M. Bartolomei, P. Sangermano, P.S. Paoloemili, R. Ricci, U. Nardi. Un esempio di approccio al controllo di conformità di una classe di prodotti cosmetici: i solari. *Cosmesi dermatologica* 37 (1991) 7\_27. 14) L. Gagliardi, G. Cavazzutti, M. Bartolomei. I filtri solari: metodiche di valutazione dell'efficacia. *Economia Farmaceutica* 2 (1990) 9\_19. 15) L. Gagliardi, M. Bartolomei. Identificazione e dosaggio del minoxidil e dell'acido trans\_retinoico in preparazioni per uso topico. *Cosmesi dermatologica*, 35 (1990) 39\_47. 16) L. Gagliardi, A. Amato, L. Turchetto, M. Bartolomei. Identificazione e dosaggio di alcuni conservanti nei prodotti cosmetici per HPLC- RP. *Cosmesi Dermatologica*, 31 (1990) 73\_87. 17) L. Gagliardi, A. Amato, L. Turchetto, M. Bartolomei, E. Malizia. Determinazione e dosaggio della benzocaina, timolo e fenolo nei prodotti farmaceutici e cosmetici. *Rivista di Tossicologia Sperimentale e Clinica*, 1\_3 (1989) 83\_89. 18) L. Gagliardi, A. Amato, M. Bartolomei. Il controllo chimico analitico come prevenzione degli effetti indesiderati dei prodotti cosmetici. *Rivista di Tossicologia Sperimentale e Clinica*, 1\_3 (1989) 75\_82.

### Projects

Europol EMPACT 2015: WP1 "Tackling illegal food supplements containing forbidden substances".

### Memberships

### Other Relevant Information