

### PERSONAL INFORMATION

**Carla Marcella Caramella**

### WORK EXPERIENCE

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February 2017- Present

#### Professor Emeritus

University of Pavia (Italy)

Teaching and research responsibilities at the Department of Drug Sciences, University of Pavia

November 2015- Present

#### Contract professor

University of Pavia (Italy)

Teaching responsibilities (undergraduate level, curricula in Pharmacy and in Pharmaceutical Chemistry and Technology: Procedure for Marketing authorization of medicinals

Teaching responsibilities (post-graduate level): Director and docent of Biopharmaceutics of the Master Course in Pharmaceutical Technologies and Regulatory Affairs, member of the Advisory Board of the Doctorate in Pharmaceutical Sciences, Biomolecules and Health Products (University of Parma), Docent of Industrial manufacturing of Active Substances and Pharmaceutical Excipients of the Doctorate of Chemical and Pharmaceutical Sciences (University of Pavia)

Italian coordinator (since 2016) of the Erasmus Mundus Joint Master Degree in Nanomedicine for Drug Delivery (ref.: 574439-EPP-1-2016-1-FR-EPPKA1-JMD-MOB)

November 1986-November 2015

#### full professor

University of Pavia (Italy)

Teaching responsibilities (undergraduate level): Biopharmaceutics: 1986-94; Industrial Pharmacy: 1994-95; Pharmaceutics: 1995-2000; Cosmetic products: 2000-2001; Biopharmacy and Pharmaceutical Technology: 2001-2012; Applied Pharmaceutical Chemistry: 2012-15

Teaching responsibilities (post-graduate level): Master in Preformulation and Pharmaceutical Development: since 2002; Master in Pharmaceutical Technologies and Regulatory Affairs: since 2012, Doctorate in Biopharmaceutics and Pharmacokinetics: 1996-2013, Doctorate in Pharmaceutical Sciences, Biomolecules and Health Products, since 2013

November 2003-October 2006

#### Dean of the Faculty of Pharmacy

University of Pavia (Italy)

Coordination of educational activities, management of Faculty budget

2002- 2005

#### Director

Interuniversity Consortium Tefarcolnova (Italy)

Promotion of educational activities and research collaborations with Institutions and Companies

1980- 1986

#### Associate Professor

University of Pavia (Italy)

Teaching responsibilities in applied medicinal chemistry and biopharmacy

1970- 1980

#### assistant professor

University of Pavia (Italy)

Research activities in the fields of pharmaceutical preformulation and biopharmacy. Applied medicinal chemistry and biopharmacy laboratory management

July 2020- 2025

#### Professor Emeritus

University of Pavia (Italy)

Italian coordinator (since 2020) of the Erasmus Mundus Joint Master Degree in Nanomedicine for Drug Delivery, renewal

### EDUCATION AND TRAINING

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- 1968- 1971 **Advanced degree in Pharmaceutical Chemistry and Technology**  
University of Pavia (Italy)  
Medicinal Chemistry, Applied medicinal chemistry, Physical Pharmacy, Biopharmacy, Pharmaceutical Technology, Pharmaceutical Analysis, Pharmacology and Toxicology, Pharmacy Law
- 1964- 1967 **Degree in Pharmacy**  
University of Pavia (Italy)  
Pharmacy Practice, Pharmaceutical care, Pharmacology, Botany, Pharmacognosy, Galenics and compounding, Cosmetics, Dispensing of medicines, Pharmacy Law

## ADDITIONAL INFORMATION

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**Expertise** Scientific and technical expertise includes: Control of APIs, development and controls of drug products (solid and semisolid dosage forms), powder characterization, tablet disintegrants, disintegration mechanisms, suspension stability, solid state characterization, dissolution, in vitro diffusion studies, in vivo-in vitro correlation, viscometry, dynamic rheology, characterization of hydrophilic polymers, characterization of semisolids, mucoadhesion mechanisms and testins, intestinal and transmucosal absorption mechanisms, absorption enhancement strategies, use of cell cultures as bioassays in formulation development, cytotoxicity tests, wound repair strategies, In vivo model for wound healing.

259 published papers, 253 cited papers, including original papers, reviews, published abstracts and miscellaneous publications, ove 310 presentations at Conferences, 17 book chapters, one text-book on Pharmaceutical Technology, H index: 48 (Scopus), 6769 citations.

Co-inventor of 15 patents, some of them are owned by companies and two of them have been transferred from the University to companies for industrial exploitation.

**Computer skills**  
Microsoft Office 2010 (Word, Excel, Powerpoint, Outlook, Publisher), Internet Explorer, Mozilla, Google Crome, Windows 10.  
Pharmacokinetic modelling programmes (Siphar, Kinetica), statistical elaboration (Statgraphics).

**Communication skills**  
Has worked for about 45 years at the University (Pharmacy Department) with teaching and training responsibilities as reader, lecturer and professor both at undergraduate and postgraduate level (Doctorate, Master courses and continuing education courses) (see work experiences).  
Has participated at many national and international conferences as presenter of research papers and has delivered more about 105 invited lectures (including plenary and key-note lectures).  
Has been nominated in committees for the evaluation of the PhD thesis dissertation by the following Universities/Schools of Pharmacy : Milano 1- I, Torino- I, Bologna-I, Geneve (CH), Groningen (NL), Granada (E ), Tolouse ( F ), Oslo ( N ), Vitoria (E), Uppsala (SE), Helsinki (F), Trieste (I), Singapore (Singapore republic), University Teknologi Mara (Malaysia), Rhodes University Republic of South Africa, Beira Interior (PT), Barcelona (ES).

**Other job-related skills (scientific reviewing)**  
Member of the Editorial Advisory Board of indexed journals (see membership).  
Extensive peer reviewing activity in the fields of pharmaceuticals, biopharmacy, pharmaceutical technology, polymer science, chemical engineering, nanotechnology and biomedical nanomedicine.  
Editor of a special issue on Chitosans biomedical applications: opportunities and challenges in Pharmaceutics, an MPDI journal.  
Participation three times, in 2005 (member), 2007 (member) and 2008 (Chairman), at the evaluation board of the Academy of Finland for the assessment of research projects in the field of Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology.

**Other job-related skills (regulatory activities)**  
Quality assessor of many applications for veterinary drugs, both national and MR/DC procedures (with Italy as RMS).  
Rapporteur/co-rapporteur's assessor in the evaluation of quality of about 50 centralized procedures, including SA.  
Quality assessor in MR/DC procedures for human drugs (with Italy as RMS).  
Quality assessor in CP/MR/DC procedures for human drugs (with Malta as RMS)  
Rapporteur and co-rapporteur for about 90 applications for the release of Certificates of suitability (CEP).

Pharmaceutical expert nominated by the Civil Court -Milano (Italy)

External expert of the WHO Biowaiver Pilot Project, HQ/TSN Technologies Standards and Norms, World Health Organization (2018-20)

- Publications** 259 published papers, including original papers, reviews, published abstracts and miscellaneous publications, over 300 presentations at Conferences, 17 book chapters, 1 Textbook in Pharmaceutical Technology, co-inventor of 15 patents
- List of recent publications including research papers, reviews, chapters in books and patents.
- Research papers and reviews (2019-2010)
- Borg, J.-J., Melchiorri, D., Sepodes, B., Caramella, C.M. et al., Optimising bench science to withstand regulatory scrutiny (Editorial), *Pharmacological Research* Volume 139, January 2019, Pages 491-493
- C.M.Caramella, A. Valli, Unguenti oftalmici a base dell'associazione corticosteroide/antibiotico: Considerazioni biofarmaceutiche e cliniche -Il caso di Betabiopital unguento oftalmico, *Minerva Oftalmologica*, 2018, Vol. 60.
- Rossi, S. Email Author, Vigani, B., Bonferoni, M.C., Sandri, G., Caramella, C., Ferrari, F., Rheological analysis and mucoadhesion: A 30 year-old and still active combination. *Journal of Pharmaceutical and Biomedical Analysis* Volume 156, 15 July 2018, Pages 232-238
- Rossi, S., Mori, M., Vigani, B., Bonferoni, M.C., Sandri, G., Riva, F., Caramella, C., Ferrari, F., A novel dressing for the combined delivery of platelet lysate and vancomycin hydrochloride to chronic skin ulcers: Hyaluronic acid particles in alginate matrices, *European Journal of Pharmaceutical Sciences* Volume 118, 15 June 2018, Pages 87-95
- Saporito, F.a, Sandri, G., Rossi, S., Bonferoni, M.C., Riva, F., Malavasi, L., Caramella, C., Ferrari, F., Freeze dried chitosan acetate dressings with glycosaminoglycans and tranexamic acid, *Carbohydrate Polymers* Volume 184, 15 March 2018, Pages 408-417
- Bonferoni, M.C., Riva, F., Invernizzi, A., Delleria, E., Sandri, G., Rossi, S., Marrubini, G., Bruni, G., Vigani, B., Caramella, C., Ferrari, F., Alpha tocopherol loaded chitosan oleate nanoemulsions for wound healing. Evaluation on cell lines and ex vivo human biopsies, and stabilization in spray dried Trojan microparticles, *European Journal of Pharmaceutics and Biopharmaceutics*, Volume 123, February 2018, Pages 31-41
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- M. Tenci, S. Rossi, M. C. Bonferoni, G. Sandri, I. Mentori, C. Boselli, A. Icaro Cornaglia, M. Daglia, A. Marchese, C. M. Caramella, F. Ferrari, Application of DoE approach in the development of mini-capsules, based on biopolymers and manuka honey polar fraction, as powder formulation for the treatment of skin ulcers, *Int. J. Pharm.*, 516 (2017) 266-277
- G. Sandri, S. Motta, M. C. Bonferoni, P. Brocca, S. Rossi, F. Ferrari, V. Rondelli, L. Cantu, C. Caramella, E. Del Favero, Chitosan-coupled Solid Lipid Nanoparticles: tuning nanostructure and mucoadhesion *Eur. J. Pharm Biopharm.*, 110 (2017) 13-17
- Tenci, M., Rossi, S., Aguzzi, C., Carazo, E., Sandri, G., Bonferoni, M.C., Grisoli, P., Viseras, C., Caramella, C.M., Ferrari, F., Carvacrol/clay hybrids loaded into in situ gelling films, *International Journal of Pharmaceutics*, Volume 531, Issue 2, Pages 676-688
- Faccendini, A., Vigani, B., Rossi, S., Sandri, G., Bonferoni, M.C., Caramella, C.M., Ferrari, F., Nanofiber scaffolds as drug delivery systems to bridge spinal cord injury, *Pharmaceutics Open Access*, Volume 10, Issue 3, September 2017.
- Marciello, M., Rossi, S., Caramella, C., Remunan-Lopez, C., Freeze-dried cylinders carrying chitosan nanoparticles for vaginal peptide delivery, *Carbohydrate Polymers* Volume 170, 15 August 2017, Pages 43-51
- Mackie, A.R., Goycoolea, F.M., Menchicchi, B., Caramella, C.M., Saporito, F., Lee, S., Stephansen, K., Chronakis, I.S., Hiorth, M., Adamczak, M., Waldner, M., Nielsen, H.M., Marcelloni, L., Innovative Methods and Applications in Mucoadhesion Research, *Macromolecular Bioscience* Volume 17, Issue 8, August 2017, Article number 1600534

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G. Sandri, M.C. Bonferoni, S. Rossi, A. Delfino, F. Riva A. Icaro Cornaglia, G. Marrubini, G. Musitelli, C. Del Fante, C. Perotti, C. Caramella, F. Ferrari, Platelet lysate and chondroitin sulfate loaded contact lenses to heal corneal lesions, *Int. J. Pharm.*, 509 (2016) 188-196

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M. Mori, S. Rossi, F. Ferrari, M.C. Bonferoni, G. Sandri, T. Chlapanidas, M. Torre, C. Caramella. "Sponge-like dressings based on the association of chitosan and sericin for the treatment of chronic skin ulcers. I. DoE assisted development", *J.PHARM.SCI.*, 105 (2016), 1180-1187

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G. Horvat, M. Budai-Szucs, S. Berko, P. Szabo-Revesz, J. Soos, A. Facsko, M. Maroda, M. Mori, G. Sandri, M.C. Bonferoni, C. Caramella, E. Csanyi. Comparative study of nanosized cross-linked sodium-, linear sodium-and zinc-hyaluronate as potential ocular mucoadhesive drug delivery systems, *Int. J. Pharm.*, 494 (2015), 321-328

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M. Mori, S. Rossi, M.C. Bonferoni, F. Ferrari, G. Sandri, F. Riva, C. Del Fante, C. Perotti, C. Caramella. Calcium alginate particles for the combined delivery of platelet lysate and vancomycin hydrochloride in chronic skin ulcers, *International Journal of Pharmaceutics*, 461 (1-2) (2014), 505-513.

G. Sandri, M. C. Bonferoni, F. Ferrari, S. Rossi, C. Aguzzi, M. Mori, P. Grisoli, P. Cerezo, M. Tenci, C. Viseras, C. Caramella, Montmorillonite-chitosan-silver sulfadiazine nanocomposites for topical treatment of chronic skin lesions: in vitro biocompatibility, antibacterial efficacy and gap closure cell motility properties, *Carbohydrate Polymers*, 102 (2014) 970-977

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M. Sorrenti, L. Catenacci, M.C. Bonferoni, G. Sandri, C. Caramella, G. Bettinetti (2010). Thermal characterization of diltiazem and lambda-carrageenan binary systems. JOURNAL OF THERMAL ANALYSIS AND CALORIMETRY (ISSN:1388-6150) p. 337 - 342 Vol. 102

G. Sandri, M.C. Bonferoni, E. H. Gokce, F. Ferrari, S. Rossi, M. Patrini, C. Caramella (2010). Chitosan-associated SLN: in vitro and ex vivo characterization of cyclosporine A loaded ophthalmic systems. JOURNAL OF MICROENCAPSULATION (ISSN:0265-2048) p.735 - 746 Vol. 27

C. Caramella, F. Ferrari, M.C. Bonferoni, S. Rossi, G. Sandri, (2010). Chitosan and its derivatives as drug penetration enhancers. JOURNAL OF DRUG DELIVERY SCIENCE AND TECHNOLOGY (ISSN:1773-2247) p. 5 - 13 Vol. 20

G. Sandri, M.C. Bonferoni, S. Rossi, F. Ferrari, C. Boselli, C. Caramella (2010). Insulin-Loaded Nanoparticles Based on N-Trimethyl Chitosan: In Vitro (Caco-2 Model) and Ex Vivo (Excised Rat Jejunum, Duodenum, and Ileum) Evaluation of Penetration Enhancement Properties. AAPS PHARMSCITECH (ISSN:1530-9932) p. 362 - 371 Vol. 11

Book Chapters (since 2012)

F. Ferrari, M. C. Bonferoni, S. Rossi, G. Sandri, C. M. Caramella (2012). Manufacture Techniques of Chitosan-Based Microparticles and Nanoparticles for Biopharmaceuticals. In: Bruno Sarmento and Jose das Neves, Chitosan-Based Systems for Biopharmaceuticals: Delivery, Targeting and Polymer Therapeutics. John Wiley & Sons, Chichester, UK p. 137 - 158

G. Sandri, M. C. Bonferoni, F. Ferrari, S. Rossi, C. M. Caramella (2014). The role of particle size in drug release and absorption. In: H.G. Merkus, G.M.H. Meesters. Particulate Products - Tailoring properties for optimal performance. vol. 19, p. 323-341, Heidelberg, New York, Dordrecht ; London; Kluwer Academic Publishers: SPRINGER, ISBN: 978-3-319-00713-7, doi: 10.1007/978-3-319-00714-4

C. M. Caramella, M. C. Bonferoni, G. Sandri, S. Rossi, F. Ferrari, E. Deller, F. Macchi. Medical devices for oral mucosal applications. In: M. J. Rathbone, S. Senel, I. Pather. Oral mucosal drug delivery and therapy. Springer, ISBN: 9781489975577

G. Sandri, S. Rossi, F. Ferrari, M. C. Bonferoni, C. Caramella. Mucoadhesive polymers as enabling excipients for oral mucosal drug delivery, Cap 4, In: ; Editors: r, Springer (2015), ISBN: . In: M. J. Rathbone, S. Senel, I. Pathe. Oral mucosal drug delivery and therapy. Springer, ISBN: 978-1-4899-7557-7

S. Rossi, F. Ferrari, G. Sandri, M.C. Bonferoni, C. Del Fante, C. Perotti, C. Caramella, Biopolymers and Hemoderivatives in Wound Healing, Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, 2015 Editor: M. Mishra, CRC Press Taylor and Francis Group (2015), ISBN 9781439898796

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Patents (since 2009)

M. C. Bonferoni, G. Sandri, S. Rossi, F. Ferrari, C. Caramella (2014) Nanoemulsioni olio-in-acqua - Universita degli Studi di Pavia MI2014A001812

F. Ferrari, S. Rossi, M.C. Bonferoni, G. Sandri, C. Caramella, P. Allegrini (2012). Composizioni farmaceutiche. Dipharma Francis Srl, Baranzate (MI) MI2012A001654

C. Caramella, M.C. Bonferoni, S. Rossi, G. Sandri, F. Ferrari, C. G. Perotti, C. Del Fante (2011). Platelet lysate and bioadhesive compositions thereof for the treatment of mucositis. Biomed Device Srl (Reggello, FI, IT). US2011/0280952 A1

C. Caramella, S. Rossi, G. Sandri, G. Gennari (2009). Antiviral topical formulations in the form of a bio-adhesive gel. Fidia Farmaceutici SpA (Abano Terme, PD, IT). WO2009031006

G. Bottoni, P. Maffei, A. Sforzini, M. Federici, C.M. Caramella, S. Rossi, C.G. Viscomi (2009) Mucoadhesive formulations useful in medical devices and in pharmaceutical formulations WO/2006/131262, publication date: 14/12/2009

**Projects** Organizational activities, both educational and research project oriented.

Supervisor of the research work of about 35 people including PhD students, post-doc and grant holders, conducted in collaboration with different research groups in different academic and industrial contexts. Has started and maintained scientific/educational collaborations with the following Universities: University of Granada (E), University of Northern Basque Country (E), University of Paris V (F), University of Groningen (NL), University of Helsinki (F), University of Uppsala (SE), University of Oslo (N), University of Svedged (HU), University of Ege (TR), Purdue University (US), University of Marseille (F), University of Rosario (AR).

Coordinator 2016-19 (University of Pavia) of the Erasmus Mundus Joint Master Degrees (EMJMD) NANOMEDICINE FOR DRUG DELIVERY (NANOMED) (intake 1 and 2), Reference number 574439-EPP-1-2016-1-FR-EPPKA1-JMD-MOB, approval by the Education, Audiovisual & Culture Executive Agency (EACEA) communicated on date 13.07.2016.

Has been Coordinator of research projects funded by University of Pavia (since 1996), CNR (1994-99) CE (INTAS 2001-03), PRIN (2002 and 2005), Cariplo Foundation on reparative medicine (2007-10), Regional Government of Marche (2009-11).

Coordinator of Research projects presently concluded (see updated Declaration of interest). with pharmaceutical companies ( e.g. Eurand International, Convatec U.K, Procter & Gamble Belgium, ALFA-Wassermann, Montereisearch, Dompe Farmaceutici, Angelini ACRAF, Rottapharm Madaus, Helsinn Healthcare SA, Fidia Farmaceutici, PH&T s.r.l., SIIT s.r.l., Aboca s.p.a., Doppel Farmaceutici S.r.l., Sanofi S.p.a., Thea Pharma) and Hospital (IRCCS Policlinico S.Matteo -Pavia) in the fields of expertise including the development of innovative technological platforms for drug delivery.

Main organizer of more than 40 events including educational seminars, workshops and symposia in the following fields: Preformulation studies, Dissolution, Prediction and modelling of pharmacokinetic and biopharmaceutical parameters, Design and development of oral drug delivery systems, Cell culture methods, Challenges and opportunities of Biosimilars, Drug delivery systems for biotech products, Pharmacokinetic studies in phase I clinical trials, Combination products and innovation in drug delivery systems, Mucoadhesion and testing methods, Regulatory expectations on drug substance impurities: authority and industry perspective, Modern analytical techniques in pharmaceutical Industry-a tool to support pharmaceutical quality and to ease regulatory process, Pharmacovigilance: present and future, Data integrity in API Industry, ASMF: GMP perspective and regulatory compliance- from starting materials to API.

**Memberships** Scientific membership

Member of the Editorial Advisory Board of Pharmaceutical Development and Technology, AAPS PharmSciTech, European Journal of Pharmaceutical Sciences, Journal of Drug Delivery Science and Technology, Journal of Pharmaceutical Sciences, Molecular Pharmaceutics, NJ Pharmacy and Pharmacology, Progress on Chemistry and Application of Chitin and its Derivatives

Editor of Journal of Drug delivery

Editor (special issue) of Pharmaceutics

Member of AAPS, Elected AAPS fellow in 2001

Member of CRS (Controlled Release Society)

Member of EUFEPS (European Federation of Pharmaceutical Scientists)

Member of the Executive Board of AFI (Italian Association of Industrial Pharmacists)

Member (Secretary) of SIFEB (Italian Society of Pharmacokinetics and Biopharmaceutics)

Regulatory Body memberships/expertise

Member of the Committee for the Evaluation of Veterinary Medicinal Products (1996-2016 ) appointed by the Italian Ministry of Public Health

Member ( since 2016) of The Technical Committee for Nutrition and Animal Health (Subcommittee for Veterinary medicines) appointed by the Italian Ministry of Public Health

Member of the ISO /TC 24 SC/ 4 (Subcommittee "Sizing by methods other than sieving") and representative of UNI therein

Expert appointed by EMEA for the scientific evaluation of centralized applications (since 1998)

Member, appointed by the Italian Agency for Medicines (AIFA), of the secretariat UVA (Evaluation and Marketing Authorization Office) (since 2012)



Expert, appointed by AIFA, for the quality of medicinals (2014)

Expert rapporteur for the procedure for the certification of suitability of monographs of the EP (since 1999)

Quality external assessor for Medicines Authority Malta (since 2017)

#### Other Relevant Information

##### Honours and Awards

"Commendatore della Repubblica Italiana" nominated by the President, 2006

Elected AAPS Fellow 2001

A.F.I. award ( 2002, 2004 and 2010) for her cooperation with the Association as an academic member

Award of " Commendatore al merito della Repubblica Italiana " (2007) for academic services

First recipient of the "Ralph Shangraw Memorial prize ", created by IPEC American Foundation, Atlanta 2008, for innovative research in the fields of pharmaceutical excipients

JDDST Award for the best article published on Journal of Drug Delivery Science and Technology in 2011

Elsevier recognition for the most cited article published on European Journal of Pharmaceutical Sciences in 2004

European Journal of Pharmaceutics and Biopharmaceutics award as " Top reviewer in 2007"

APhA (American Pharmacists Association) award as "Outstanding reviewer of the Journal of Pharmaceutical Sciences, 2012"

APhA (American Pharmacists Association) award as "Outstanding reviewer of the Journal of Pharmaceutical Sciences, 2017"

International Journal of Pharmaceutics certificate as "Outstanding reviewer 2018"