

## Carla Marcella Caramella, Pharm D



### CURRENT POSITION

-Professor Emeritus, Department of Drug Science, University of Pavia, Pavia, Italy  
-Contract Professor, European Procedures for Marketing Authorization of Medicinals  
Coordinator of Advanced post-graduate Program in Pharmaceutical Technologies and Regulatory Affairs  
Italian coordinator of the EMJMD in Nanomedicine for Drug Delivery

### WEBSITES

**ORCID ID** <https://orcid.org/0000-0002-1261-1525>

**Google Scholar** <https://scholar.google.it/citations?user=DGbOWfAAAAAJ&hl=it>

**Scopus Author ID**

<https://www.scopus.com/results/authorNamesList.uri?name=name&st1=caramella&st2=carla+marcella&institute=university+of+Pavia&origin=cto>

**Pub Med** <https://pubmed.ncbi.nlm.nih.gov/?term=caramella+carla>

**EMAExpertsDB** (June 2023)

[https://www.ema.europa.eu/sites/default/files/ContactsandExperts/experts\\_files/ccaramella\\_CV\\_en.pdf](https://www.ema.europa.eu/sites/default/files/ContactsandExperts/experts_files/ccaramella_CV_en.pdf)

### PERSONAL

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### EDUCATION / AFFILIATIONS /POSTS

1964- 1967 Degree in Pharmacy-University of Pavia  
1968- 1971 Advanced degree in Pharmaceutical Chemistry and Technology University of Pavia (Italy)  
1970- 1980 Assistant professor- University of Pavia  
1980- 1986 Associate Professor. University of Pavia  
2002- 2005 Director Interuniversity Consortium TefarcoInnova (Italy)  
2003- 2006 Dean of the Faculty of Pharmacy University of Pavia  
1986- 2015 full professor University of Pavia  
November 2015- Present Contract professor  
2007-2023-Coordinator of the Advanced Program (post-graduate) in Pharmaceutical Technology and Regulatory affairs  
2018--Italian Coordinator of the Erasmus Mundus Joint Master Degree in Nanomedicine for Drug Delivery  
2017- Present Professor Emeritus University of Pavia

### RESEARCH ACTIVITIES

#### Participation in Research Projects-FUNDING

Carla Caramella has been Coordinator of research projects funded by the 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).

Has been Coordinator of Research projects sponsored/supported by pharmaceutical companies ( e.g. Eurand International, Convatec U.K, Procter & Gamble Belgium, ALFA\_Wassermann, Monteresearch, Dompè 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 by Hospitals (IRCCS Policlinico S.Matteo –Pavia) in her fields of expertise including the development of innovative technological platforms for drug delivery (approx. 1.0 M€). She is presently senior scientific consultant of the research projects lead by Proff C. Bonferoni and S. Rossi at the Department of Drug Sciences.

Previous research interest and scientific expertise include: 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, intestinal and transmucosal absorption mechanisms, absorption enhancement strategies, thermogelling systems for topical administration, mucoadhesion mechanisms and testing. More recent research interest include: mucopenetration and nanoparticles, use of cell cultures as bioassays in formulation development, including nanoobjects, cytotoxicity tests, in vivo model for wound healing, development of advanced medications for wound healing, including nano fibers and nanocomposites, electrospinning, development of polymeric nanoparticles based on natural and semisynthetic polysaccharides and polymer combinations.

## **TEACHING ACTIVITIES**

### **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;

European Procedures for MAA of Medicinals: presently

### **Teaching responsibilities (post-graduate level):**

Master in Preformulation and Pharmaceutical Development: since 2002, Dispersed system

Master in Pharmaceutical Technologies and Regulatory Affairs: since 2012, Solid dosage forms

Doctorate in Biopharmaceutics and Pharmacokinetics: 1996-2013, Dissolution and bioavailability

PhD program in Chemical and Pharmaceutical Sciences, and Related Industrial Innovation: Industrial production of API and pharmaceutical excipients (since 2014)

PhD programs in the Macro-areas of Science and Technology and Life Sciences: Nanomedicine

Regulatory Aspects within the frame of the workshop on Research and Nanomedicine (since 2019)

## **PRIZES-HONORS**

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 “, IPEC America Foundation, Atlanta 2008

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”

Elsevier (European Journal of Pharmaceutical Sciences) Certificate of Excellence in Reviewing, 2016

## CONFERENCE ORGANIZATION

**Organization activities** (as President or member of the scientific/organizing Committee) (since 2008)

- Workshop on “Biosimilari: sfide e opportunità“, Pavia, 23-24 September 2008, in collaboration with AFI, CRS Italian Chapter and Consorzio TEFARCO Innova
- Meeting on “La farmacocinetica nello sviluppo del farmaco“, Milano, 5-6 febbraio 2009, in collaboration with Università degli Studi di Milano, Dipartimento di Scienze Farmacologiche
- Workshop on " Drug delivery systems for biotech products“, Pavia, 24-25 March 2010, in collaboration with CRS Italian Chapter and AFI
- Workshop on “Principi di farmacocinetica rilevanti per gli studi clinici di fase I“, Fondazione IRCCS Policlinico S.Matteo, Pavia, 19 September 2012
- Workshop on “Combination products and innovation in drug delivery systems“, AAPS Annual Meeting, San Diego (CA), 1-5 Novembre 2014
- 14th International Conference of the European Chitin Society ICCS EUCHIS 2015, Munster 31 August-4 September 2015
- Workshop on Mucoadhesion, ICCS EUCHIS 2015, Munster 31 August-4 September 2015
- AFI Annual Symposium, member of the Scientific Committee since 2006

### Recent organization activities

- NANOMED Workshop” FROM BIOTECHNOLOGY TO NANOBIOLOGY AND VACCINES“, Pavia, 11\_13 July 2022.
- 14th International Conference of the European Chitin Society (EUCHIS 2023) and the 15th International Conference on Chitin and Chitosan (15th ICCS), Siglufjörður, Iceland, Sept. 11 – 14th, 2023.
- Pharmacopeias: overview, uses and related activities. A guide towards a correct use University of Pavia (Italy), 17th November 2023 Aula Magna. Collegio A. Volta

Within the mentoring/tutoring activities 40 educational seminars/tutorials, were organized (see last paragraph).

## PROFESSIONAL AFFILIATIONS

- SITELF (Italian Association of Pharmaceutical Technology and Legislation)
- APGI/APV (Association de Pharmacie Galenique Industrielle)
- European Federation of Pharmaceutical Scientists (EUFEPS)
- AAPS (American Association of Pharm. Scientists) (Elected Fellow 2001)
- Controlled Release Society (CRS)
- CRS -Italian Chapter
- European Chitin Society (member of the Board)
- Member of the Executive Board of AFI (Italian Association of Industrial Pharmacists)
- Member (Secretary) of SIFEB (Italian Society of Pharmacokinetics and Biopharmaceutics)
- Galenos Network for novel Drug delivery Exploitation and Education

## PROFESSIONAL ACTIVITIES

### Editorial activities:

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

### 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)  
13/01/2022 European Medicines Agency Page 8/9  
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)

### **Research Evaluation Activities:**

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.  
Evaluator, nominated by the Italian Ministry of University and Research, of PRIN (Progetti di Ricerca di Interesse Nazionale) Projects, 2017 call for application.  
Evaluator, nominated by University of Modena e Reggio Emilia, of FAR 2022 and 2023 Projects.  
President/member of committees for the evaluation of the PhD thesis dissertation nominated by the following Universities/Schools of Pharmacy : Milano 1- I, Torino- I, Bologna-I, Geneve (CH), Groningen (NL), (Singapore republic), University Teknologi Mara (Malaysia), Rhodes University Republic of South Africa, Beira Interior (PT), Barcelona (ES).

### **PATENTS**

Co-inventor of 15 patents, national and/or european and/or PCT applications. Some of them are owned by companies and two of them have been transferred from the University to companies for industrial exploitation.

### **PUBLICATIONS (GENERAL)**

258 papers peer-reviewed journals, 12 chapters in books (or series), 477 Abstracts in proceeding of National & International conferences, 17 book chapters, 1 Textbook in Pharmaceutical Technology, co-inventor of 15 patents. Participation in > 300 International conferences/workshops.  
Invited speaker in >100 National and International scientific meetings/workshops/conferences.

### **METRICS**

**Google Scholar 735** cited documents: **Citations** 11096 (all), 4036 (since 2019); **h-index**: 62 (all), 36 (since 2019); **i10-index**: 180 (all) , 106 (since 2019);  
**Scopus** 258 cited documents: **Citations**: 8155; **h-index**: 53

### **REPRESENTATIVE PUBLICATIONS**

- Zofia Nuc , , Gloria Brusotti , Laura Catenacci , Ana Grenha , Jorge F. Pontes , Joana Pinto da Silva , Ana Maria Rosa da Costa , Paola Moro , Chiara Milanese , Pietro Grisoli, Milena Sorrenti , Aldona Dobrzycka-Krahel, Maria Cristina Bonferoni and Carla Marcella Caramella, *Pontastacus leptodactylus* (Eschscholtz, 1823) and *Faxonius limosus* (Rafinesque, 1817) as New, Alternative Sources of ,Chitin and Chitosan, *Water* 2023, 15, 3024; [doi.org/10.3390/w15173024](https://doi.org/10.3390/w15173024)
- Sara Perteghella , Alice Garzoni, Alessandro Invernizzi, Milena Sorrenti, Cinzia Boselli , Antonia Icaro Cornaglia, Daniele Dondi, Simone Lazzaroni, Giorgio Marrubini , Carla Caramella ,

Laura Catenacci, and Maria Cristina Bonferoni, Nanoemulsions of Clove Oil Stabilized with Chitosan Oleate—Antioxidant and Wound-Healing Activity, *Antioxidants* 2023, 12, 273; [doi.org/10.3390/antiox12020273](https://doi.org/10.3390/antiox12020273)

- Dalila Miele, Laura Catenacci , Silvia Rossi , Giuseppina Sandri, Milena Sorrenti , Alberta Terzi, Cinzia Giannini , Federica Riva , Franca Ferrari, Carla Caramella and Maria Cristina Bonferoni,\* Collagen/PCL Nanofibers Electrospun in Green Solvent by DOE Assisted Process. An Insight into Collagen Contribution. *Materials* 2020, 13, 4698; [doi:10.3390/ma13214698](https://doi.org/10.3390/ma13214698)

Marco Ruggeri, Eleonora Bianchi, Silvia Rossi , Barbara Vigani, Maria Cristina Bonferoni , Carla Caramella, Giuseppina Sandri \* and Franca Ferrari, Nanotechnology-Based Medical Devices for the Treatment of Chronic Skin Lesions: From Research to the Clinic, *Pharmaceutics* 2020, 12, 815; [doi:10.3390/pharmaceutics12090815](https://doi.org/10.3390/pharmaceutics12090815)

- Nurulaini Harjoha, Tin Wui Wonga, Carla Caramella, Transdermal insulin delivery with microwave and fatty acids as permeation enhancers, *International Journal of Pharmaceutics* 584 (2020) 119416, [doi.org/10.1016/j.ijpharm.2020.119416](https://doi.org/10.1016/j.ijpharm.2020.119416)

F. Fahmideh, N. Marchesi, L. I. M. Campagnoli, L. Landini, C. Caramella, A. Barbieri, S. Govoni and A. Pascale Effect of troxerutin in counteracting hyperglycemia-induced VEGF upregulation in endothelial cells: a new option to target early stages of diabetic retinopathy? *Frontiers in Pharmacology*, August 2022; [DOI 10.3389/fphar.2022.951833](https://doi.org/10.3389/fphar.2022.951833)

Barbara Vigani, Caterina Valentino, Giuseppina Sandri, Carla Marcella Caramella, Franca Ferrari ,Silvia Rossi, Spermidine Crosslinked Gellan Gum-Based “Hydrogel Nanofibers” as Potential Tool for the Treatment of Nervous Tissue Injuries: A Formulation Study, *International Journal of Nanomedicine* 2022:17 3421–3439.

Electrospinning Technologies in Wound Dressing Applications

Giuseppina Sandri, Silvia Rossi, Maria Cristina Bonferoni, Carla Caramella, Franca Ferrari

Book Editor(s): Joshua Boateng, First published: 10 January 2020

[doi.org/10.1002/9781119433316.ch14](https://doi.org/10.1002/9781119433316.ch14)

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

- 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 traxenamic 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
- Bonferoni, M.C., Sandri, G., Rossi, S., Delleria, E. Invernizzi, A., Boselli, C., Cornaglia, A.I., Del Fante C., Perotti, C., Vigani, B., Riva, F., Caramella, C., Ferrari, F., Association of alpha

tocopherol and ag sulfadiazine chitosan oleate nanocarriers in bioactive dressings supporting platelet lysate application to skin wounds(Article), *Marine Drugs*, open access Volume 16, Issue 2, February 2018, Article number 56

- 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
- 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, *Pharmaceuticals Open Access*, Volume 10, Issue 3, September 2017.
- 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.
- Caramella, C., Conti, B. , Modena, T., Ferrari, F., Bonferoni, M.C., Genta, I., Rossi, S., Torre, M.L., Sandri, G., Sorrenti, M., Catenacci, L., Dorati, R., Tripodo, G. Controlled delivery systems for tissue repair and regeneration. *Journal of Drug Delivery Science and Technology*, 32 (2016), 206-228
- M. Mori, S. Rossi, F. Ferrari, M.C. Bonferoni, G. Sandri, M. Tenci, F. Riva, C. Del Fante, G. Nicoletti, C. Caramella. "Sponge-like dressings based on the association of chitosan and sericin for the treatment of chronic skin ulcers. II. Loading of the hemoderivative platelet lysate", *J. PHARM. SCI.*, 105 (2016) 1188-1195
- Fontana, Flavia; Mori, Michela; Riva, Federica; Makila, Ermei; Liu, Dongfei; Salonen, Jarno; Nicoletti, Giovanni; Hirvonen, Jouni; Caramella, Carla; Santos, Helder, "Platelet Lysate-Modified Porous Silicon Microparticles For Enhanced Cell Proliferation in Wound Healing Applications", *ACS APPL.MATER. INTERFACES*, 2016, 8 (1), pp 988-99
- G. Amasya, G. Sandri, A. Onay-Besikci, U. Badilli, C. Caramella, M. C. Bonferoni, N. Tarimci, "Skin localization of Lipid Nanoparticles (SLN/NLC): Focusing the Influence of Formulation Parameters", *Current Drug Delivery* 13(999), January 2016
- A. Rossi, C. Conti, G. Colombo, L. Castrati, C. Scarpignato, P Barata, G. Sandri, C. Caramella, R. Bettini, F. Buttini, P. Colombo. Floating modular drug delivery systems with buoyancy independent of release mechanisms to sustain amoxicillin and clarithromycin intra-gastric concentrations, *Drug Development and Industrial Pharmacy*, 42 (2), (2016), 332-339
- M. Budai-Szucs, G. Horvat, B. A. Szilagyi, B. Gyarmati, A. Szilagyi, S. Berko, P. Szabo´-Revesz, G. Sandri, M. C. Bonferoni, C. Caramella, J. Soos, A. Facsko, E. Csanyi, Cationic thiolated poly(aspartamide) polymer as a potential excipient for artificial tear formulations, *Journal of Ophthalmology*, article number 2647264 (2016)
- M.C. Bonferoni, G. Sandri, E. Delleria, S. Rossi, F. Ferrari, Y. Zambito, C. Caramella. Palmitoyl Glycol Chitosan Micelles for Corneal Delivery of Cyclosporine, *J. Biomed. Nanotechnol.*, 12 (2016), 231-240
- C. Caramella, S. Rossi, F. Ferrari, M. C. Bonferoni, G. Sandri. Mucoadhesive and thermogelling systems for vaginal drug delivery, *Adv. Drug Delivery Rev.*, 92 (2015) 92, 39-52

#### CHAPTERS IN BOOKS-BOOK SERIES

17 Chapters in Books or book series

## **BOOK**

Textbook in Pharmaceutical Technology

## **INVITED PRESENTATIONS**

>100 INVITED PRESENTATIONS (Invited, Keynote and Plenary speaker) in International Conferences and Workshops,

### **MENTORING -MAJOR CONTRIBUTIONS TO THE EARLY CAREERS OF RESEARCHERS**

- Mentor for about 30 years of certainly more than 100 hundreds Master theses of students in Pharmacy and Chemistry Pharmaceutical Technology (5 year curricula)
- Mentor for 20 years of about one hundred students of the post-graduate Advanced Program in Pharmaceutical Technology and Regulatory Affairs.
- 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. She has promoted and maintained educational/scientific 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 (N2), University of Sveged (HU), University of Ege (TR), Purdue University (US), University of Marseille (F), University of Rosario (AR). Through this network many undergraduate and graduate students had the opportunity to spend study periods abroad under different student mobility programs.
- Currently mentoring the master thesis work of four students.
- During the years has organized of about 40 educational seminars/tutorials, mainly directed to the graduate students, on 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. Pharmacovigilance: present and future, Data integrity in API Industry, ASMF: GMP perspective and regulatory compliance\_ from starting materials to API.