

CURRICULUM VITAE

1. PERSONAL DETAILS

Claudio I. BERNARDI

Date of birth: June 27th 1959

Position: Preclinical/Regulatory Toxicology Consultant

Nationality: Italian

2. EDUCATION

1983 Doctor in Veterinary Medicine (D.V.M.), University of Milan

1999 Diplomate in Lab. An. Science and Medicine, University of Milan

3. LANGUAGES

English (written and oral)

French (written and oral)

4. PROFESSIONAL EXPERIENCE

	Establishment	Position
1984	Italian Army	Veterinary Officer
1985	Private Veterinary Lab.	Histopathologist
1987	Zambeletti-Beecham/Safety Dept	Toxicological Pathologist
1989	Bracco / Preclinical Research Labs.	Head of Pathology and Animal Care Units
1993	FICE/Preclinical Safety named in 1993 Pharmacia	General Toxicology, Study Director (short-, long-term studies)
1995	Pharmacia	Head of TSA/Animal Care and Service Team Toxicologist Secretary of the Ethic Committee
1996	Pharmacia & Upjohn	Head of Animal Care & Treatment
1999	Pharmacia & Upjohn	Experimental Toxicology (in vivo toxicology, planning, Lab. Animal. Med. & Care) Director
2000	Pharmacia & Upjohn	Toxicology Operations (in vivo Toxicology, Planning, Lab. Anim. Med. & Science), Director - Project Toxicologist Chair of the Ethic Committee
July 2002 – 14 May 2004	Pharmacia Italia Spa Pfizer Group Inc.	Toxicology Operations (in vivo Toxicology, Planning, Lab. Anim. Med. & Science), Director -

		Project Toxicologist Chair of the Ethic Committee
May 2004	Nerviano Medical Sciences/ Preclinical Development	Preclinical Operations & Compliance, Director Chair of the Ethic Committee
From 01.02.2009	Accelera	Compliance & Administration, Director Chair of the Ethic Committee
From 01.08.2022 to 30.06.2026	Accelera	Chief Operating Officer Chair of the AWB (OPBA)

5. OTHER RELEVANT EXPERIENCE/ACCREDITATION

- Professor of "Preclinical Toxicology" - University of Milan
- National Register Certified Italian Toxicologist (RENTIC; EUROTOX Accredited)
- Member of the "PARERE" Network established by the Italian Health Minister
- Member of EU-NetVal (JRC Ispra; Network for the Validation of Alternative Methods)
- Member of the RENTIC Commission (Evaluation of new membership applications)

6. MEMBERSHIP/PROFESSIONAL ASSOCIATIONS

- National DVM Register (Albo Medici Veterinari) - Full Member
- Italian Society of Lab. Animal Sciences (AISAL) – Full Member (formerly Vice President)
- Italian Society Toxicological and Experimental Pathology (SIPTS)- Governing Board
- European Society of Lab. Animals Veterinarians (ESLAV) – Full Member (formerly President)
- Italian Society of Toxicology (SITOX) - Full Member
- European Federation of Pharmaceutical Industries (EFPIA) - Italian Representative "Research Animal Welfare" Expert Group
- Society of Toxicology (SOT) – Full Member
- Farindustria – Focus Group "Ricerca Pre-clinica e Clinica" – Technical Expert
- SITOX – Board Member

7. PUBLICATIONS and COMMUNICATIONS

- 1) Bernardi C. Epidemiologia e patogenesi della Listeriosi nell'animale Atti della "Giornata di Studio su Listeriosi: diagnosi, patologia e terapia". Istituto Superiore di Sanita' - Nutrition Foundation of Italy - Milano, 23 Ottobre 1990
- 2) Bernardi C., M. Brughera. Impiego dei primati non umani a fini scientifici: analisi retrospettiva ed attuale delle normative di legge in materia di utilizzo ed importazione.
- 3) Bernardi C., Moneta D., Brughera M., Di Salvo M., Lamparelli D., Moneta D. and Mazuè G. and Iatropoulos M.J. Haematology and Clinical Chemistry in Rats: Comparison of Different Blood Collection Sites. Comparative Haematology International (1996, 6:160-166)

- 4) Bernardi C., Sammartini U., Brughera M. and Pinciroli G. Longevity, body weight, and food consumption in Sprague-Dawley rats fed ad-libitum. Proceedings of the sixth Felasa Symposium (Basel, 1996)
- 5) Sammartini U., Bernardi C., Brughera M. and Pinciroli G. Longevity, body weight, and food consumption in CD-1 mice fed ad-libitum. Proceedings of the sixth Felasa Symposium (Basel, 1996)
- 6) Bernardi C., Colombo P., Moneta D. Effects of restraining and ketamine hydrochloride injection in hematology and biochemistry in cynomolgus monkeys (in progress)
- 7) Moneta D., Bernardi C., Colombo P., Mazué G. Hematologie et biochimie sanguine chez le cynomolgus (*Macaca fascicularis*): Comparaison entre animaux d'élevage de capture. IX Colloque de la SFDP – LYON
- 8) Bernardi C. Institutional Ethics Committee for the Correct Use of Laboratory Animals in R&D Proceedings IV Symposium AISAL Milan, 23-24 October 1997
- 9) Bernardi C. Aspetti applicativi e teorici della sperimentazione animale: il confronto con il Decreto Legislativo No. 116/92. Ministero della Sanità: Atti del II Corso Istituto Superiore della Sanità Roma –1998
- 10) Della Torre P., Imondi A. P.; Bernardi C., Podestà A., Moneta D., Riflettuto M.G., Mazué G. Cardioprotection by dexrazoxane in Rats treated by doxorubicin and paclitaxel. Cancer Chemotherapy and Pharmacology 44 (1999) 2, 138-14
- 11) Carù F., Bernardi C., Dho L., Rosa B., Brughera M. Communication: "Preliminary experience with improved repeated partial hepatectomy in nonhuman primates". LAVA-ESLAV Joint Meeting, 10th March 2000, Dublin.
- 12) Bernardi C., Cavalletti E., Cocilovo A., Costa P., De Francesco L., Dorigatti R., Filippeschi S., Guaitani A., Manzoni L., Matteucci G., Melloni E., Perretta G., Sanguineti M. Le figure professionali nella sperimentazione animale: documento AISAL per un adeguamento alle linee guida Europee. Cronache Farmaceutiche, 1 (22-28) 2000
- 13) Carù F., Rosa B., Bernardi C., Petry T.W. Celecoxib: a possible new perspective in postoperative analgesia of laboratory animals. ESLAV/AISAL Joint Meeting, 9-11 September 2001
- 14) Amanpudr S, Bernardi C, Chamberland G, DeHaven R, Fillman-Holliday D, Guittin P, Hansen S, Jensen R, David Johnson D, Mack P, Petursson C, Syracuse E, Rogan D, Roy D, Smith D, Sparrow S, Strnad C, Turner P, Weekley B: The International Symposium on Regulatory Testing and Animal Welfare: Recommendations on Best Scientific Practices for Safety Evaluation Using Nonrodent Species. ILAR Journal V43 Supplement 2002 Regulatory Testing and Animal Welfare
- 15) Degrassi A., Giusti A. M., Russo M., Steidler S., Rosa B., Carù F., Pesenti E., Bernardi C., Nerviano Medical Science s.r.l., Nerviano, Italy. "Non-invasive imaging techniques: MRI application in experimental oncology". 5th ESLAV Scientific Meeting:Imaging, Immunology and Vets, June 12th-13th, 2004.
- 16) Carù F., Steidler S., Fornasier M., Arrigoni C., Bernardi C., Worldwide Safety Sciences, Pharmacia Italy (Division of Pfizer Inc.); "Evaluation of an enrichment device for nonhuman primates and assessment of its impact on animal behavior and welfare". 9th FELASA Symposium, 14th-17th June 2004, Nantes, France
- 17) Ugo Bonfanti, Domenica Lamparelli, Paolo Colombo & Claudio Bernardi, Hematology and serum chemistry parameters in juvenile cynomolgus monkeys (*Macaca fascicularis*) of Mauritius origin: comparison between purpose-bred and captured animals - J Med Primatol doi:10.1111/j.1600-0684.2009.00345.x
- 18) Bernardi C., "Scientific and regulatory approaches for the preclinical safety evaluation of biologics" – Toxicology Letters September 2009 (Volume 189S)

- 19) Bernardi C., Brughera M. – Pharmaceutical Toxicology in Practice – A Guide to Non-Clinical Development - Chapter 2: “The Regulatory Environment” – Wiley Publishing Company (2010 – ISBN 9780470371374)
- 20) R. Kalman, I.A.S. Olson, C. Bernardi, F.van den Broek, A. Bronstad, I. Gyertyan, A. Lang, K.A. Marinou, W. Zeller - The COST Manual of Laboratory Animal Care and Use: Refinement, Reduction, and Research - Chapter 5: Ethical Evaluation of Scientific Procedures: Recommendations for Ethics Committee – CRC Press (2010 – ISBN 9781439824924)
- 21) Bernardi C. “Non-human primate models: their value, and the current EU perspective on 3Rs (the SCHER Report)”; Proceedings of the 11th FELASA Symposium (Helsinki, 2010); published by FELASA, 2011, pag. 65-71.
- 22) G. Di Gallo, E. Riccardi, E. Brambilla, F. Ruffini; C. Bernardi; G. Martino: Foetal-derived Human Neural Stem/Progenitor Cells (hNPCs): Safety profile in the Mouse following Single Intracerebroventricular (ICV) Administration – 53rd Annual Meeting of the Society of Toxicology and Tox Expo 2014- Phoenix, Arizona, USA
- 23) G. Di Gallo, L. Nobili, M. Russo, E. Binda, C.I. Bernardi; A.L. Vescovi: Human-recombinant Bone Morphogenetic Protein 4 (hrBMP4): Safety profile after 7-day continuous Intracerebral (IC) and IV Administration in the mouse. 54th Annual Meeting of the Society of Toxicology and Tox Expo 2015 – San Diego, California, USA
- 24) C.I. Bernardi, E. Giannotti, M. Magistrelli, G. Pennella, C. Arrigoni : Lymphocytes subpopulations and cytokines as useful preclinical biomarkers following treatment with monoclonal antibodies (mAbs), Eurotox 2016, Seville 04-06 September 2016
- 25) G. Di Gallo, M. Magistrelli, G. Pennella, M. Russo, E. Giannotti, C. Bernardi: “Safety Assessment in the Development of CAR-T cells Projects”, Society of Toxicology (SOT), Baltimore, USA; March 10-14, 2019
- 26) Cauli E, Marzorati S, Bernardi C, Rasponi M. Generation of the first design concept of a liver on chip for assessing drug toxicity and metabolism in the hepatobiliary environment. JRC Summer School, May 2021, online (Poster Presentation).
- 27) Simona Marzorati , Alberto Ghiglieri, Guido Di Gallo, Claudio Bernardi: Assessment of in vitro and in vivo assay to exploit the potential of cells and tissue-engineered medical products: Accelera’s Experience. (Poster Presentation).
- 28) Cauli E, Marzorati S, Rasponi M, Bernardi C. Set-up and preliminary validation of a modular high-throughput microfluidic system for assessing drug toxicity and metabolism in the hepatobiliary environment. Second SINERGIA Summer School, November 2021, Brno, Czech Republic (Poster and Scientific Presentation).
- 29) Bernardi C.I. - Joint Conference of the European Federation for Primatology and the Gesellschaft für Primatologie (EFP-GfP 2022) - Session D3 – Symposium: Is it time to phase out lab research on non-human primates – “Perspectives from the Pharma environment and Regulatory Agencies”; Royal Burgers' Zoo, Arnhem, NL, June 1-3, 2022
- 30) Cauli E, Marzorati S, Rasponi M, Bernardi C. Design and preliminary characterization of a new liver-on-chip model for assessing drug toxicity and metabolism in a similar physiological environment. MPS World Summit, May - June 2022, online (Abstract).
- 31) Cauli E, Marzorati S, Rasponi M, Bernardi C. Accelera Liver on Chip. Third SINERGIA Summer School, June 2022, Maastricht, The Netherlands, (Poster and Scientific Presentation).

- 32) Cauli E, Marzorati S, Rasponi M, Bernardi C. Characterization of in Vitro drug toxicity and metabolism through a new liver-on-chip model. EUROoCS Conference, July 2022, Grenoble, France (Poster Presentation).
- 33) Elisa Cauli, Simona Marzorati, Marco Rasponi, and Claudio Bernardi – “Design and preliminary characterization of a new liver on-chip model as a valuable additional tool for assessing in vitro drug toxicity and metabolism in a similar physiological environment” - Abstracts of the 1st Microphysiological Systems World Summit, New Orleans, 2022; ALTEX Proceedings, Volume 10, No. 1, ISSN 2194-0479 (2022)
- 34) Roberta Visone, Ferran Lozano, Simona Marzorati, Caterina Pernici, Alessandro Cordiale, Claudio Bernardi, Enrico Pesenti, Marco Rasponi and Paola Occhetta: "A human beating heart on chip for on-line screening of drug cardiotoxicity"; ESTIV 2022, Sitges 21-25 November 2022 (submitted)
- 35) Cauli E, Piutti C, Rasponi R, Bernardi C. Functional characterization of a new liver-on-chip model for in vitro drug toxicity and metabolism studies. JRC Summer School, May 2023, Ispra, Italy (Poster and Flash Presentation).
- 36) Cauli E, Piutti C, Rasponi R, Bernardi C. Development and functional characterization of a microphysiological system for assessing in vitro drug toxicity and metabolism in the hepatobiliary environment. MPS World Summit, June 2023, Berlin, Germany (Poster Presentation).
- 37) Cauli E, Polidoro MA, Marzorati S, Bernardi C, Rasponi M, Lleo A. "Cancer-on-chip: a 3D model for the study of the tumor microenvironment." Journal of Biological Engineering, 2023
- 38) Longo M., Tamborini E., Messina M., Zanzottera V., Russo M., Recordati C., Bernardi C., Canesi S. "Valutazione preclinica della tossicità a carico del SNC nel soggetto pediatrico: tecniche istologiche in neonati di ratto", poster presentation February SITOX 2023
- 39) Bernardi C., Longo M., Canesi S., Tamborini E., Messina M., Zanzottera V., Russo M., Bianchi D., Recordati C. "Preclinical assessment of CNS toxicity in newborn Sprague-Dawley rats: histological, histochemical and immunohistochemical evaluations, poster presentation September EUROTOX 2023