



## Curriculum Vitae

Personal information **Barbara Bonamassa**

### Work experience

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1. Employer: Italian Medicines Agency (AIFA) \_ Innovation and Pharmaceutical Strategy Division (Ex European Assessment Unit).
  - Start date: 032021
  - End date:
  - Position: Committee for Advanced Therapies (CAT) alternate member
  - Activities: Concerning the quality aspects of Advanced Therapy Medicinal Products (ATMPs): assessment of dossiers for marketing authorization granted under the centralized procedure, assessment of EMA scientific advice, assessment of Priority Medicines (PRIME) eligibility request, support to the innovation through the EMA Innovation Task Force (ITF), writing and revision of EMA guidelines and question and answer documents on the quality & GMP aspects of Advanced Therapy Medicinal Products (ATMPs).
  - Country: Italy
2. Employer: Oloker Therapeutics S.r.l.
  - Start date: 012021
  - End date: 012021
  - Position: Quality assessor (consultant) for Advanced Therapy Medicinal Products (ATMPs)
  - Activities: Assessment of Advanced Therapy Medicinal Product (ATMP) quality aspect development (01/01/2021\_15/01/2021).
  - Country: Italy
3. Employer: World Health Organization (WHO)
  - Start date: 102020
  - End date:
  - Position: Quality assessor (consultant) for biotherapeutic products [26/10/2020 \_ 31/12/2020 & 04/05/2021 \_present]
  - Activities: Assessment of the quality aspects of Biotherapeutic Products (BTPs) (dossiers), revision and update of prequalification guidelines in the field of quality & advice on pharmaceutical quality issues with focus on Biotherapeutic Products (BTPs), for the Prequalification Unit of the World Health Organization (WHO) \_ Medicines Assessment Team (PQT/MED).
  - Country: Switzerland
4. Employer: Italian Medicines Agency (AIFA) \_ Innovation and Pharmaceutical Strategy Division (Ex European Assessment Unit).
  - Start date: 062018
  - End date: 092020
  - Position: Committee for Advanced Therapies (CAT) expert
  - Activities: Concerning the quality aspects of Advanced Therapy Medicinal Products (ATMPs): assessment of dossiers for marketing authorization granted under the centralized procedure, assessment of EMA scientific advice, assessment of Priority Medicines (PRIME) eligibility request, support to the innovation through the EMA Innovation Task Force (ITF), writing and revision of EMA guidelines and question and answer documents on the quality & GMP aspects of Advanced Therapy Medicinal Products (ATMPs).
  - Country: Italy
5. Employer: Italian Medicines Agency (AIFA) \_ Innovation and Pharmaceutical Strategy Division (Ex European Assessment Unit).
  - Start date: 102015
  - End date:
  - Position: Quality assessor [executive biologist (15/12/2021 \_ present), temporary contract holder – Biologist (01/10/2017 – 30/09/2020 & 26/01/2021 – 30/06/2021), technical\_scientific officer (01/10/2015 – 09/11/2016 & 23/11/2016 \_ 30/09/2017)]
  - Activities: Concerning the quality aspects of biological medicinal products with emphasis on Advanced Therapy Medicinal Products (ATMPs): assessment of dossiers for marketing authorization granted under the centralized procedure, assessment of dossiers for investigational medicinal products (IMPD) and substantial amendments, assessment of national and EMA scientific advice, assessment of Priority Medicines (PRIME) eligibility request, support to the innovation through the EMA InnovationTask Force (ITF); assessment of nominations for CAT and CHMP rapporteurships/peer reviews.
  - Country: Italy
6. Employer: University of Padua, Department of Molecular Medicine.
  - Start date: 062015
  - End date: 092015
  - Position: Senior post\_doctoral research associate.
  - Activities: Development of research projects focused on: 1) gene therapy, 2) role of HCV\_mediated oxidative stress in the liver physiopathology; paper and grant writing; supervision of junior scientists.
  - Country: Italy
7. Employer: Italian Medicines Agency (AIFA)
  - Start date: 072014
  - End date: 082015
  - Position: Trainee, European Assessment Unit (now Innovation and Pharmaceutical Strategy Division).
  - Activities: Learning of dossier assessment and scientific advice for Advanced Therapy Medicinal Products (ATMPs); learning of the main pharmaceutical regulatory legislation, with particular emphasis on Advanced Therapy Medicinal Products (ATMPs).

- Country: Italy
8. Employer: Bambino Gesù Children's Hospital, Department of Oncohematology.
    - Start date: 122012
    - End date: 112013
    - Position: Post\_doctoral research associate.
    - Activities: Development of research projects focused on: 1) tumor epigenetics, 2) setting up of transgenic animal models (CreERT2\_LoxP) for tumor biology study; paper and grant writing.
    - Country: Italy
  9. Employer: Fondazione Mario Negri Sud, Department of Translational Pharmacology.
    - Start date: 072011
    - End date: 092012
    - Position: Post\_doctoral research associate/fellow.
    - Activities: Development of research projects focused on gene therapy and viral gene delivery systems for degenerative pathology targeting (cancer and atherosclerosis); paper and grant writing.
    - Country: Italy
  10. Employer: University of Pittsburgh, Department of Pharmaceutical Sciences, School of Pharmacy.
    - Start date: 082009
    - End date: 062011
    - Position: Visiting PhD student and post\_doctoral research associate/fellow.
    - Activities: Development of research projects focused on gene therapy and non viral gene delivery systems for liver function transcriptional study and genetic disease treatment; management of research grants; paper and grant writing.
    - Country: United States
  11. Employer: National Research Council (CNR), Institute of Clinical Physiology, Laboratory of Pharmacogenetics and Drug Metabolism.
    - Start date: 052008
    - End date: 082008
    - Position: Visiting PhD student.
    - Activities: Molecular biology technique development for the fulfillment of research projects focused on: 1) oxidative stress and liver function change, 2) development of anti\_oxidants for degenerative disease treatment.
    - Country: Italy
  12. Employer: University of Bologna, Department of Pharmacy and Biotechnology (previously Department of Pharmacology), Laboratory of Molecular Toxicology.
    - Start date: 012007
    - End date: 122009
    - Position: PhD student.
    - Activities: Development of research projects focused on: 1) oxidative stress and liver function change, 2) development of anti\_oxidants for degenerative disease treatment.
    - Country: Italy

## Education and training

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1. Subject: University of Rome "Sapienza" (Department of Public Health and Infectious Diseases).
  - Start date: 032016
  - End date: 022017
  - Qualification: Advanced Training Course in Statistical Methods for the Biomedical Research and Practice.
  - Organisation:
  - Country: Italy
2. Subject: Italian Medicines Agency (AIFA) \_ University of Rome "Sapienza" (Department of Physiology and Pharmacology Vittorio Erspamer).
  - Start date: 122013
  - End date: 092014
  - Qualification: Master in Drug Regulatory Affairs, 110/110 magna cum laude.
  - Organisation:
  - Country: Italy
3. Subject: Alma Mater Studiorum \_ University of Bologna.
  - Start date: 012007
  - End date: 122009
  - Qualification: Doctor of Philosophy (PhD) in Pharmacology and Toxicology.
  - Organisation:
  - Country: Italy
4. Subject: Alma Mater Studiorum \_ University of Bologna.
  - Start date: 112006
  - End date:
  - Qualification: Board certification as a licensed biologist (Section A number: AA\_074240 from 10/12/2015 to present).
  - Organisation:
  - Country: Italy
5. Subject: Alma Mater Studiorum \_ University of Bologna.
  - Start date: 2004
  - End date: 2006
  - Qualification: Master degree in Molecular and Cellular Biology, 110/110 magna cum laude.
  - Organisation:
  - Country: Italy
6. Subject: Alma Mater Studiorum \_ University of Bologna.
  - Start date: 2001
  - End date: 2004
  - Qualification: Bachelor degree in Biological Sciences, 110/110 magna cum laude.
  - Organisation:
  - Country: Italy

## Additional information

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### Publications

1. Bonamassa B, Gasparini P, Pompilio G, Aiuti A, Foggi P (2021) The importance of starting materials: quality and regulatory considerations for cell\_based therapies. *Cell & Gene Therapy Insights* 7(2): 273–280.
2. Bonamassa B, Canistro D, Sapone A, Vivarelli F, Vornoli A, Longo V, Paolini M (2016) Harmful effects behind the daily supplementation of a fixed vegetarian blend in the rat model. *Food Chem Toxicol.* 97: 367\_374.
3. Bonamassa B†, Ciccarese F†, Antonio VD, Contarini A, Palù G, Alvisi G (2015) Hepatitis C virus and host cell nuclear transport machinery: a clandestine affair. *Frontiers Microbiol.* 6: 619. † Equal contribution.
4. Canistro D, Boccia C, Falconi R, Bonamassa B, Valgimigli L, Vivarelli F, Soletti A, Genova ML, Lenaz G, Sapone A, Zaccanti F, Abdel\_Rahman SZ & Paolini M (2014) Redox\_based flagging of the global network of oxidative stress greatly promotes longevity. *J Gerontol A Biol Sci Med Sci.* 70: 936\_943.
5. Feitelson MA, Bonamassa B, Arzumanyan A (2014) The roles of hepatitis B virus encoded X protein in virus replication and the pathogenesis of chronic liver disease. *Expert Opin*

Ther Targets. 18, 293\_306. 6. Tomaselli S†, Bonamassa B†, Alisi A, Nobili V, Locatelli F, Gallo A (2013) ADAR enzyme and miRNA story: a nucleotide that can make the difference. *Int J Mol Sci.* 14, 22796\_22816. † Equal contribution. 7. Bonamassa B & Moschetta A (2013) Atherosclerosis: lessons from LXR and the intestine. *Trends Endocrinol Metab* 24, 120\_128. 8. Bonamassa B, Ma Y & Liu D (2012) Glucocorticoid receptor-mediated transcriptional regulation of N-acetyltransferase 1 gene through distal promoter. *AAPS J* 14, 581\_590. 9. Bonamassa B, Hai L & Liu D (2011) Hydrodynamic gene delivery and its applications in pharmaceutical research. *Pharm Res* 28, 694\_701. 10. Bonamassa B & Liu D (2010) Nonviral gene transfer as a tool for studying transcription regulation of xenobiotic metabolizing enzymes. *Adv Drug Deliv Rev* 62, 1250\_1256. 11. Novelli M, Bonamassa B, Masini M, Funel N, Canistro D, De Tata V, Martano M, Soletti A, Campani D, Paolini M & Masiello P (2010) Persistent correction of hyperglycemia in streptozotocin-nicotinamide-induced diabetic mice by a non-conventional radical scavenger. *Naunyn Schmiedeberg's Arch Pharmacol* 382, 127\_137. 12. Canistro D, Affatato AA, Soletti A, Mollace V, Muscoli C, Sculco F, Sacco I, Visalli V, Bonamassa B, Martano M, Iannone M, Sapone A & Paolini M (2010) The novel radical scavenger IAC is effective in preventing and protecting against post-ischemic brain damage in Mongolian gerbils. *J Neurol Sci* 290, 90\_95. 13. Canistro D, Bonamassa B, Pozzetti L, Sapone A, Abdel-Rahman SZ, Biagi GL & Paolini M (2009) Alteration of xenobiotic metabolizing enzymes by resveratrol in liver and lung of CD1 mice. *Food Chem Toxicol* 47, 454\_461. 14. Crochemore C, Virgili M, Bonamassa B, Canistro D, Pena\_Altamira E, Paolini M & Contestabile A (2009) Long-term dietary administration of valproic acid does not affect, while retinoic acid decreases, the lifespan of G93A mice, a model for amyotrophic lateral sclerosis. *Muscle Nerve* 39, 548\_552. 15. Sapone A, Canistro D, Bonamassa B, Biagi GL & Paolini M (2009) Hidden paradoxes in generic drug substitution affecting pharmacotherapy. *J Biomed Biotechnol* 2009, 801984. 16. D'Aleo V, Del Guerra S, Martano M, Bonamassa B, Canistro D, Soletti A, Valgimigli L, Paolini M, Filippini F, Boggi U, Del Prato S & Lupi R (2009) The non-peptidyl low molecular weight radical scavenger IAC protects human pancreatic islets from lipotoxicity. *Mol Cell Endocrinol* 309, 63\_66. 17. Canistro D, Pozzetti L, Sapone A, Broccoli M, Bonamassa B, Longo V, Lubrano V, Barillari J, Biagi GL & Paolini M (2008) Perturbation of rat hepatic metabolizing enzymes by folic acid supplementation. *Mutat Res* 637, 16\_22. 18. Sapone A, Bonamassa B, Canistro D, Pozzetti L & Paolini M (2007) High-dose vitamin A. *Lancet* 370, 740. 19. Barillari J, Iori R, Broccoli M, Pozzetti L, Canistro D, Sapone A, Bonamassa B, Biagi GL & Paolini M (2007) Glucoraphasatin and glucoraphenin, a redox pair of glucosinolates of brassicaceae, differently affect metabolizing enzymes in rats. *J Agric Food Chem* 55, 5505\_5511.

## Projects

## Memberships

\_ European Society of Gene and Cell Therapy (ESGCT) (Membership number: 136149). \_ The European Hematology Association (EHA) (Membership number: 042953, expiry: 01/01/2021).

## Other Relevant Information

HONOURS AND AWARDS \_ European Commission and other EU bodies external expert (EX2020D393013) (08/2020-present) \_ European Medicines Agency (EMA) expert (04/2016-present); \_ Editorial board member for the scientific journal "Gene and Cell Therapy" (Science Publishing Group) (04/2015-present); \_ Italian Medicines Agency (AIFA) expert (02/2015-present); \_ Ranked 1st at the admission exam - Master in Drug Regulatory Affairs, University of Rome "Sapienza" - Italian Medicines Agency (AIFA); \_ Italian Foundation for Cancer Research (FIRC/AIRC) Fellowship - FIRC/AIRC; \_ Rotary International Ambassadorial Fellowship/Research Grant \_ Rotary International; \_ Marco Polo Fellowship - Alma Mater Studiorum - University of Bologna; \_ Italian Ministry of Education Fellowship - Italian Ministry of Education. TEACHING RESPONSIBILITIES Supervision of undergraduate experimental theses (University of Bologna, Bologna, Italy). POSTER AND PODIUM PRESENTATIONS 1. Bonamassa B. The European Experience on Testing of Advanced Therapy Medicinal Products. Podium presentation \_ 2nd Annual Gene Therapy Analytical Development Summit \_ Philadelphia (PA, USA), November 30 - December 30, 2020. 2. Bonamassa B. Analytical Testing of Advanced Therapy Medicinal Products: The European Experience So Far. Podium presentation \_ CASSS Analytical Technologies (AT) Europe 2020 Symposium, Lisbon (Portugal), November 3\_6, 2020. 3. Bonamassa B, Ma Y, Liu D. Glucocorticoid receptor-mediated transcriptional regulation of N-acetyltransferase 1 gene through distal promoter. Poster (LB570) - Experimental Biology 2012 - San Diego Convention Centre, San Diego (CA, USA), April 21\_25, 2012. 4. Bonamassa B. Transcriptional regulation of the human N-acetyltransferase I promoters. Podium presentation - University of Pittsburgh, School of Pharmacy Research Retreat - Seven Spring (PA, USA), June 8\_9, 2010. 5. Bonamassa B, Canistro D, Longo V, Messina A, Lubrano V, Sapone A, Andreotti C, Costa G, Biagi GL, Paolini M. Drug metabolism and antioxidant defence modulation-based anticancer strategy: "5 a day for a better health" alimentary plan versus mono-colour vegetarian diets. Poster - Italian Society of Pharmacology, 34<sup>th</sup> National Meeting - Rimini (Italy), October 14\_17, 2009. 6. Bonamassa B. Colourful fruit and vegetable-based anticancer strategy: insights into drug metabolizing enzymes, antioxidant defences and oxidative stress. Podium presentation \_ XIII National Seminar for PhD Students in Pharmacology - Siena (Italy), Certosa di Pontignano, June 27\_30, 2009. 7. Bonamassa B, Canistro D, Longo V, Messina A, Lubrano V, Sapone A, Pozzetti L, Andreotti C, Costa G, Biagi GL, Paolini M. I colori della frutta e della verdura come strategia chemio preventiva: modulazione di enzimi del drug-metabolism ed antiossidanti nel modello animale. Poster - Italian Society of Toxicology, XV National Meeting - Verona (Italy), January 19\_22, 2009. 8. Bonamassa B. Enzyme-based anticancer dietary manipulations: from the varied and coloured "5 a day" to the single serving. Poster \_ XII National Seminar for PhD Students in Pharmacology - Siena (Italy), Certosa di Pontignano, September 22\_25, 2008. 9. Bonamassa B. Drug metabolism modulation by "integrated" fruit and chemoprevention. Poster \_ XI National Seminar for PhD Students in Pharmacology - Siena (Italy), Certosa di Pontignano, September 24\_27, 2007. 10. Bonamassa B, Barillari J, Canistro D, Pozzetti L, Sapone A, Iori R, Biagi GL and Paolini M. Cancer chemoprevention: manipulation of xenobiotic metabolizing enzymes by glucoraphasatin and glucoraphenin found in Brassicaceae. Poster - Italian Society of Pharmacology, 33<sup>rd</sup> National Meeting - Cagliari (Italy), June 6\_9, 2007. OTHER SCIENTIFIC MEETINGS ATTENDED 1. EMA expert meeting on genome editing technologies used in medicinal product development. CAT members. European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; October 18th, 2017. 2. CAT Expert Meeting \_ Scientific and regulatory considerations for AAV-based gene therapy. CAT members. European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; September 6th, 2017. 3. EU Network Regulatory Awareness Session on Early Access. Experts from the EMA committees and working groups. European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; June 12th, 2017. 4. First anniversary of PRIME: experience so far. Multi-stakeholder meeting. European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; May 19th, 2017. 5. Sagetis Biotech ITF briefing meeting - SAG 1001 (Oncolytic adenovirus) Experts from the EMA Innovation Task Force and the EU Innovation Network. European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; March 31st, 2017. 6. Assessor training on viral safety evaluation of biotechnological medicinal products. Drs. Blümel Johannes, Cavaleiro Sanches Ana, Kluge Kristina, Qualikene\_Gonin Wahiba, Stühler Albert. European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; December 2nd, 2017. 7. Committee for Advanced Therapies (CAT) workshop: scientific and regulatory challenges of genetically modified cell-based cancer immunotherapy products Workshop Chair: Paula Salmikangas, CAT Chair European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; November 15th\_16th, 2016. 8. Benefit\_Risk training session Drs. Pieter de Graeff, Kristina Dunder, Francesco Pignatti; European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; September 19th, 2016. 9. EU Network awareness session on the EMA's role in supporting innovation Dr. Armin Ritzhaupt; European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; September 5th, 2016. 10. Validation of Analytical Methods Dr. Christoph Kefeder; European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; September 2nd, 2016. 11. Terapie Avanzate: il vero futuro della medicina? Drs. Marie-Georges Besse, Pierluigi Navarra, Maria Cristina Galli, Guido Pantè, Alfredo Nicosia, Andra Bacigalupo; Fondazione Policlinico A. Gemelli, Largo Agostino Gemelli 8, 00168 Rome, Italy; June 21st, 2016.

12. Innovation Task Force (ITF) meeting with Intellia Therapeutics – CRISPR. Innovation Task Force (ITF) dell’Agenzia Europea dei Medicinali (EMA); European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; May 25th, 2016. 13. La ricerca clinica parla europeo, la nuova sfida per istituzioni ed imprese. Agenzia Italiana del Farmaco (AIFA) e Farmindustria; Auditorium Massimo, Via Massimiliano Massimo 1, 00144 Rome, Italy; January 21st, 2016. 14. Pharmacogenetics: on the way to regulation and clinical application. Drs. Cristine Gispén de Wied, Bert Leufkens, Jan Schellens, Falk Ehmann, Dorothy Toh, Ron van Schaik, Violeta Stoyanova; CBG\_MEB, Graadt van Roggenweg 500, 3531 AH Utrecht, Netherlands broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; February 5th, 2016. 15. Paediatric Investigation Plans (PIPs) for Advanced Therapy Medicinal Products (ATMPs). Drs. Thorsten Olski and Giovanni Lesa; European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; December 17th, 2015. 16. CAT webinar on ATMP classification. Drs. Patrick Celis, Paula Salmikanga, Belaid Sekalli and Nicolas Ferry; European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; December 11th, 2015. 17. Rapps and CoRapps experience in the assessment of a biosimilar product candidate for etanercept: a collection of quality, nonclinical and clinical challenges. Drs. Niklas Ekman & Christian Mayer (quality); Drs. Lehtolainen, Dalkilic Pauliina & Günter Waxenecker (nonclinics); Drs. Kurki Pekka, Mäki Ikola Outi, Andrea Laslop & Rene Anour (clinics); Austrian Medicines and Medical Devices Agency (AGES), Traisengasse 5, 1200 Wien, Austria broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; October 15th, 2015. 18. Assessor training in general statistical principles. Committee for Medicinal Products for Human Use (CHMP)’s Biostatistics Working Party; European Medicines Agency (EMA), 30 Churchill Place, London E14 5EU, UK broadcasted c/o Italian Medicines Agency (AIFA), Via del Tritone 181, 00187 Rome, Italy; May 21st\_22nd, 2015.