



Curriculum Vitae

Personal information **Dario Fiorenza**

Work experience

1. Employer: Ministero della Salute, Direzione generale della sanità animale e dei farmaci veterinari _ Ufficio 4 Medicinali Veterinari
 - Start date: 05/2021
 - End date: N.A.
 - Position: Chemist
 - Activities: • Evaluation of new marketing authorizations (MAs) of veterinary medicinal products with purely national procedure, mutual recognition procedure and decentralized procedure (Part II dossier) • Evaluation of Variations type IA/IAin, type IB and type II according to Commission Regulation (EC) No 1234/2008 • Evaluation of VMPs Worksharing procedures according to Commission Regulation (EC) No 1234/2008 • Evaluation of Active Substance Master File (ASMF) procedure _ European Drug Master File (EDMF) procedure • Evaluation of Variations requiring assessment (VRAs) and Variations not requiring assessment (VNRAs) according to Articles 60 to 68 of Regulation EU 2019/6 and the Commission Implementing Regulation (EU) 2021/17 of 8 January 2021
 - Country: Italy
2. European Directorate for the Quality of Medicines (EDQM)
 - Start date: November 2022
 - End date: November 2025
 - Position: Member of Group of Experts No. 15V (Veterinary Vaccines and Sera) – European Pharmacopoeia
 - Activities: Drafting and revision of texts in the field of immunological veterinary medicinal products
3. Employer: Fondazione SDN
 - Start date: 02/2013
 - End date: 04/2021
 - Position: Head of Radiopharmacy – Quality Assurance Manager – Qualified Person
 - Activities: • Management of the Quality System EU cGMP • Production and quality control of radiopharmaceuticals 18_fluorinated, 99m_techetium and peptides containing gallium_68 • Labelling of biologically active macromolecules for PET / SPECT / MRI / NIR for diagnosis of cancer and inflammatory diseases. • Management of Regulatory Affairs • Audits according to ISO 9001:2015, ISO/IEC 17015:2005, ISO 14001:2015, OHSAS 18001:2008. • Physico_chemical and microbiological analysis of radiopharmaceuticals according to European Pharmacopoeia monograph. • Preparation, Verification and Execution of: Factory Acceptance Test (FAT), Site Acceptance Test (SAT), Installation/Instrument Qualification (IQ), Operations Qualification (OQ), Process Validation (PV), Performance Qualification (PQ), Design Qualification (DQ), Risk Analysis e Risk Assessment, Validation Master Plan (VMP), Cleaning Validation Project Plan (CVPP), Process Validation Project Plan (PVPP), Site Master File, Drug Master File, Bioburden Protocol, Mediafill, IMPD, URS, SOP.
 - Country: Italy
4. Employer: SDN SpA
 - Start date: 07/2011
 - End date: 01/2013
 - Position: Radiopharmacist – Quality Assurance Manager
 - Activities: • Management of the Quality System according to Good Preparation of radiopharmaceuticals (Italian Pharmacopoeia XII ed.) • Production and quality control of radiopharmaceuticals 18_fluorinated, 99m_techetium and peptides containing gallium_68 • Production and quality control of 2_18F_2_deoxy_D_glucopyranose • Marking of autologous cells with radiopharmaceuticals (granulocytes, erythrocytes) • Conducting audits according to ISO 9001:2008.
 - Country: Italy
5. Employer: IRCCS SDN/Università degli studi di Napoli 'Federico II'
 - Start date: 09/2016
 - End date: 09/2021
 - Position: University professor of General Hygiene (SSD: MED/42)
 - Activities: University professor of General Hygiene (SSD: MED/42) Bachelor degree course in Medical Radiology techniques for images and Radiotherapy
 - Country: Italy

Education and training

1. Subject: Università degli studi "Federico II" di Napoli – Department of Veterinary Medicine
 - Start date: 02/2022
 - End date: 10/2025
 - Qualification: Postgraduate Specialization in Inspection of Foods of Animal Origin
 - Country: Italy
2. Subject: Università degli studi del Sannio – Department of Science and Technology
 - Start date: 11/2022
 - End date: 10/2024
 - Qualification: Bachelor degree in Food Technology
 - Country: Italy
3. Subject: Università degli studi "Federico II" di Napoli – Department of Advanced Biomedical Sciences

- Start date: 10/2019
 - End date: 10/2022
 - Qualification: PhD in Biomorphological and Surgical Sciences
 - Experimental thesis on Nuclear Medicine, title: "Fully automated synthesis of novel TSPO PET imaging ligand [¹⁸F]Fluoroethyltemazepam and methodology of nanoincapsulation in lipid matrices" Tutor Prof. Silvana Del Vecchio/Prof. Marco Salvatore
 - Country: Italy
4. Subject: Università degli studi "Federico II" di Napoli
- Start date: 10/2014
 - End date: 06/2015
 - Qualification: Master degree in Marine Biology
 - Organisation: Experimental thesis on Analytical Chemistry, title: "Implementation of a quality system control in an academic laboratory" Tutor Prof. Marco Trifuoggi
 - Country: Italy
5. Subject: Università degli studi "Federico II" di Napoli
- Start date: 10/2010
 - End date: 07/2014
 - Qualification: Master degree in Veterinary Medicine
 - Organisation: Thesis on Avian pathology, title: "Aspergillosis in falconidae" Tutor Prof. Ludovico Dipineto
 - Country: Italy
6. Subject: Università degli studi "Federico II" di Napoli
- Start date: 10/2005
 - End date: 07/2010
 - Qualification: Master degree in Pharmaceutical Chemistry and Technology
 - Organisation: Summa Cum Laude Experimental thesis on Organic Chemistry, title: "Glycolipids and galactolipase in marine diatomee" Tutor Prof. Valeria Costantino
 - Country: Italy

Additional information

Publications

2021 Dario Fiorenza, Emanuele Nicolai, Carlo Cavaliere, Ferdinando Fiorino, Giovanna Esposito, Marco Salvatore, "Fully Automated Synthesis of Novel TSPO PET Imaging Ligand [¹⁸F]Fluoroethyltemazepam" Journal: *Molecules* Editor: MDPI • Objectives: Herein, we developed a novel fluorinated benzodiazepine ligand, [¹⁸F]Fluoroethyltemazepam ([¹⁸F]F_FETEM), for positron emission tomography (PET) imaging of translocator protein (18 kDa). Methods: [¹⁸F]F_FETEM was radiolabelled with an automated synthesizer via a one_pot procedure. We conducted a [¹⁸F]F_aliphatic nucleophilic substitution of a tosylated precursor followed by purification on C18 and Alumina N SPE cartridges. Quality control tests was also carried out. 2020 Carlo Cavaliere, Liberatore Tramontano, Dario Fiorenza, Vincenzo Alfano, "Gliosis and Neurodegenerative Diseases: The Role of PET and MR Imaging" Journal: *Frontiers in Cellular Neuroscience* Editor: Frontiers • Glial activation characterizes most neurodegenerative and psychiatric diseases, often anticipating clinical manifestations and macroscopical brain alterations. Although imaging techniques have improved diagnostic accuracy in many neurological conditions, often supporting diagnosis, prognosis prediction and treatment outcome, very few molecular imaging probes, specifically focused on microglial and astrocytic activation, have been translated to a clinical setting. 2019 Ernesto Forte, Dario Fiorenza, Enza Torino, Angela Costagliola, "Radiolabeled PET/MRI Nanoparticles for Tumor Imaging" Journal: *Journal of Clinical Medicine* Editor: MDPI • The development of integrated positron emission tomography (PET)/ magnetic resonance imaging (MRI) scanners opened a new scenario for cancer diagnosis, treatment, and follow up. Multimodal imaging combines functional and morphological information from different modalities, which, singularly, cannot provide a comprehensive pathophysiological overview. Molecular imaging exploits multimodal imaging in order to obtain information at a biological and cellular level. 2019 Leggiero E, Labruna G, Jaffaldano L, Lombardo B, Greco A, Fiorenza D, "Helper_dependent adenovirus_mediated gene transfer of a secreted LDL receptor/transferrin chimeric protein" Journal: *Gene Therapy* Editor: Nature • Familial hypercholesterolemia (FH) is a genetic hyperlipidemia characterized by elevated concentrations of plasma LDL cholesterol. Statins are not always effective for the treatment of FH patients; unresponsive patients have poor prognosis and rely on LDL apheresis. In the past, we developed safe and effective gene therapy strategies for the expression of anti_atherogenic proteins using PEGylated helper_dependent adenoviral (HD_Ad) vectors. 2018 Aiello M, Cavaliere C, Fiorenza D, Duggento A, Passamonti L, Toschi N, "Neuroinflammation in Neurodegenerative Diseases: Current Multimodal Imaging Studies and Future Opportunities for Hybrid" Journal: *Neuroscience* Editor: Elsevier • Positron emission tomography (PET) provides spatially localized information about brain metabolism and function and innovative tracers have extended this potential to the study of neuroinflammation (NI), an important process in the pathophysiology of several neurological disorders. However, PET is limited by low spatial resolution. Conversely, Magnetic Resonance Imaging (MRI) affords high_resolution information about brain anatomy and metabolism which can complement PET related information. 2017 Enza Torino, PhD, Luigi Auletta, PhD, DVM, Dario Fiorenza, DVM, PharmD, "Multimodal imaging for a theranostic approach in a murine model of B_cell lymphoma with engineered nanoparticles." Journal: *Nanomedicine* • In this work, we demonstrated the ability of core_shell chitosan_HANPs decorated with pA20_36 to specifically target A20 cells and reduce the tumor burden in a murine xenograft model. We monitored tumor growth using high_frequency ultrasonography and demonstrated targeting specificity and kinetics of the NPs via in vivo fluorescent reflectance imaging. This result was also confirmed by ex vivo magnetic resonance imaging and confocal microscopy.

Projects

Memberships

21/12/2015 Speaker ECM course "PET/RM: IL PRESENTE E IL FUTURO" provider "FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 145362 Edition 1) 18/12/2015 Speaker ECM course "MN: IMAGING MOLECOLARE NELLE PATOLOGIE NEUROLOGICHE" provider "FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 145359 Edition 1) 25/11/2015 Speaker ECM course "RISCHIO CHIMICO, BIOLOGICO E RADIOPROTEZIONE" provider "FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 143530 Edition 1) 23/11/2015 Speaker ECM course "SISTEMI DI GESTIONE DELLA QUALITÀ APPLICATI ALLE STRUTTURE SANITARIE" provider "FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 143529 Edition 1) 23/11/2015 Speaker ECM course "SISTEMI DI GESTIONE DELLA QUALITÀ APPLICATI ALLE STRUTTURE SANITARIE" provider "FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 143529 Edition 1) 15/12/2014 Speaker ECM course "MN: IMAGING IBRIDO NEI TUMORI DELLA TESTA E DEL COLLO" provider "IRCCS FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 113028 Edition 1) 12/12/2014 Speaker ECM course "MN: IMAGING MOLECOLARE NELLE PATOLOGIE ONCOLOGICHE" provider "IRCCS FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 112740 Edition 1) 05/12/2014 Speaker ECM course "MN: IMAGING MOLECOLARE NELLE PATOLOGIE NEUROLOGICHE" provider "IRCCS FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 112318 Edition 1) 21/11/2014 Speaker ECM course "PET/RM: IL PRESENTE E IL FUTURO" provider "IRCCS FONDAZIONE SDN PER LA RICERCA E L'ALTA FORMAZIONE IN DIAGNOSTICA NUCLEARE" (ID_Event 111282 Edition 1) 2015 Area Inspections and Approvals, Office Permissions Office, Italian Drug Agency (AIFA). Recognition capability to act as a Qualified Person for the purposes of art. 52 of Legislative Decree 24 April 2006, n. 219. From 21/02/2011 to 25/02/2011 UNI EN ISO 19011:2003, UNI EN ISO 9001:2008. Auditor/Lead Auditor, Evaluator for Quality System Management.

Other Relevant Information

Courses Conferences Seminars

15/05/2023 – 19/05/2023 European Course: Better Training for Safer Food Online Course on "Food safety crisis preparedness non-EU". The main goal of the training programme is to provide specialised and advanced training against the backdrop of the INFOSAN framework of global cooperation in the area of food safety crisis preparedness and management.

26/04/2023 – 28/04/2023 IEEE MeAVeAS 2023 Committee "Measurements and Applications in Veterinary and Animal Sciences".

16/11/2022 Aggiornamento sulla Legislazione Farmaceutica Internazionale e Linee guida farmaceutiche - Edizione 2022 NSF HEALTH SCIENCES

23/09/2022 – 26/09/2022 "XIX Ischia Advanced School of Organic Chemistry IASOC 2022". The main focus of IASOC 2022 is on "The Moving Frontiers of Organic Synthesis". This theme collects the most efficient strategies, the main targets currently pursued in the fields of life sciences and materials technology, new approaches to smart molecules and functional systems.

04/05/2022 – 05/05/2022 Spring School in Transferable Skills - Università degli studi di Napoli "Federico II". Focus on developing skills in grant and CV writing, and how to get a faculty position, overview of the breadth of interviews that can be expected on your interview journey, discussion about team management, public engagement, gender equality and communication in academia and research.

04/04/2022 – 08/04/2022 European Course: Better Training for Safer Food Online Course on "Official Control Regulation (OCR)". The overall objectives of the training are to spread knowledge and best practices in relation to new Official Control Regulation (OCR); to improve comprehension of this complex area of work and further harmonise the approaches and practices of the MS to verify compliance with the legal requirements in the field of statutory controls.

01/07/2021 – 05/07/2021 "Quality Risk Management ciclo di vita del prodotto dei prodotti farmaceutici" – Symposium AFI. Examples of applications of Quality Risk Management at different stages of the product life cycle, from research and development, to data integrity problems of chemical quality control, to control of microbiological contamination and to supplier audits

24/05/2021 – 28/05/2021 European Course: Better Training for Safer Food Online Course on "Antimicrobial Resistance: Phase II". The overall objective of the training is to work towards reinforcing engagement and collaboration with international organisations and intensify cooperation with countries outside of the European Union on AMR.

15/09/2020 – 15/12/2020 "How to write a paper and present experimental results" Federico II University of Naples in collaboration with the University Language Center. Processes to select appropriate journals and titles, and to efficiently write each section of a manuscript, strategies to respond to referee comments and to enhance clear and effective English communication skills.

February 2020 – May 2020 "Management R&D" Federico II University of Naples in collaboration with TECUP, the innovative start-up that supports technology transfer. Industrial Research Programs, regulatory and funding sources, planning and management methods from a project management perspective.

17/06/2019 5th World Congress on Medical Imaging & Clinical Research, Conference Series Ilc LTD, UK, Roma The WCMICR conference is an international forum for the presentation of technological advances and research results in the fields of Medical Imaging and Clinical Research. The conference bring together leading researchers, engineers and scientists in the domain of interest from around the world.

16_19/04/2015 Italian Association of Nuclear Medicine and Molecular Imaging (AIMN). XII National Congress of the Italian Association of Nuclear Medicine and Molecular Imaging, Palacongressi Rimini (Italy).

17/12/2012 "Course of production of radionuclides for medical uses" IRCCS National Cancer Institute _ Pascale Foundation, Naples, Italy