The unit of "regulatory sciences in biomedicine and translational drug development" deals with drug discovery, technology transfer and regulatory sciences in biomedicine. The contact person for the Unit is Dr. Pasquale Pierimarchi (https://orcid.org/0000-0003-4803-0631), supported by collaborators Dr. Gianluca Sferrazza and Dr. Manuela Zonfrillo. The team carries out scientific and intellectual property enhancement activities for preclinical and clinical development of drugs and medical devices through technical, scientific and regulatory support. The unit has in-depth knowledge of European and United States regulatory frameworks and related guidelines for the development and commercialization of medicines, medical devices and in vitro diagnostics (Sferrazza G et al and Pierimarchi P. Exp Rev Clin Pharm 2017. - Nicotera G, Sferrazza G and Pierimarchi P. Front in Med 2019 - Sferrazza G et al and Pierimarchi P. Aging Clin Exp Res 2019).

Regulatory knowledge is supported by consolidated experience in the evaluation of basic, translational, industrial research projects relating to preclinical and clinical trials of drugs and medical devices. These skills have led to carry out assessment activities of preclinical and clinical trials at the Italian Medicines Agency (2010-2016), of biomedical projects in the Sustainable Industry calls, PON 2014-2020 and Innovation Agreements in life sciences on behalf of del MUR and MISE (2013-2020) in collaboration with prof. Iervasi, director of IFC and projects promoted by startups and spin-offs (collaboration with startup accelerator in Life Sciences of the Golinelli Foundation 2018-20). The Unit is a partner of startups and spin-offs, small and large companies (MgShell / Politecnico di Milano - Silk Biomaterials - Special Product's Line) for the optimization of drugs and medical devices developed by them through technology transfer activities (experimental proof of concept and scientific and regulatory due diligence) as part of collaboration agreements and projects financed by the MISE, for example Brevetti +, a call aimed at supporting the innovative and competitive capacity through the enhancement and the economic exploitation of patents on national and international markets ((Fregnan F et al Pierimarchi P et al. Front Bioeng Biotech 2020; Alessandrino A et al Pierimarchi P et al. Front Bioeng Biotech 2019; Alessandrino A et al Pierimarchi P et al. Biomat Sci 2019).

The unit collaborates with the Department of Pediatrics of La Sapienza University in the context of clinical studies aimed at identifying the association between metabolic syndrome, NAFLD/NASH and cardiovascular diseases in pediatric patients (Pacifico L. et al. Pierimarchi, P Chiesa "Front Pediatr 2020 - Pacifico L. et al P Pierimarchi, C Chiesa. Front in Endocrin 2020). The unit also carries out drug discovery activities, screening molecules on different in vitro models (Sferrazza G et al. Pierimarchi P, Zonfrillo M and Serafino AL. Front in Pharm 2020 - Serafino AL et al. Zonfrillo M, Sferrazza G and Pierimarchi P .. Biomed Pharmacother 2018; Sferrazza G. et al. Pierimarchi P and, Serafino AL. Acta Pharm Sinica B 2020). Recently this activity has been enhanced thanks to the development of new collaborations (Faculty of Pharmacy of the University of Bari and Faculty of Pharmacy of the University of Pavia) both for the identification and development of innovative anticancer molecules generated by chemical synthesis techniques and innovative computational techniques such as virtual screening (structure and ligand based drug design) and docking studies, and for the subsequent development phase of the formulations.

References:
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