EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brief biography

Marisa Papaluca
Senior Scientific Advisor

Scientific Committees Regulatory Science Strategy (SciRS)

Current Responsibilities

Marisa was appointed in March 2015 Agency as Senior Scientific Advisor in the Research and Development Division and since 1st September 2016 moved in to the advisory function of Scientific Committees Regulatory Science strategy.

In her new position Marisa co-chairs the EU Innovation offices Network with focus on the strengthening the overall EU regulatory support to innovation and the establishment of the EMA Regulatory Science Observatory, a matrix function aiming at informing strategies for the support of successful development of innovative medicines and modernisation of regulatory tools for the benefit of individuals, public health and society at large. She is also responsible for a number of projects in collaboration with European and international partners and stakeholders at the forefront of Next Gen Medicines and Patient Centred Medicine innovation for the benefit of patients and society as a whole.

Brief Employment History

MD, Internal Medicine specialists, Marisa joined the EMA in late 1994.

Appointed Deputy Head of Quality sector up to 2002, of the Efficacy and Safety Sectors up to 2009, Head of office until 2015, Marisa pioneered regulatory science work, at European and International level, to support emerging therapies and technologies with open discussions with innovators, involving of the best expertise available among partners and stakeholders and planning ahead for effective and efficient regulatory work.

Main achievements include

- The initiation and establishment of innovative regulatory science platforms and processes (e.g. Innovation Task Force, Business Pipeline Project, biomarkers and methods regulatory qualification)

to support innovation, regulatory preparedness and contributions to environmental analysis and strategic EMA Road Maps;

- The establishment of specialised expert groups and working parties covering emerging therapies (e.g. Gene and cell therapy Pharmacogenomics, Biosimilars, nanomedicines);
- The establishment of the first EMA Scientific Support and Projects Office focussing on:
  - Specialised Disciplines support to the Committees in multidisciplinary areas (statistical methodology, non-clinical drug development, environmental risk assessment, clinical pharmacology);
  - Reinforced functionality of the Business Pipeline function and of the Innovation Task Force, transitioning and expanding functions of the latter into the current EU Innovation offices Network.