



**Xavier Luria**, MD is an independent consultant, founder and CEO at DDR (Drug Development and Regulation - [www.ddrmedic.com](http://www.ddrmedic.com)), located in Barcelona, Amsterdam and London.

He was Head of Safety and Efficacy of Medicines at the European Medicines Agency (EMA) 2005-2012, where he coordinated regulatory teams from the 28 European Member States in order to evaluate medicinal products for the whole European Union. Dr. Luria was in charge of several cross-agency projects, including implementation of electronic submissions using eCTD and the development of other IT tools, review and reorganization of CHMP's Working Parties, coordination and expansion of the EMA's Scientific Advisory Groups (SAG), and new methodologies on Benefit/Risk assessment.

Prior to joining the EMA, Dr. Luria worked for 18 years in the pharmaceutical industry, including 10 years as International Medical Director with responsibilities in international clinical development, medical affairs, drug safety and biometry, and other corporate functions.

In addition to Dr. Luria's specialty in internal medicine, and pharmaceutical medicine and biostatistics (University Autonomous Barcelona), he has developed expertise in several specific therapeutic areas, carried out postgraduate qualification in clinical pharmacology, drug development and regulation (Tufts University School of Medicine, Boston), and he is a recognized expert on regulatory systems and benefit-risk assessment (modelling, development and methodologies).

Furthermore, he is module chair at an IFAPP-King's College Postgraduate Course, Senior Visiting Lecturer at the King's College in London and lecturer at several other academic institutions in Europe and USA.

He is also Expert Consultant at NDA Partners from 2012, and member of the advisory board of several biopharmaceutical and medical devices companies and serves as consultant and regulatory service provider to many others in Europe, Japan, US, Australia, Israel and Latin America.