Veterinary Big Data Stakeholder Forum
Event programme

1 – 2 June 2021
VIRTUAL EVENT

Objectives

In recent years, reflections have progressed on how medicines regulation could be enhanced by digital technologies. Whilst substantial advancements occurred in the use of such solutions in the regulation of medicines for human use, the use of digital technologies in the veterinary regulatory domain is an unexplored yet potentially fertile territory.

This forum is an opportunity to bring together regulators, industry, farm management system providers, academia, consumers and practitioners to:

- build awareness on the use of innovative digital technologies in the veterinary regulatory environment

- share needs, ambitions and opportunities

- inspire future activities shaping the development of the European Veterinary Big Data Strategy

More information: EMA Veterinary Data Strategy

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

Programme

The programme will include updates on the use of Big Data and new digital technologies in veterinary medicines regulatory activities and provide an opportunity to learn and contribute to the European Veterinary Big Data strategy.

Sessions will focus on:

- Use of Big Data, advanced analytics and Real-World Evidence (RWE) in the management of veterinary health

- Big Data in the monitoring of efficacy and risks with concrete applications in the area of:

    o   Antimicrobial Resistance control

    o   Environmental Risk Assessment

    o   Pharmacovigilance

    o   RWE for demonstrating efficacy/ effectiveness

- The way ahead: insights of the European Veterinary Big Data Strategy driving the evolution of regulatory activities toward more data-driven and sustainable activities.

EUROPEAN MEDICINES AGENCY
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List of speakers, chairs, moderators and panellists

Emer Cooke	*European Medicines Agency*
Thomas Heberer	*HMA Management Group*
Ivo Claassen	*European Medicines Agency*
Ilaria Del Seppia	*European Medicines Agency*
Jeroen van de Ven	*MSD Animal Health Intelligence Global*
Nancy De Briyne	*Federation of Veterinarians of Europe*
Joachim Lübbo Kleen	*CowConsult*
Emma Strömfelt	*AniCura Group*
Ulrich Göggerle	*AniCura Group*
Elise Tatone	*Health Canada*
Andrea Osborn	*Canadian Food Inspection Agency*
Errol Strain	*U.S. Food and Drug Administration*
Fernanda Dórea	*Swedish National Veterinary Institute*
Peter Arlett	*European Medicines Agency*
Zoltan Kunsagi	*European Medicines Agency*
Jeroen Dewulf	*Ghent University*
Michael Empl	*European Medicines Agency*
Ad Ragas	*Radboud University*
Jos Olaerts	*European Medicines Agency*
Rondeep Bhui	*Boehringer Ingelheim Vetmedica GmbH*
Sandra Bertulat	*Federal Office of Consumer Protection and Food Safety*

List of speakers, chairs, moderators and panellists

Cat Stirling	*Zoetis*
Andrea Wright	*Zoetis*
David Murphy	*Committee for Medicinal Products for Veterinary Use*
Ciro Catuto	*University of Turin*
Claudia Kamphuis	*Wageningen University*
Ermanno Cavalli	*European Food Safety Authority*
Klaus Hellmann	*Association of Veterinary Consultants*
Rick Clayton	*AnimalhealthEurope*
Hesha Duggirala	*FDA/Center for Veterinary Medicine*
Rens van Dobbenburgh	*Federation of Veterinarians of Europe*
Ricardo Carapeto García	*Spanish Agency of Medicines and Medical Products*

Emer Cooke, *Executive Director, EMA*

Emer Cooke is as of 16 November 2020 the new Executive Director of the European Medicines Agency, based in Amsterdam. She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for a term of 2 years.

She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020. In this role, Ms Cooke was responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies.

Ms. Cooke is a pharmacist with master's degrees in science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission.

Dr Ivo Claassen, *Head of Veterinary Medicines Division, EMA*

In 2018, Ivo Claassen joined the European Medicines Agency (EMA) as Head of the Veterinary Medicines Division. He is the co-chair of the joint EMA-HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation. He is the accountable executive for the development and implementation of the IT-systems supporting the Veterinary Regulation. He is a former member of EMA's Committee for Medicinal Products for Veterinary Use (CVMP).

Dr Claassen has over 30 years of experience in vaccine production, quality assurance and control, research and development and regulatory affairs, both for human and veterinary vaccines. Before joining the Agency, he developed projects in Asia, Africa and the Middle East on capacity building of institutional infrastructure for veterinary infectious disease control and supported local vaccine development and production.

Professor Dr Thomas Heberer, *HMA Management Group*

Prof. Dr. Thomas Heberer is head of department at the Federal Office of Consumer Protection and Food Safety (BVL) since 2010. His department is responsible for the authorization and registration of veterinary medicinal products (VMPs) in Germany and is also in charge of many other related issues such as antimicrobial resistance or crisis management of VMPs. His career also includes work in environmental research at university, he was head of the section "Residues of Medicinal Products" at the Federal Institute for Risk Assessment (BfR) and head of the Food Institute Oldenburg of the Lower Saxony State Office for Consumer Protection and Food Safety (LAVES). Thomas Heberer is teaching toxicology and modern instrumental analysis as an adjunct professor at the Technical University of Berlin. In 2004, he received the research award from the German Chemical Society for his pioneering research on the occurrence and fate of pharmaceutical residues in the environment.

Ilaria del Seppia, *Data Scientist, European Medicines Agency*

Ilaria Del Seppia received her degree in Chemistry and Pharmacy from the University of Pisa (Italy) in 2003 and she is working at the European Medicines Agency (EMA) since 2005.

In July 2020, she joined the EMA Veterinary Medicines Division as Data Scientists leading the development and implementation of the EMA Veterinary Data Strategy (2021 – 2027) and oversighting data-aspects during the implementation of the Veterinary Medicines Regulation (EU) 2019/6. She coordinates the activities of the EU Veterinary Big Data Team formed by EU Medicines Network experts for the development of the EU Big Data strategy for the use of advanced analytics and emerging digital technologies in the veterinary regulatory domain. As previous experience, Ilaria served as data analyst and project manager in the Pharmacovigilance division and the Information Management division at EMA, coordinating the implementation of the first EU database on medicines for human use (XEVMPD/Art.57 database) and its integration with key regulatory processes.

At international level, she led the standardisation activities within ICH (ICH M5) and ISO forum as co-editor/co-lead of the international standards on identification of medicinal product (ISO IDMP 11615, 11616 and 11238) in synergy with international

partners (such as FDA, Health Canada, Japan, EDQM, WHO, EU medicines regulatory network experts). She contributed to the implementation of the Master Data Management services based on IDMP standards for the Substance and Product data (i.e. as part of the SPOR programme).

Jeroen van de Ven, *Vice President MSD Animal Health Intelligence Global*

Jeroen van de Ven DVM, MBA is the leader of MSD Animal Health Intelligence (formerly known as Antelliq), a specialized operating unit which takes its name from the company's strategic vision for animal health intelligence and data expertise. Jeroen is responsible for extending the range of the market-leading technology and services. This operating unit within MSD Animal Health encompasses the well-recognized and market-leading brands of Allflex Livestock Intelligence, Sure Petcare, Biomark and Vaki, including the recent acquisitions of IdentiGen and Quantified Ag. Previously, van de Ven, a practicing veterinarian in The Netherlands, was Associate Vice President for MSD Animal Health's global ruminants' business.

He joined MSD Animal Health in 2005 and served as Technical Manager for the Benelux Region, Regional Director for Northern Europe and General Manager for Belgium and Luxembourg. He is a graduate of Concordia University in Canada with a BS degree in chemistry, Ghent University in Belgium with a DVM degree and Vlerick School of Management in Belgium with an MBA degree.

Nancy De Briyne, *Executive Director, Federation of Veterinarians of Europe*

Nancy De Briyne studied veterinary medicine in Ghent (Belgium), graduating in 1996. After working as a veterinary practitioner in Belgium and the UK, she works since 2000 for the Federation of Veterinarians of Europe (FVE) being currently Executive Director of the FVE. The FVE Strategic plan 2021-2025 has 5 pillars; one of them being embracing new technology.

In respect to medicines, she published papers on antimicrobials, antibiotic sensitivity testing and adverse events of medicines. She is member of the Management Board of the European Medicines Agency representing the veterinary profession.

She is also a diplomate of the European College of Animal Welfare and Behavioural medicine, subspecialty Animal Welfare Science, Ethics and Law and is member of the EU Platform on Animal Welfare. ResearchGate profile

Dr Joachim Lübbo Kleen, *CowConsult*

Dr Joachim Lübbo Kleen, born 1974, was raised on a dairy farm in northwest-Germany. He studied veterinary medicine at the University of Veterinary Medicine Hanover and the University of Pretoria. After graduation in 2001, Joachim spent a research period at Utrecht University and worked as practicing veterinarian. From 2006 he did a residency at Glasgow University and qualified as Diplomate of the European College of Bovine Health Management (ECBHM) in 2009.

Since 2011, Joachim is self-employed as consultant with his company CowConsult. His clients are large dairy farms, furthermore he is consulting companies and in the field of feeding, animal health and data analysis. Joachim is lecturer at the University of Applied Sciences in Osnabrück and active in professional development of farmers and vets. His interests are ruminal physiology, data analysis and risk management of dairy farms. A special focus of his work is interpersonal communication.

Emma Strömfelt, *Chief Digital Officer, AniCura Group*

Emma joined AniCura late 2018 as Chief Digital Officer. Before joining AniCura, Emma has been active as a start-up entrepreneur and CEO within digitally native companies within travel & telecom and as Head of Innovation for a major Swedish bank. Emma Strömfelt holds a Master of Science degree (MSc) in International Business Administration and has lived in eight different countries.

Ulrich Göggerle, *Chief Medical Officer, AniCura Group*

Ulrich Göggerle is a veterinarian by training and a national specialist in Small Animal Medicine. Dr Göggerle completed his training at LMU Munich and Purdue University, West-Lafyette IN, USA. He has been working in different work settings from University clinic to private practice before stepping into the role as a Chief Medical Officer for AniCura in 2019. Currently, Dr Göggerle is transitioning to a new position within Mars Veterinary Health International and Diagnostics, in which he be responsible for medical educational pathways & veterinary relations for Europe and UK.

Dr Elise Tatone, *Veterinary Drugs Directorate, Health Canada*

Elise Tatone is the Senior Science Advisor for the Clinical Evaluation Division of the Veterinary Drugs Directorate (VDD) at Health Canada. Elise joined VDD as an evaluator 5 years ago, after completing her doctorate in Veterinary Epidemiology in 2016 and her Doctor of Veterinary Medicine in 2011, both from the University of Guelph. Dr. Tatone provides Health Canada with senior clinical guidance and management overview during the review and approval of veterinary drug submissions and clinical trials. She also advises on complex veterinary drug issues and stakeholder relations that often have implications across other the Government of Canada's Health Portfolio. Her particular areas of interest include One Health approaches to the reduction of antimicrobial resistance, improving access to novel veterinary therapeutics and evidence-based veterinary medicine.

Dr Andrea Osborn, *Canadian Food Inspection Agency*

Dr Andrea Osborn is a veterinarian in the Animal Health Science Directorate, Canadian Food Inspection Agency. She has worked for the CFIA since 2006 in a variety of roles including the implementation of regulatory amendments; the development of Import and Export programs for aquatic animals; and the development and implementation of a Compartmentalization program for international trade of live aquatic animals and their gametes.

Andrea currently coordinates the Community for Emerging and Zoonotic diseases which uses automated information mining, in combination with multidisciplinary member perspectives to provide early warning of emerging and zoonotic disease threats. Andrea is actively engaged with the Canadian Animal Health Surveillance System (CAHSS) as a steering committee member and provides early warning information to multiple species network surveillance groups including poultry, beef, swine and the Canadian Swine Health Intelligence Network.

Dr Errol Strain, *Division of Animal and Food Microbiology, U.S. Food and Drug Administration*

Dr Errol Strain joined the Division of Animal and Food Microbiology in the Office of Research at the FDA's Center for Veterinary Medicine in 2019 where he is responsible for bioinformatic analysis of drug-resistant pathogens for the National Antimicrobial Resistance Monitoring System. From 2010 to 2018 he was the Supervisor for the Biostatistics and Bioinformatics Staff in the Office of Analytics and Outreach at the Center for Food Safety and Applied Nutrition where he helped to create bioinformatics pipelines and workflows for the FDA GenomeTrakr program. He received his Bachelor of Science degree in Biochemistry from Purdue University in 1998 and his Ph.D. in Bioinformatics from North Carolina State University in 2006. Dr Strain's research at the FDA has focused on the application of genomic methods for surveillance and prediction of antimicrobial resistance in foodborne bacterial pathogens.

Dr Fernanda Dórea, Epidemiologist, *Swedish National Veterinary Institute*

Fernanda Dórea received her veterinary degree from the University of Brasilia (Brazil) in 2004. In Brazil she worked as a field veterinarian dealing with animal disease surveillance, awareness and training; and later managing and analysing epidemiological information. Following growing interest in quantitative methods in animal health, she pursued a master's degree in infectious disease modelling (USA) and a PhD in epidemiology (Canada). Dr Dórea has developed and implemented veterinary syndromic surveillance systems using laboratory data in Canada and in Sweden. In her current position in the Swedish National Institute (SVA) she conducts applied research and development using statistical and machine learning tools to extract actionable information from animal health data. Her research in the last 5 years has focused on syndromic surveillance, data-driven surveillance, and data interoperability and reusability through the use of ontologies.

Dr Peter Arlett, *Head of Data Analytics and Methods Taskforce, EMA*

Peter Arlett is Head of the Data Analytics and Methods Task Force and Co-chair of the Big Data Task Force at the European Medicines Agency. He has twenty-five years of experience of drug benefit risk management and of delivering programs of major change in regulation and legislation. This experience has been gained through organizations at national, European, and international level.

Zoltan Kunsagi, *Scientific specialist in Antimicrobials Resistance, EMA*

Zoltan graduated as a veterinarian from the University of Veterinary Medicine of Budapest, Hungary in 1999 and holds additional master's degrees as a specialist for toxicology (2003) and an analytical chemist specialised in chromatography techniques (2009). Between 1999 and 2014 he worked as a laboratory analyst, a researcher and a consultant in Hungary (Central Agricultural Office), Belgium (European Commission, DG Joint Research Centre) and Saudi Arabia (Saudi Food and Drug Authority).

In 2014 Zoltan joined EMA and since then he is working in the Veterinary Division's antimicrobial resistance team. He provides support to the Agency's CVMP Antimicrobials Working Party (AWP), the Antimicrobial Advice ad hoc Expert Group (AMEG) and the main contributor from EMA to the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA).

Professor Jeroen Dewulf, *Veterinary Epidemiology, Ghent University*

Jeroen Dewulf graduated in 1998 as a veterinarian from the Faculty of Veterinary Medicine of the Ghent University, Belgium. In 2002 he finished his PhD on the epidemiology and control of classical swine fever. In that same year he received a Master of Science degree in veterinary epidemiology from the University of Utrecht, the Netherlands (cum laude). He became diplomat in the European College of Veterinary Public Health in 2005.

He is full professor and the head of the Veterinary Epidemiology Unit and is supervising over 10 PhD students who are doing research in the field of veterinary epidemiology. He is (co-) author of over 300 A1 publications in the field of veterinary epidemiology with a H-index of 45. He is the principal author of

the annual Belgian report on antimicrobial consumption in animals (BelVetSac) and chair of the JPI-AMR network on quantification of antimicrobial consumption in animals at herd level. Since 2009 he is member of the scientific committee of the Belgian federal food Agency and is the founder and chair of board of the center of expertise on antimicrobial use and resistance in animals (AMCRA) in Belgium. He is also the author of the book "Biosecurity in animal production and veterinary medicine" as well as the book "8 Myths on antimicrobial resistance disproved, practical guide for reducing antibiotic use in animal husbandry". ResearchGate profile

Dr Michael Empl, *Scientific Administrator, EMA*

Michael graduated as a veterinarian from the University of Veterinary Medicine Hannover in 2010 and is a Veterinary Specialist for Pharmacology and Toxicology as well as a European Registered Toxicologist. He holds a doctorate in veterinary medicine and a PhD in toxicology. Between 2010 and 2018 he worked as researcher at the Institute for Food Toxicology of the University of Veterinary Medicine Hannover. Before joining European Medicine Agency's Veterinary Pharmaceuticals Service as Scientific Administrator dealing with veterinary medicinal product and MRL applications as well as safety and environmental risk assessment-related issues in mid-2019, he briefly worked at the Fraunhofer Institute for Toxicology and Experimental Medicine in Hannover. He provides support to the Agency's Joint CVMP/CHMP 3Rs Working Group (J3RsWG) and to the CVMP Environmental Risk Assessment Working Party (ERAWP). ResearchGate profile

Professor Ad Ragas, *Radboud University*

Ad Ragas (1964) studied biology and obtained his PhD at the Radboud University in Nijmegen, the Netherlands where he currently holds a position as an associate professor in Environmental Sciences. His main expertise is the modelling of human and ecological risks of chemicals, covering emissions, fate, exposure, toxicokinetics and adverse effects in humans, farm animals and species of ecological interest. He actively participates in several large research projects on pharmaceuticals and contaminants of emerging concern, i.e. PREMIER, SPRINT, LABPLAS and SUSPECt. He chairs the Dutch scientific advisory committee on quality standards for air and water, and the Dutch Interuniversity Committee on Environmental Sciences.

Jos Olaerts, *Head of Veterinary Risk and Surveillance Service, EMA*

Jos graduated as a veterinarian from the University of Gent, Belgium in 1991 and holds an additional master's degrees in statistics (1997) from the University of Hasselt.

Following a period in equine veterinary practice (1991-1993), Jos became a research assistant at the department of Physiology, University of Liege (1994-1996). Between 1997-1998 he worked as veterinary assessor for the Belgian Ministry of Health, having joined the European Medicines Agency (EMA) in 1999.

Within the EMA, he started as scientific administrator and supported several working parties. Over the years, the main activity has shifted predominantly to the field of pharmacovigilance where he now heads the service of veterinary risk and surveillance.

Rondeep Bhui, *Head of Global Pharmacovigilance, Boehringer Ingelheim Vetmedica GmbH*

Rondeep (Ronnie) Bhui represents Health for Animals (Pharmacovigilance Taskforce). He is currently Head of Global Pharmacovigilance at Boehringer Ingelheim Animal Health. He is a Biomedical Scientist by education and went straight into industry after University. Ronnie has held both Subject Matter Expert (SME) and Leadership roles within Human Pharmaceuticals (Consultancy, CROs, Generic and Innovator) and Animal Health. He also represents industry in the VICH Pharmacovigilance Working Party.

Dr Sandra Bertulat, *Assessor in efficacy and target animal safety, BVL*

Dr. Sandra Bertulat received her degree in Veterinary Medicine. Afterwards, she worked in the field of university research for several years specializing in bovine health management as well as animal reproduction and was responsible for a multitude of studies utilizing data from farm management systems as well as advanced analytics.

In 2017 Dr. Bertulat joined the Federal Office for Consumer Protection and Food Safety as an assessor and is responsible for clinical aspects of marketing authorization procedures for veterinary medicinal products.

Since February 2020 she is one out of two veterinary members of the Big Data Steering group and also became a member of the EU Veterinary Big Data Team responsible for the development of the EU Big Data strategy for the use of advanced analytics and emerging digital technologies in the veterinary domain. In addition, in October 2020, Dr. Bertulat was elected as member of the CVMP Efficacy Working Party.

Dr Catrina Stirling, *Director of Regulatory Affairs, Zoetis*

Dr Catrina (Cat) Stirling graduated from the University of Edinburgh with a degree in Virology before doing a PhD in Veterinary Immunology at the Pirbright Institute/University of Sussex. She then spent 4 years as a post-doc at Pirbright working on DNA vaccines for FMDV and ASFV immunology before joining the UK Veterinary Medicines Directorate (VMD). After 2 years at VMD she moved to Pfizer Animal Health, now Zoetis focusing on regulatory affairs, she is currently Director of Regulatory affairs focusing on companion animal vaccines and biologicals. She is an expert on immunological and biological product development and registration as well as 3Rs aspects of vaccine release.

Dr Andrea Wright, *Director International Outcomes Research, Zoetis*

Dr Andrea Wright graduated from Colorado State University in 1990. She completed an internship at Peterson and Smith in Ocala Florida before moving to the University of Saskatchewan to complete a Masters in Large Animal Internal Medicine. After the residency she was a research associate in the Microbiology department developing an ELISA for Estrone Sulfate. She returned to private practice as an associate and then practice owner for many years before joining industry in 2003 with Henry Schein. Her role as the Manager of Veterinary Tech Services reporting to the President of Technology gave insight into all business aspects of veterinary practices. In 2011, Dr Wright completed an MBA and joined Zoetis as the Marketing Manager of Equine Biologics. In this role she set marketing strategy and working closely with the sales force, Technical Services team, Outcomes Research, Marketing Communications and agencies. In 2013, she joined the Outcomes Research team for Companion Animal supporting the dermatology, Pain and Sedation, Veterinary Business Services, Biologics and antimicrobial portfolios. In 2016, Dr Wright joined the International Outcomes Research group as part of the Center of Excellence to support all Companion Animal and Equine products.

Dr David Murphy, *Chair of Committee for Medicinal Products for Veterinary Use*

David Murphy graduated as a vet from University College Dublin in 1990. Between 1990 and 1997, he worked and studied at the University of Glasgow's School of Veterinary Medicine.

Following a period in veterinary practice in Ireland, he joined the Health Products Regulatory Authority in 1999 as a safety and efficacy assessor. Between 2009 and May 2016, Dr Murphy was the Irish representative on the Committee for Medicinal Products for Veterinary use (CVMP) of the European Medicines Agency. Currently (since June 2016), he is the Chair of the CVMP.

Professor Ciro Catuto, *University of Turin*

Ciro Cattuto, PhD is an Associate Professor of Computer Science at the University of Turin (Turin, Italy) and a Principal Researcher at ISI Foundation (Turin, Italy). His interests include Data Science, Complex Systems, Public Health, and the Social Impact of data. He holds a PhD in Physics from the University of Perugia, Italy and has worked at the University of Michigan, USA, at the Enrico Fermi Center and Sapienza University in Rome, at the Frontier Research System of RIKEN, Japan. He is a principal investigator of the SocioPatterns collaboration, an international effort on studying social networks with wearable sensors, with applications to epidemiology. He is editorial board member of Nature Scientific Data, EPJ Data Science, Data & Policy. He was organizer and chair of leading conferences in Data Science and Complex Systems. He is a Fellow of the European Laboratory for Learning and Intelligent Systems (ELLIS), and has served as an expert in the Italian Government's Covid-19 data-driven task force. Webpage

Dr Claudia Kamphuis, *Researcher, Wageningen University*

Dr. ir. Claudia Kamphuis is an animal scientist with an MSc degree in Preventive Animal Health and Welfare. She successfully defended her PhD thesis called "Making sense of sensor data; detecting clinical mastitis in automatic milking systems" in 2010. After that, she and her family moved to New Zealand to work at the Farm Technology Group at DairyNZ for almost three years, to go back to Wageningen in 2013.

Making sense of sensor data has been the red thread throughout her research, but with a clear goal to connect domain knowledge with data science and IT to enable big data analyses in the livestock domain since her position at Wageningen Livestock Research (WLR) in 2016. She is now project leader of several big data related projects at WLR, where she aims at developing new methods to store and analyse data, and to develop new tools that we could not do before the Big Data era.

Ermanno Cavalli, *Senior Data Scientist, EFSA*

Ermanno Cavalli currently holds the position of Senior Data Scientist in the Assessment and Methodological Support Unit in EFSA. He is currently leading a project aimed at joining forces from European Union Agencies in deploying of Artificial Intelligence. He joined EFSA in 2006 and held several managerial positions in Information Technology.

He worked for Siemens Mobile in the years 1993-2006, where he held the position of Software Development Manager and led several large projects about development of software for managing large telecommunication networks.

He started his career in Olivetti in 1985, where he covered the position of System Software Developer until 1993. He collaborated to several projects aimed at software development for operating systems and relational databases.

He received his Master's Degree in Computer Engineering from University of Bologna (Italy) in 1985.

Ricardo Carapeto García, *AEMPS*

Ricardo Carapeto García is a veterinarian with more than 10 years of experience in the regulatory field of veterinary medicines. He combines his work as Head of Service of Environmental Risk Assessment at the Spanish Agency of Medicines and Medical Devices (AEMPS) with the participation in the CVMP as co-opted member and in the CVMP Environmental Risk Assessment Working Party where is the current Chair.