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Annex

About the authors

Thomas Lönngren, Executive Director, n. Swedish. Education: Qualified pharmacist from the University of Uppsala Faculty of Pharmacy. MSc in social and regulatory pharmacy. Post-graduate studies in management and health economics.

Career to date: From 1976 to 1978, lecturer at University of Uppsala. Mr L önngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990 during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1982 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He is Executive Director of the EMEA since January 2001.

Peter Christoph Schulz. After completion of medical school and service as a medical officer in the army, training in internal medicine in institutions in Germany and the USA. Since 1995 in the Pharmaceutical Industry, since 1996 safety officer at Bayer Vital, the German marketing organisation for pharmaceutical products of the Bayer AG.

Current responsibility for case handling and regulatory issue management as well as IT development. Current involvement in three electronic data exchange projects with regulatory authorities. Special interest in system analysis, process engineering and application development for cardiology (EKG, Holter Monitoring), and ebusiness in pharmaceutical industry and hospitals.

Franco Rinaudo. Franco has been working with the Joint Research Centre of the European Commission since 1974. He has a nuclear physics background and has been involved in Nuclear Reactor safety until early eighties. He than moved to the JRC AI labs, dealing with hypertext research and programming. Having gained a significant experience in computing and networking, especially in the pharmaceutical sector, Franco was seconded to the EMEA in London since the opening of the agency, to provide support to the co-operation network between EC, EMEA and the National Regulatory Authorities of the EU.

He manages a small team in London, responsible for the operation of the network and the associated services (web publishing, co-operation, secure document transfer, network management and monitoring . . .). He works in strict co-operation with the European Commission services responsible for the Pharmaceutical sector (DG ENT/F), the EMEA, the National Authorities and liase with the pharmaceutical industry in a number of technical projects.

Arthur P. Meiners trained and later worked as an internist-nephrologist in several hospitals in the Netherlands before joining the Agency for the Medicines Evaluation

Board in 1991 as a clinical assessor. Since its start in 1995 he has been head of the pharmacovigilance department and member of the Pharmacovigilance Working Party of the CPMP. He has been involved in electronic adverse reaction reporting pilot projects and with MedDRA from the beginning.

Stan van Belkum (MSc, pharmacists) has been working for more then 8 years within the National Institute for Public Health and the Environment n the Netherlands initially as quality reviewer and later on as Deputy Head of the Medicines Evaluation Department. He has been chemical-pharmaceutical Expert of the EMEA for the Centralised Procedure and member of the CPMP/CVMP Quality Working Party on behalf of the Dutch Medicines Evaluation Board.

Currently Stan van Belkum is Information Manager within the Agency for the Medicines Evaluation Board. He is member of several national and international working groups on electronic regulatory submissions. Amongst these are the EU Regulatory Delegation for ICH-M2, EU Telematics Implementation Group (TIG) on electronic submissions and the International Reviewer Forum.

Shigekoto Kaihara, M.D., D.M.Sci. Dr. Kaihara received his M.D. degree (1961) and D.M.Sci. degree (1966) at Tokyo University School of Medicine. From 1966 to 1969 he was a research associate at Johns Hopkins Hospital in USA. After serving several years as a staff physician in Department of Internal Medicine, at University of Tokyo Hospital, he became Professor and Director of Hospital Computer Center, University of Tokyo Hospital. He retired from University of Tokyo in 1997 and became the Director of National Okura Hospital. In 2000, he became the director of the Medical Information System Development Center. He plays a key role in medical informatics in Japan and internationally as Director of WHO collaborating Center for Medical Informatics, President of Japan Society of Medial Informatics and in his past appointment as President for International Medical Informatics Association (IMIA). He is also the Scientific Advisor to the Ministry of Education, Science and Culture and is involved with various health related committees in Ministry of Health and Welfare. Recently he served as Japanese National Coordinator of G7 Health Care Application Project.

Mihoko Okada, Ph.D. Mihoko Okada obtained her BS in Mathematics from Tokyo Women's Christian College, MS in Computer Science from the University of Nebraska-Lincoln, and Ph.D. in Medical Science from Brain Research Institute, Niigata University. In 1984, she became an associate professor of Statistics at Niigata University, and in 1991, she became a professor at Suzuka University of Medical Science. She is presently a professor at the Department of Medical Informatics, Kawasaki University of Medical Welfare. Her research interests include statistical databases, pharmaceutical databases, information modeling and information management in healthcare. She has been a member of ICH M2 EWG since 1996.

Christina Winter qualified in medicine (Trinity College Dublin, 1975) and then obtained a M.D. on thermoregulation. She was a lecturer in cardiovascular medicine with experience in clinical trials. Christina joined Glaxo in 1993 and is now Head of

the Safety Physicians, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline. She is a Qualified Person for Pharmacovigilance and medical terminology advisor. She was in the first MEDDRA working party, an EFPIA representative at ICH M1 and is involved with the European MedDRA User Group and chairman of the EFPIA MedDRA Task Force.

David Drakeford, Deputy Head of Sector for information technology, EMEA, n. Irish. Education: Honours degree in experimental physics, and MSc in electronic engineering from Trinity College Dublin. Career to date: David Drakeford worked with Telecom Eireann where he managed the implementation of a national data communications network. In 1987, he joined Coopers & Lybrand where he was a senior management consultant specialising in the management and financial control of large, primarily IT-related, projects. He was also involved in numerous multinational project management and business analysis assignments, including managing the implementation of a worldwide information management system for clinical trials on behalf of a Swiss-based pharmaceutical company. He joined the EMEA in February 1997.

Esteban Gonzalez Juarros qualified in Mathematics. He managed the development of information systems in pharmaceuticals including databases of medicinal products and prices, regulatory tracking systems, electronic group management, document modelling and automatic document generators, integration of drug dictionaries and medical dictionaries, safety reporting systems, extranets and web sites. Projects in which he has participated include EudraNet, EudraTrack, ERS, IMP and www.eudra.org. He chaired the Telematics committee, the EudraNet working group and the European Joint Pharmacovigilance Pilot, and represented EU at the ICH M2 and E2BM Expert Working Groups.

Silvia Valverde. Qualified as a Spanish lawyer in 1992. Specialised in European Community Law (master's degree) at the Granada University in 1992 and at the Brussels University (ULB) in 1994. Registered in the Granada Bar in 1998. Trained in European pharmaceutical law at the European Medicines Evaluation Agency (EMEA) from March 1998 to July 1998. Since September 1998 working in London as a lawyer in the Healthcare team (sub-group of Lifesciences group) of CMS Cameron Mckenna, an international commercial law partnership.

Sabine Brosch, Deputy Head of Sector for pharmacovigilance, safety and efficacy of medicines, b. 17 August 1963, n. Austrian.

Education: Masters Degree in pharmacy and Doctor of Natural Sciences Degree in pharmacology from the University of Vienna. Post-graduate studies in pharmacology at the University of Melbourne and Auckland. Career to date: From 1988 to 1992 Dr. Brosch worked as an assistant professor at the Department of Pharmacology and Toxicology at the University of Vienna, where she was specialised in electrophysiology. In 1992 she moved to the Pharmacovigilance Department at the Austrian Ministry of Health and completed a 6-month regulatory traineeship at the European Commission, DG Enterprise, Pharmaceuticals and Cosmetics, in 1995. She joined the EMEA in November 1996.