

**7<sup>th</sup> EGA Annual Symposium on Biosimilar Medicines  
“Towards Global Development and Monoclonal Antibodies”  
23 - 24 April 2009 - London**



**Thomas Lönngren**

Mr Thomas Lönngren is Executive Director of the European Medicines Agency (EMA) since 1 January 2001.

He qualified as a pharmacist from the University of Uppsala in 1976 and holds an MSc in social and regulatory pharmacy. From 1976-78 he was a lecturer at Uppsala University, Sweden.

He served with the Swedish National Board of Health and Welfare from 1978-90 with responsibilities including herbal medicines, cosmetics, medical devices, narcotics and contraceptives. During 1982-92 he acted as senior pharmaceutical consultant for the Swedish International Development Agency's health cooperation programme in Vietnam.

In 1990 he was appointed Director of Operations of the Swedish Medical Products Agency, later becoming Deputy Director-General of the Agency. He was elected an Honorary Member of the Royal Pharmaceutical Society of Great Britain in 2003 and made an Honorary Fellow of the Royal College of Physicians in 2004.



**Christian K. Schneider, MD**

Dr. Christian Schneider is MD by education and works as Head of Division “EU Co-operation/Microbiology” at the Paul-Ehrlich-Institut, the German Federal Agency for Sera and Vaccines. He is the Chairman of the Committee for Advanced Therapies (CAT), and a co-opted member of the CHMP, the Committee for Medicinal Products for Human Use at the European Medicines Agency EMA, for the area of “Quality and safety (biological), with expertise in Advanced Therapies - Gene, Cell and Tissue Therapies”.

He is also the chairman of the CHMP Working Party on Similar Biological Medicinal Products (BMWP). He has been actively involved in the drafting of several multidisciplinary guidelines.

Before he joined the Paul-Ehrlich Institut, Christian Schneider was working for more than two years as a postdoctoral researcher at the Max-Planck-Institute of Neurobiology (Martinsried, Germany), where he worked in experimental T cell immunology. During his clinical career, Christian Schneider worked in the field of clinical immunology and hemato-oncology (Department of Internal Medicine III, University Erlangen-Nuremberg, Germany).



**Falk Ehmann, MD, PhD**

Dr. Falk Ehmann is currently Scientific Administrator in the specialised group for Anti-Infectives and Vaccines in the Safety and Efficacy Sector in the Human Unit of the European Medicines Agency (EMA). He held numerous and various positions and responsibilities within this Unit since October 2004.

His current responsibilities include,

- being secretariat of the Working Party for Biosimilar Medicinal Products where he is involved in centralised Marketing Applications for Biosimilar Medicinal Products, drafting the working program of the BMWP, development of guidelines, and scientifically supporting the Scientific Advice and Orphan Drug and Sector.
- He is member of the current CHMP/EMA initiative for a new approach to Benefit/Risk assessment.

Prior to joining the EMA Dr. Ehmann was a Public Health Researcher at the Robert Koch Institute in Berlin and Medical Intern at different University Hospitals including Bordeaux, Geneva and Tanzania.

Falk Ehmann wrote his PhD thesis in the department for Cellular Signal Transduction at the University Hospital Hamburg-Eppendorf in the Center of Experimental Medicine of the Institute of Biochemistry and Molecular Biology.

He holds numerous Diplomas and Certificates. The detailed CV will be provided with the event material.



**Jan Petracek, MD**

Dr. Jan Petracek qualified as physician from Charles University in Prague. In 2000 he joined the State Institute for Drug Control, serving as medical assessor in Clinical Trials and Pharmacovigilance Unit of Czech national authority. Two years later he was promoted to Head of Pharmacovigilance, and put in charge of the development of national pharmacovigilance system according to the EU requirements. He was representing the Czech Republic in the CPMP/CHMP Pharmacovigilance Working Party and in various other ad hoc expert groups and task forces. He joined the Risk Management Team of the European Medicines Agency in 2006, and is now responsible for peer review of the assessments of Risk Management Plans, signal detection in pharmacovigilance, and risk management of advanced therapy medicinal products. His research focuses on quality and safety in healthcare, and links between pharmacovigilance and patient safety.



**Peter Wieninger, Mag. rer. soc. et oec.**

Head of Department of Medicines at Main Association of Austrian Social Security Institutions

Membership of Professional Bodies:

**International:**

- Representative of Austria in the Network of Competent Authorities of Pricing and Reimbursement of the European Union
- Representative of the European Social Insurance Platform (ESIP) in the Working Group on Pricing” of the European Commission;
- Member (deputy) of the Transparency Committee of the European Union;
- Member of MEDEV-Committee;
- Member of Piperska-Group on Rational Use of Medicines

**National (examples):**

- Member (Deputy) of Austrian Taxkommission,
- Member (Deputy) of Austrian Taxausschuss,
- Member (Deputy) of Austrian Abgrenzungskommission.

The detailed CV will be provided with the event material.



**Greg Perry**

Greg Perry established the European Generic Medicines Association (EGA) in 1993 and has been the association’s fulltime Director General since 1999. He is a founding member of the International Generic Pharmaceutical Alliance (IGPA) and has served on its management committee since its creation in 1997. He served as Editor of the Journal of Generic Medicines from 2003 -2008 and was member of the SCRIP Awards Panel from 2004-2008. Greg is also CEO of GPA Ltd.

Greg was awarded the Golden Cross of Merit of the Republic of Poland in 2004 for his contribution to industry and European integration. In 2005 he was granted Honorary Life Fellowship of TOPRA in recognition of his contribution to European pharmaceutical regulatory affairs.

Greg has over 20 years experience in European public affairs and business.. He is a Member of various organisations including the International “Who’s Who” of Professionals, the Institute of Directors (UK), Friends of the British Museum and Friends of the Royal Academy.

Greg has an MA in European Integration, a BSocSc (Hons) in International Studies and a Diploma in Classical Studies.



**Alan Sheppard**

Alan Sheppard is Global Head - Generics. In this role he is responsible for leading the generic initiatives and offerings from IMS Health. Alan has over 30 years experience within the pharmaceutical industry covering the full spectrum of innovative medicines, generics, biological, vaccines and OTC medicines.

Having held senior positions within sales and marketing, business development, and general management he has extensive experience in mergers and acquisitions, partnering, licensing, product development, manufacturing and R&D. Previous positions include:

- Executive Vice-President, Europe Generics, Dr Reddy’s Laboratories Ltd
- Vice-President, Global Corporate Strategy Pliva
- European Marketing Director for Medeva
- General Manager, Rhône-Poulenc Rorer UK
- UK Manger Institute Merieux



**Aaron (Ronny) Gal, PhD**

Dr. Ronny Gal is the specialty pharmaceuticals industry analyst at Sanford C. Bernstein & Co., LLC, a leading independent research firm based in New York and London. Mr. Gal provides research and investment insight on specialty and generic pharmaceutical stocks to institutional clients around the world. His work has been recognized in third party surveys such as *Institutional Investor* and Greenwich Associates. In the generic sphere, Mr. Gal’s current research focuses on paragraph IV challenges and biosimilars.

Prior to joining Bernstein, Mr. Gal worked at Canon, spearheading the imaging company’s efforts to launch a life sciences business. Previously, he served as a Principal at the Boston Consulting Group (BCG), advising clients in the pharmaceutical and health care delivery sectors.

Mr. Gal, who was awarded a PhD in Biochemistry from the Massachusetts Institute of Technology, is a travel enthusiast and has lived and worked on three continents. In addition to his passion for court transcripts and FDA dockets, he is an avid runner and beer brewer.



**Marcy Macdonald, BS, MBA, RAC**

Marcy Macdonald is Director of Global Regulatory Affairs, at Hospira Inc. one of the key leaders in the pursuit of biosimilar products. Marcy has been in the pharmaceutical industry almost 20 years, 18 of which have been in Regulatory Affairs, managing and leading teams in obtaining product approvals encompassing many dosage forms and therapeutic areas. She is the regulatory lead in developing Hospira’s global biosimilar positions particularly in the European and US regulatory sector. Marcy is also a member of the EGA European Biopharmaceuticals Group (EBG) and the GPHA Biopharmaceutical Taskforce in the US where she has provided input to congressional staff members and government offices as the legislative biogeneric path in the United States is established.

Prior to joining Hospira, Marcy was the Director of Regulatory Affairs at Apotex Corp where she built the US regulatory presence for the organization specifically focusing on parenteral dosage forms.



**Juliana M. Reed**

Juliana Reed is the Director of the Office of Government Affairs for Hospira, Inc., overseeing the global function for the company. Hospira has government affairs representatives in Washington, DC; Sacramento, California, Canberra, Australia and in other regions on an as needed basis. Hospira, headquartered in Lake Forest, Illinois, U.S.A., is a global specialty pharmaceutical and medication delivery company driven by its vision of Advancing Wellness™. Bringing proven leadership and experience, Hospira provides solutions to help improve the productivity, safety and effectiveness of patient care. In early 2007, Hospira acquired Mayne Pharma to become the world leader in specialty generic injectable pharmaceuticals. In 2008, Hospira launched Retracrit™, one of Europe’s first biosimilar EPOs.



**Bram van Dijck**

20 year plus experience in healthcare - hospital/medical supplies, pharmaceuticals, medical nutritionals - in senior sales, marketing, business development, general management and international BU positions with pharmaceutical companies Abbott Laboratories, Knoll/ BASF Pharma (now Abbott), Organon International (now Schering-Plough). In addition co-founder of vaccine company (biotechnology).



**Paul Greenland, BSc, MBA**

Paul Greenland is the Director of Biosimilar Marketing for EMEA at Hospira, Inc., a specialty pharmaceutical company headquartered in Lake Forest, Illinois, USA. Based in Leamington Spa, UK, he is responsible for the commercial development of Hospira’s biosimilar portfolio across Europe, Middle East and Africa. Since early 2008 he has coordinated launches of Hospira’s first biosimilar product, Retacrit, across 14 countries within the EU and is now preparing the ground for further introductions over the next few years. Mr Greenland has been employed in a variety of commercial roles in the pharmaceutical industry for almost 20 years with extensive experience in both the Australian and European markets. For the past 10 years he has been directly involved in the field of biopharmaceuticals. He holds a Bachelor of Science degree and an MBA from Edinburgh Business School.



### Udo Meurle

Mr. Udo Meurle is the Commercial Operations Manager responsible for Sandoz Biopharmaceutical Portfolio in Western Europe, North America and Japan. Previously Mr Meurle was Head of Global Strategic Marketing for Sandoz Biopharmaceutical portfolio (2007-2009). Mr Meurle has also held a number of roles in Strategic planning/marketing whilst working for ratiopharm International (1996-2003) before leading ratiopharm's operations in Belgium as Managing Director (2003-2007). Prior to his appointment at ratiopharm Mr Meurle held a number of Senior Commercial and Marketing positions in Abbott Germany (1991-1996) and Boehringer Ingelheim/Dr Karl Thomae GmbH (1982-1991)



### Suzette Kox

Suzette Kox is Senior Director Scientific Affairs of the European Generic medicines Association (EGA) and coordinator for the European Biopharmaceuticals Group (EBG) of the EGA, the EMEA-EGA Working Group and the EGA Safety & Pharmacovigilance Working Group.

Suzette is also Member of the Science Committee of the International Generic Pharmaceutical Alliance (IGPA) and belongs to the visiting faculty of the School for International Training: Department Development Studies and Public Health in Geneva, Switzerland.

Previously she worked for 10 years in regulatory affairs and management for the German generic company *ratiopharm* and was Chair of the EGA Regulatory & Scientific Affairs Committee and Member of the EGA Board and Executive Committee.

Before joining the generic industry, she followed a hospital and retail pharmacy career. Along with a degree in pharmacy (Paris) she holds a postgraduate diploma in anatomy-pathology.



### Andreas Premstaller

Born in Meran / Italy, Andreas Premstaller studied Chemistry at the Leopold-Franzens-University in Innsbruck, Austria. There, he worked for four years in Professor Christian Huber's group at the Institute of Analytical Chemistry and Radiochemistry. His research focused on novel techniques for the separation of biomolecules and the hyphenation of these methods to mass spectrometry for the analysis of oligonucleotides, DNA and proteins. After obtaining his Ph.D. in 2000, Dr. Premstaller extended his work in the field of mass spectrometry and miniaturized separation systems for biomolecules during a Postdoctoral fellowship at the Stanford Genome Technology Center in Palo Alto, CA, in Peter Oefner's group (Erwin Schrödinger Fellowship of the Austrian Science Fund).

Andreas Premstaller joined the analytical development group of Sandoz Biopharmaceuticals in 2002. As Head of Analytical Characterization of Biopharmaceutical Operations, he has been responsible for the characterization of recombinant protein products for the Novartis/Sandoz group. He is currently the Head of Technical Development at Biopharmaceutical Operations in Kundl, Austria.



### Hye Na Kang, V.M.D

#### Education

1991 Bachelor degree in Biology - College of Natural Science, Sungshin Women's University Seoul, South Korea  
1993 Master degree in Physiology - College of Natural Science, Sungshin Women's University, Seoul, South Korea  
2007 V.M.D in Veterinary Microbiology, College of Veterinary Medicine, Konkuk University, Seoul, South Korea

#### Experience

Dr. Hye Na Kang joined the Quality, Safety and Standards Team of the Immunization, Vaccines and Biologicals department of WHO as a Scientist on last February. Prior to joining WHO as a secondment of Korean government, she was working for more than twelve years at Korea Food and Drug Administration. Dr. Kang has professional experience in regulation of biologicals and biological standardization. During the first six years, she built up the experience of reviewing document for approval, establishing national standards, quality control including lot release testing, and GMP inspections. In 2004, she worked for the project to develop HCV DNA vaccine at Vaccine and Infectious Disease Organization in Saskatchewan of Canada. After she came back to Korea, she played a leading role to develop written guidelines at the national level and to innovate the policy of national lot release system as a deputy director.

In 2000, Dr. Kang got the best research award of Korea Food and Drug Administration with the project named "Standardization of potency test of coagulation factor VIII products", and she was the best government officer to lead the innovation in 2007.



### Ingrid Schwarzenberger

After her studies of Biology at the University of Innsbruck, Austria, Ingrid joined Biochemie GmbH in Kundl, Austria, in 1984. Since then she has filled various positions within the regulatory departments of the company and was dealing with worldwide active substance registrations and CEP applications as well as with applications for finished dosage forms in all regions of the world, including the US.

In 2001 Ingrid became Head of the Regulatory Affairs Department for Biopharmaceuticals at Sandoz and has since then been dealing with all filings for Omnitrope® in Europe, US and Australia and also with the successful biosimilar applications of Binocrit® and Zarzio® in Europe. Ingrid is also an active member of the European Biopharmaceuticals Group (EBG) of the EGA.



### Cecil Nick, B.Sc. (Hons.), FTOPRA,

Vice President (Biotechnology), PAREXEL Consulting, Uxbridge, UK.

Expertise: A regulatory professional with over 25 years experience, Cecil Nick joined PAREXEL in February 2001 and has been involved with issues relating to biosimilarity, clinical development biotech and orphan drug submissions and also issues and training relating to the above and the Common Technical Dossier and eCTD. Specifically relating to biosimilars he has been involved with two submissions, a large number of scientific advice procedures and in the design of a many clinical trial programs.

Cecil joined PAREXEL in 2001 from Novo Nordisk Ltd. where he gained considerable experience in the development and registration of biotechnological products and NCE's. He has also previous Regulatory experience with Farmitalia Carlo Erba, May and Baker, London International Group and Lundbeck. In addition he has knowledge of health economic assessments, quality assurance, pharmaceutical distribution and clinical research. He has authored many articles published in GCP Journal and Regulatory affairs Journal.

Credentials: University of Cape Town, B.Sc., Biochemistry, 1976

University of Cape Town, B.Sc. (Hons.), Biochemistry, 1978

Fellow of TOPRA

Member of the TOPRA Biotechnology Special interest Group

Course Leader for Biotechnology Module for MSc in Regulatory Affairs run under auspices of Cardiff University.



### **Bruce Clark, PhD**

Dr. Bruce Clark is Vice President of Regulatory and Medical Affairs for Apotex Inc. based in Toronto, Canada. Apotex is Canada's largest generic pharmaceutical manufacturer. He is responsible for the global Regulatory and Medical functions and is an executive member of the Apotex management team. He currently is a member of the EGA European Biopharmaceuticals Group (EBG). Dr Clark received his PhD in Molecular Neurobiology from the University of Toronto and was a Post-Doctoral Fellow in the Departments of Medicine and Genetics at the Hospital for Sick Children in Toronto. Prior to joining Apotex in 2004. Dr Clark was President of Biomed Partners Inc. a consulting company and previously held roles as Vice President of Scientific Affairs for Sanofi-synthelabo and Director of Regulatory Affairs for GlaxoWellcome.



### **Anita O'Connor, PhD**

Dr. Anita O'Connor is Senior Director for Biopharmaceutical Development at MDS Pharma Services. She has more than 20 years of experience in regulatory affairs for the pharmaceutical, medical device, food, and animal drug industry. She worked for the U.S. Food and Drug Administration (FDA) for 16 years in the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Veterinary Medicine (CVM), the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of the Commissioner (OC). As an FDA pharmacology and toxicology reviewer in CBER, she specialized in drugs produced by biotechnology and worked on hundreds of INDs and pre-INDs for biotechnology drugs. She was the lead pharmacology reviewer for the Biologic License Applications (BLAs) for Orencia®, Avastin®, Kevivance®, Remicade®, Remair®, and Rituxan®. In 2007 she wrote a chapter for a reference book on biopharmaceutical development, available July 14, 2008 [*Preclinical Safety Evaluation of Biopharmaceuticals: A Science-Based Approach to Facilitating Clinical Trials* (Hardcover) by Joy A. Cavagnaro (Editor)].



### **Dr. med. Sandy Eisen**

Dr Sandy Eisen is Chief Medical Officer for TEVA Pharmaceuticals Europe, reporting to the President of TEVA Europe and with responsibility for all medical affairs and clinical research operations and standards, and clinical regulatory strategy.

He qualified as a medical practitioner with a medical degree from Cambridge University, and holds postgraduate medical qualifications from both the Royal College of Physicians and the Royal College of Surgeons in London.

He was previously Vice President for Portfolio and Scientific Affairs with TEVA Europe, reporting to the head of TEVA Europe and responsible for all portfolio activities with the EU, including regulatory affairs.

Before joining TEVA he was Vice President for Clinical with PAREXEL Consulting, working in the London office of PAREXEL International.

Prior to joining PAREXEL Dr Eisen was Senior Medical Officer at the Medicines Control Agency (now the MHRA) of the Department of Health in London for 13 years, working in all areas of UK and EU regulatory affairs.

During the last 8 years of his time at the Medicines Control Agency, Dr Eisen was Senior Medical Assessor in the New Drugs Unit of the Licensing Division of the MCA dealing with both UK and European (Centralised and Mutual Recognition) applications in all therapeutic areas. He also assessed abridged, biological and CTX applications during this period.

Dr Eisen has lectured and written on regulatory topics for many years, and organised and participated in many regulatory affairs courses, including those organised by BIRA, TOPRA, and the WHO.

Dr. Eisen is also Chair of the European Biopharmaceuticals Group (EBG) of the EGA.



### **Prof. Dr. med. Christoph Renner**

Acting director, Department of Hematology, University Hospital Zürich, Switzerland

#### **Education**

1973-1986 High school in Bergisch Gladbach; Nicolaus-Cusanus-Gymnasium  
1986-1990 Study of chemistry, University Cologne, Germany  
1986-1993 Study of medicine, University Cologne, Germany  
1991 Elective hematology Prince of Wales Hospital, Sydney (Australia)  
1993-95 Intern, Saarland University Medical School, Department of Hematology/Oncology, Homburg, Germany  
1995-1997 Resident, Saarland University Medical School, Department of Hematology/Oncology, Homburg, Germany  
1993-1997 Study coordinator, German high grade Non-Hodgkin-Lymphom study group (DSHNHL)  
1999- Resident, Saarland University Medical School, Department of Hematology/Oncology, Homburg, Germany  
2001 Board certification internal medicine  
2001-6/05 Consultant, Saarland University Medical School, Department of Hematology/Oncology, Homburg, Germany  
10/2003 Board certification Hematology/Oncology  
Implementation of a phase I/II clinical trials centre, Homburg, Germany  
7-10/2005 Senior consultant, Saarland University Medical School, Department of Hematology/Oncology, Homburg, Germany  
10/2005 ESMO examination  
11/05-8/08 Senior consultant, Department of Oncology, University Hospital Zürich, Switzerland  
9/2008- Acting director, Department of Hematology, University Hospital Zürich, Switzerland

The full scientific career will be provided with the event material.



### **Dr. med. Michael Muenzberg**

Global Medical Director SANDOZ Biopharmaceuticals at SANDOZ Headquarters Holzkirchen/Germany

The position includes the following responsibilities -

- Proactively contributing to shaping the SANDOZ Biopharmaceuticals strategy from a medical perspective
- Maintaining solid organizational understanding of global epidemiologic events, therapeutic trends and "unmet needs" in SANDOZ Biopharmaceuticals focus areas
- Assisting in prioritization and selection of therapeutic areas, modes of action and target molecules for SANDOZ Biopharmaceuticals, including Target Product Profile selection and definition
- Organizing and supervising the late stage clinical development programme, including design and execution of Phase IV and Post-Marketing Surveillance (PMS) / Post-Approval Safety Studies (PASS) Trials in close cooperation with development, regulatory affairs and marketing
- Approving the medical part and local adaptation of brand plan and medical training material
- Leading the international key opinion leader program, including set strategy for / decide participation in international workshops and satellite symposia; provide guidelines for local KOL programs, as needed
- Leading the publication strategy, both for SANDOZ Biopharmaceuticals overall and specific products; provide guidelines for local publication strategy, as needed
- Defining global and approving national 'publication mix' (journals, posters, symposia, round tables, etc.); approve global and national publication content
- Ensuring all guidelines and good practices are implemented in the medical organization, including Good Clinical Practices and Standard Operating Procedures
- Managing the medical team, setting clear, attainable objectives for each team member that are aligned with and contribute to the success of SANDOZ Biopharmaceuticals

- Developing and retaining key talent through implementation of pathway/career plans and ensuring succession planning
  - Proactively shaping the medical team organization and processes in an entrepreneurial, innovative spirit, responding to the needs of a newly created organization within a pioneering business area
  - Cooperating closely with and support country medical management
- The full CV will be provided with the event material



**Dr. med. Udo Mueller**

**Education:**

1977: Medical Diploma - State Medical Institute, Moscow  
 1985: M.D., Ph.D. Medical Oncology / Clinical Pharmacology - German Academy of Sciences, Berlin

**Qualification:** Board certified Clinical Pharmacologist and Medical Oncologist

**Brief Chronology of Employment:**

**Since 2008:** Global Medical Director BioGenerics, Teva Pharmaceutical Ind. Ltd. Israel

**2002 - 2007:** Director Global Medical Marketing Baxter Oncology [ASTA Medica Oncology was acquired by Baxter Healthcare Inc. End of 2001]

**1999 - 2001:** Head International Medical Department Oncology, ASTA Medica AG Frankfurt (Germany); since January 2001 Head Medical Product Management ASTA Medica Oncology

**1995 - 1998:** Medical Director Oncology, Laboratoires Pierre Fabre / Pierre Fabre Pharma

**1992 - 1994:** Central Medical Adviser, International Clinical Research and Development, Ciba - Geigy Ltd., Basel (Switzerland)

**1991 - 1992:** Senior Manager Marketing and Sales Department, Farmitalia Carlo Erba Ltd., Freiburg i. Br. (Germany)

**1977 - 1991:** Senior Physician and Clinical Research Director at the Central Institute for Cancer Research of the German Academy of Sciences, Berlin (Germany)

**Professor Colin. B. Brown BSc MD FRCP**

Consultant Renal Physician and Ex-Professor of Clinical Nephrology Renal Medicine and Transplantation, University of Sheffield, UK