

USP-EDQM-NIBSC 2ND WORKSHOP ON THE CHARACTERISATION OF HEPARIN PRODUCTS

19-20 June 2008

SPEAKERS' BIOGRAPHICAL NOTES

Dr. Ali Al-Hakim obtained his degree in Chemistry from The American University in Lebanon. He studied for his Ph.D. at the University of East Anglia, Norwich, England and obtained his Ph.D in 1984. During the period 1984-1988, he was a Research Scientist at Agricultural Genetics Company in Cambridge, England (development of on-radioactive nucleic acids hybridization probes). From 1988-1991, he was a Postdoctoral Research Assistant at College of Pharmacy - University of Iowa, Iowa City (worked on the Chemistry and Biochemistry of Sulfated Polysaccharides). In 1991, he joined Wyeth Pharmaceuticals, NY, Department of Research and Development and worked on the development of Low Molecular Weight Heparin drug product.

Dr. Al-Hakim joined the FDA in 1994. He is currently the Heparin Expert for the agency and a Branch Chief in the Office of New Drug Quality Assessment - Division of Pre-marketing 1.

Mr. Pascal Anger obtained his degree in analytical chemistry from ESPCI in Paris, France in 1981. He has since held different positions in the analytical development organization in entities (France and the USA) which are now part of sanofi-aventis.

Dr. Hanno Binder obtained his degree in chemistry from the university of Innsbruck/Austria. He studied for his Ph.D. at the same university and obtained his Ph.D. in 1978. During the period 1978 – 1982 he was research assistant at the university of Innsbruck/Austria.

He joined Sandoz GmbH in 1982 and from 1982 – 1996 he was appointed as group leader and finally as head of the analytical R&D laboratories, being responsible for the development of β -lactam antibiotics.

He changed to Quality Assurance of Sandoz GmbH in 1996 and is now in the position as Head of Quality Management of Sandoz International.

Since 1998 he has been member of expert group 7 (antibiotics) of EDQM.

Dr. Emmanuelle Charton holds a PhD in Biochemistry from the *Institut National Agronomique de Paris-Grignon*. She undertook research in the laboratory of an international food & cosmetics company in the United Kingdom, before joining the pharmaceutical industry as a quality control assistant, where she was involved in process validation for new registrations. She has over 10 years experience at the EDQM as a scientific administrator to the groups of experts elaborating monographs on biologicals and as a supervisor to the corresponding work in the EDQM laboratory. She is still responsible for the work related to microbiological chapters of the Ph. Eur. In 2006 she was appointed as Deputy to the Head of the European Pharmacopoeia Department.

Dr. Bernd W.K. Diehl graduated in 1986 and received his Ph.D. from Faculty of Chemistry, Marburg University, Germany. In 1988 he was appointed by Bayer AG, Leverkusen, German as Head of NMR Laboratory of Plant Protection Centre Monheim. He founded Spectral Service Laboratory in 1990, an independent Research Institute for Analytical Services in Cologne, Germany.

Published Works: Books, Reviews and approx. 50 scientific papers concerning NMR. Partly university lecturer at the Universities of Marburg and Bonn.

Association Memberships: GDCh, AOCS, I.L.P.S. (Scientific secretary, Reference laboratory), AOAC (member of different working groups), IASC (International Aloe Science Council, Reference laboratory), FAH (Member of the Analytical Working Group).

Dr. Thomas Freudemann studied chemistry in Germany (University of Tübingen) and the US (University of Massachusetts) and obtained his degree "Diplom-Chemiker" from the University of Tübingen in 1999. He earned his Ph.D. at the University of Tübingen in 2002 researching a topic in analytical chemistry (CGE & on-line CGE-ESI/MS coupling for antisense oligonucleotide analysis) in Prof. E. Bayer's group. In 2003 he joined former Biochemie GmbH in Schafhenau (Austria), now Sandoz GmbH, in the role of Laboratory Head IPC Analytical Labs. In 2008 he was appointed Head IPC Analytical & Technical Process Support Labs in matters concerning IPC analytics, quality control, process development and troubleshooting in API production.

Mr. Georg Goestl obtained his degree in chemistry from Technical University, Vienna. He graduated in 1986. He started his professional experience in 1987 at Immuno AG in different roles of rising responsibilities within the Quality Control and Quality Assurance teams. In 1997 Immuno AG was merged with Baxter.

He is Head of Quality Assurance at the Baxter facility located in Vienna, Austria. Since 1997, nominated as the Qualified Person for Baxter AG, Vienna, he is responsible for release of all batches of plasma-derived and recombinant products. Since 2006 he is member of the "Blood Commission" by the Austrian MoH.

Dr. Gyöngyi S. Gratzl graduated in 1986 from Chemical Engineering, Technical University of Budapest, Hungary and received her Ph.D. in 1991 from Analytical Chemistry, Technical University of Budapest, Hungary. She joined, from 1990 to 1993 as postdoctoral fellow, the Department of Biomedical Engineering, Case Western Reserve University, Cleveland. In 1990, she was appointed by the Cleveland Clinic Foundation as Research Scientist of Investigative Hematology.

She developed her career as Senior Scientist of Parenteral Dosage Forms and Controlled Release Systems at Ben Venue Laboratories, Bedford Ohio. She currently works as a Senior Development Pharmaceutical Scientist at Boehringer-Ingelheim. Since 1992 she has been member of AAPS, ACS and PDA.

Dr. Elaine Gray joined the National Institute for Biological Standards and Control (NIBSC) in 1979, and completed her PhD at NIBSC in 1986. Since 1996 she has been a Principal Scientist in the Haemostasis Section and is responsible for control and standardisation of antithrombotics, blood coagulation factors and inhibitors.

Prof. Dr. Ulrike Holzgrabe obtained her degree in chemistry from the University of Marburg and her degree in pharmacy from the University of Kiel (Germany). She studied for her Ph.D. at the University of Kiel (Germany). She obtained her Ph.D in 1983. During the period 1983-1990 she was research assistant at the University of Kiel (Germany). From 1990 - 1999 she was assoc. Prof. in Pharmaceutical Chemistry at the University of Bonn, and since 1999 full professor in Pharmaceutical Chemistry at the University of Würzburg, Germany.

Since 1992 she is a member of the Committee of the German Pharmacopoeia (at the Federal Institute of Drugs and Medical Devices, BfArM) and head of the committee of Pharmaceutical Chemistry, since 2001 Member of the Committee of the European Pharmacopoeia and head of the Expert Group 10D (Chemical Substances); since 2002 she is member of the scientific board of the BfArM.

Dr. Céline Houiste obtained her degree in chemical engineering from ECPE in Lyon, France, 2006. She simultaneously obtained a Ph.D in Pharmacy. She then joined sanofi-aventis Process Development Biotechnology.

Dr. Craig Jackson obtained a B.S. degree in zoology from Washington State University, Pullman, WA, USA in 1963 and a Ph.D. degree in biochemistry from the University of Washington, Seattle, WA in 1967. Between 1968 and 1969 he was a post-doctoral fellow at Unilever Research, Division of Chemical Physics, Port Sunlight, Cheshire, UK. He was appointed Asst. Prof. Biological Chemistry, Washington Univ. School of Medicine, St. Louis, MO in 1969 and promoted to Prof. Biol. Chem. and Assoc. Prof. Internal Medicine in 1974. He served as Scientific Director, SE Michigan Region, American Red Cross, Detroit, MI from 1984 until 1992. In 1992 he became President, Reagents Applications, Inc., San Diego, CA, a medical laboratory diagnostic reagents manufacturer. In 2000 he co-founded Hemosaga Diagnostics Corporation and where he is currently President and Chief Technical Officer.

Dr. Kristian B. Johansen obtained his masters degree in chemical engineering in 1975 from the Technical University of Denmark (DTU). He received his Ph.D. in 1979 from the Institute of Biochemistry DTU.

In 1978 he joined the Neonatal Department, Rigshospitalet, University of Copenhagen as Research Biochemist. In 1981 he was appointed project manager at Nordisk Insulin Laboratorium (now Novo-Nordisk) in Copenhagen, Denmark.

From 1983 to 2007 Dr. Johansen was employed by LEO Pharma, Denmark. From 1983 – 1988 he was Project Manager for the development of the LMW-heparin, Tinzaparin. In 1988 he was appointed Head of the Heparin Research Laboratory and in 1993 Director for R&D of Biological Products. From 2004 -2007 Dr. Johansen served as Pharmaceutical Expert and Scientific Adviser.

From 2007 Dr. Johansen has been heading the pharmaceutical development and outsourcing at Zealand Pharma, Denmark.

Since 2006 Dr. Johansen has been a member of the USP ad hoc Heparin Advisory Panel and is now acting as co-chair.

Mr. Peter Jongen obtained his degree in pharmacy from Utrecht University in the Netherlands in 1986. From 1986 until 1990 he was scientific officer at the National Institute for the Quality Control of Drugs. In 1991 he joined the National Institute for Public Health and the Environment as a senior scientific officer with special expertise in biological medicinal products. Mr Jongen is pharmaceutical assessor for biological medicinal products on the behalf of the Medicines Evaluation Board in the Netherlands. From 1993 until 2000 he was in charge of control authority batch release testing of vaccines and blood products. From 2000 he is project manager of the post marketing testing of biological medicines and of several projects with respect to research on new methods for the quality control of biological medicines. Since its establishment he took part in several advisory groups of the European OMCL Network. Mr Jongen is since November 2007 chairman of European Pharmacopoeia expert group 6: Biological substances and of the Glycan Mapping Working Party. He is an alternate member of the Dutch delegation.

Dr. Nana Kawasaki graduated in 1986 from Hokkaido University and received her Ph.D. in 1996 from Faculty of Pharmacy, Hokkaido University in Japan. She joined, from 1986 as a researcher, National Institute of Health Sciences. In 1998 she was appointed as section chief at division of Biological Chemistry & Biologicals. She has been member of the JP expert committees to prepare the drafts: Panel on Nomenclature (since 2001) and Panel on Biologicals (since 2004).

Dr. Larry Kelly obtained his degree in applied chemistry from Salford University in the UK. He studied for his Ph.D at the Australian National University (Canberra). He obtained his Ph.D in 1981. He has worked in industry in the UK and USA before taking a position on the staff at the Australian National University. In 1987 he joined the Antibiotics Section of National Biological Standards Laboratory (later to become the Therapeutic Goods Administration) in Canberra where he was a reviewer of applications to market antibiotic products in Australia as well as head of the chemical testing laboratory in the section. In 2003 he became director of the TGA Laboratories with responsibility for the chemical, biological and medical device laboratories.

Mr. Daisuke Koga graduated in 1994 and received a master's degree in Pharmaceutical Sciences in 1996 from Tokyo University, Japan. He studied in Applied Therapeutics from 1999 to 2001 in the school of Clinical Pharmacy, University of Southern California.

Since 2007 he has been a Review Coordinator for Pharmaceutical Affairs Bureau, Ministry of Health, Labour and Welfare in matters concerning New Drug Approvals.

Prof. Philippe Lechat is Physician, Cardiologist and Clinical Pharmacologist, Graduate from Paris VI University in 1976. He obtained his PhD thesis in 1982 and was nominated Professor of Pharmacology in 1990. He became head of the Pharmacology department of Pitié-Salpêtrière Hospital in 1999 in Paris. In June 2007, he was nominated Head of Evaluation of drugs and biological products at the French Regulatory Agency AFSSAPS. He is alternate member for France at the CHMP since July 2007.

Dr. Rhonda Lecky obtained her degree in pharmacy from Trinity College, Dublin in Ireland. She obtained her Ph.D in 1992 from Trinity College, Dublin also. She joined the LEO Pharma, Dublin in 1993 where she held positions in GMP compliance and validation and as a Qualified Person.

Since 1997 she has been QA/QC Manager for Wexport Limited, the LEO Pharma heparin sodium and tinzaparin sodium manufacturing site.

Dr. Ian McEwen obtained his degree in organic chemistry from the University of Gothenburg, Sweden, 1989. During the period of four years, he was research assistant and ass. Prof at the University of Gothenburg, Sweden. From 1994, he was assoc. Prof. From 1994, he has been senior lecturer in organic chemistry and NMR spectroscopy at the University of Karlstad, Sweden. He has worked at Pharmacia and at Nobel industries at different intervals. He is now NMR specialist at the Swedish Medical Products Agency (MPA).

Dr Giuseppe Mascellani obtained his degree in Chemistry from Ferrara University in Italy in 1965. He attended to the Specialization School in Analytical Chemistry at the University of Bologna (Italy) in the years 1967 – 1968.

During the period 1965 – 1971 he was analyst in QAS of a private pharmaceutical company. During the period 1971 – 1977 he was researcher at the laboratory of organic synthesis, in the R&D department of a private company, in the medicinal chemistry fields: β -lactam-, rifamycin-, and quinolonic antimicrobial agents, cardiovascular and anti-inflammatory substances.

During the period 1978-1982 he was Director of R&D Laboratories in a private pharmaceutical Company in Bologna (Italy).

In the period 1982 – 1984 he was Professor under contract at the Faculty of Pharmacy of Universities of Bologna and Ferrara (Italy). In the same period he was charged with the job of Director of R&D of a private pharmaceutical company in Milano (Italy).

Since the year 1985 till now, he has been manager and consultant in a private company that produces extractive drug substances (polysaccharides, proteins, enzymes...) in Modena (Italy).

He is co-author of about 70 papers on Medicinal Chemistry published on international journals. He has been designed as inventor or co-inventor of more than 20 granted patents concerning medicinal chemistry substances.

Dr. Barbara Mulloy obtained a B.Sc. in Biochemistry at Bedford College, University of London in 1970. She joined the National Institute for Biological Standards and Control in 1975, as a Junior Technical Officer in the Chemistry Section. After studies at Birkbeck College, her Ph. D. in Chemistry was awarded by the University of London in 1992. Since 2001 she has been Principal Scientist in the Laboratory for Molecular Structure at NIBSC.

Dr. Jochen Norwig obtained his degree in pharmacy in 1982 (Free University of Berlin). He studied for his Ph.D. at the Free University, faculty of Pharmaceutical Technology and obtained his Ph.D. in 1990. He joined BfArM in 1990 and became the secretary to Pharmaceutical Technological Expert Committee of the German Pharmacopoeia Commission. Since 1996 he is member of the Powder Working Party and the Standard Terms Working Party of the Ph.Eur.-Commission and since 2006 he is member of the BfArM PAT-Group.

Christian F. Petersen: MSc. Chem. Eng. 1999, Head of Department, Biological Process Development 2003.

Dr. Patrick N. Shaklee obtained his Ph.D. in Biochemistry from the University of Illinois (USA) in 1985 under the direction of Professor H. Edward Conrad. Following postdoctoral work at the University of Wisconsin, Dr. Shaklee was Assistant Professor of Biochemistry at the University of North Texas from 1989-1992. From 1992-1994, he was Scientist III at Glycomed Incorporated, and from 1994-2000 was Senior Research Scientist at Scientific Protein Laboratories. From 2000 thru 2008, Dr. Shaklee has been President and Director of Technical Operations at BioCascade Incorporated in Arlington, Wisconsin.

Dr. Shaklee's career has focused on development of chemical, physical, and bioanalytical tools for glycosaminoglycan analysis, with a particular focus on heparin and the chondroitin sulfates. During graduate work, Dr. Shaklee developed chemical disaccharide analysis techniques for the chondroitin sulfates and keratan sulfate, demonstrated that low levels of 2-sulfated glucuronic acid were present in heparin, and subsequently discovered a specific glucurono-2-sulfatase present in human and avian lysosomal extracts. Later, in conjunction with James Knobloch, he showed the general utility and applicability of multi-angle laser light scattering to LMW-heparin molecular weight determinations. Most recently, Dr. Shaklee and BioCascade have offered chromogenic testing services, validation studies, test kits, and consulting to clients within the hemostasis industry. Since 1999, Dr. Shaklee has been an active member of the WHO Working Group on Harmonized Methods for Unfractionated Heparin Potency Determination, and served from 2000-2007 on the USP Expert Committee on Blood and Blood Products.

Dr. Patrick Soon-Shiong, former assistant professor of Surgery and Medical at UCLA, performed the world's first encapsulated islet transplant in a diabetic patient and developed the nanoparticle delivery technology upon which the cremophor-free form of paclitaxel compound known as ABRAXANE[®] is based.

Dr. Soon-Shiong's research has been recognized by the Association for Academic Surgery Award for Research, the American College of Surgeons Schering Scholar, the Royal College Physicians and Surgeons Research Award, the Peter Kiewit Distinguished Membership in Medicine Award, and the International J.W. Hyatt Award for Service to Mankind. Dr. Soon-Shiong received the 2006 Gilda Club Award for the advancement of cancer medicine and is a recipient of a 2007 Ellis Island Medal of Honor. He is a co-inventor of over 50 issued U.S. patents and has published more than 100 scientific papers.

Dr. Soon-Shiong currently serves on the Board of Directors for the National Institute of Transplantation, two advisory boards for the RAND Corporation, the RAND Center for Asia Pacific Policy and the RAND Health Board of Advisors, and the Board of Trustees for the

Saint John's Health Center in Los Angeles, California and the Advisory Board of the California NanoSystems Institute at UCLA.

Mr. Jean-Marc Spiesser studied Pharmacy at the University of Strasbourg and obtained his Masters Degree (postgraduate) in Applied Industrial Pharmaceutics at the University of Montpellier in 1973.

After different positions in the Research and Pharmaceutical Industry he joined the Technical Secretariat of the European Pharmacopoeia Commission at the Council of Europe in Strasbourg. Jean-Marc Spiesser is currently Head of the Department of Biological Standardisation, OMCL Network & HealthCare (DBO) at the EDQM, a department which manages:

- the OMCL Network including for the time being about 90 participating Official Control Laboratories all over Europe involved in both the human and the veterinary field. In 1994, he initiated the inter-communication between Official Medicines Control Laboratories (OMCL) within Europe by developing a real European Network governed by general common policies and operational guidelines, especially in the areas of: Quality Assurance; market surveillance for pharmaceuticals commercialised in Europe through both systems (centralised and decentralised); and batch release activities by Official Control Authorities for biologicals.
- the activities of the Biological Standardisation Programme aimed at:
 - developing and validating new methodologies and particularly those *in vitro* methods which are alternative methodologies to *in vivo* animal bio-assays and
 - establishing the European working standards and reference materials for biologicals (hormones, vaccines and blood derivatives).
- the Blood transfusion and Organ transplantation activities.
- and since January 2008, the activities related to the protection of patients from counterfeit medicines and pharmaceutical crime.

Dr. Anita Szajek received her Ph.D. degree from the chemistry department at University of Wisconsin in Madison, and her BS in chemistry from the University of Illinois at Urbana-Champaign.

Dr. Szajek was postdoctoral fellow at National Institutes of Health and Parke-Davis Pharmaceuticals (now Pfizer-Ann Arbor). From 1997-2000, Dr. Szajek was senior scientist at Antex Biologics Inc., Gaithersburg, Maryland, where she worked on identifying novel vaccine candidates using SELDI (Surface Enhanced Laser Desorption and Ionization) technology. From 2000-2005, Dr. Szajek was senior scientist in Pharmaceutical Sciences department at Human Genome Sciences Inc. (HGSI), Rockville, Maryland where she worked on both purification process developments, scale-up and analytical assay development from preclinical to Phase III. Dr. Szajek is currently Senior Scientist at the United States Pharmacopoeia (USP).

Dr. Giangiacomo Torri studied bioorganic chemistry at University of Pavia. He joined the research group of Prof. B. Casu at the 'G. Ronzoni' Institute in 1973. He was Harold Hibbert Fellow (1979-1980) at the "Department of Chemistry", of McGill University of Montreal (Canada), guest of prof. A.S. Perlin as visiting scientist.

Since 2000 he is the Director of the Ronzoni Institute and since 2003 he is President of the "Consortium for NMR research in biotechnology and material science". He is expert in the chemistry and biochemistry of bioactive carbohydrates and carbohydrate polymers. Since 2007 he has been expert for the working party on Nuclear Magnetic Resonance Spectrometry of EU Pharmacopoeia Commission (EDQM).

Dr. Chidambaram Subramanian Venkatesan graduated in 1992 from Annamalai University in India and received his Ph.D. in 2001 from Faculty of Organic Chemistry, Indian Institute of Science, India. In 1998 he was appointed by Gland Pharma Ltd, India as Senior Chemist of Research & Development.

He developed his career as Manager of Process and Analytical development at Gland Pharma Ltd. He is currently Vice-President at Gland Pharma Ltd.

Dr. Christian Viskov graduated in 1989 from Ecole Supérieure d'Ingénierie de Pétrolechimie et de Synthèse Organique Industrielle (Marseille) and received his Ph.D. in 1993 from Université de Provence - Marseille (France). In 1995, he was appointed by Rhone-Poulenc-Rorer as Process development chemist, Research and Development.

He developed his career as Research Investigator in Discovery Research and created the Glycochemistry Unit in 2001 (Aventis). He is currently Glycochemistry Group Leader in Sanofi- Aventis.

Dr. Jeanine Walenga received her education at the University of Illinois (Champaign and Chicago, Illinois, USA), Université Pierre et Marie Curie Paris VI, (Paris, France), and Loyola University Chicago (Maywood, Illinois, USA) in the fields of medical laboratory sciences and pharmacology. She is certified as a medical technology specialist by the American Society of Clinical Pathologists and the National Certification Agency for Clinical Laboratory Scientists.

She is a Professor in the Departments of Thoracic-Cardiovascular Surgery and Pathology of the Stritch School of Medicine (Loyola University Chicago), Co-Director of the Hemostasis and Thrombosis Research Laboratories, and Director of the coagulation clinical laboratories. Since 2006 she has been member of the Heparin Advisory Panel of the US Pharmacopoeia.

Dr. Marcus Wittstock obtained his degree in biology from the University of Oldenburg in Germany. He studied for his Ph.D at the University of Wuerzburg, Germany, which he obtained in 2000.

Since 1998 he has been Clinical Research Associate for Pharm PlanNet Contract Research GmbH in Germany in matters concerning clinical trials. In 2001 he joined the Unit "Risk Assessment Procedures, Pharmacovigilance Inspections" of the Pharmacovigilance Division in the Federal Institute for Drugs and Medical Devices (BfArM). He is since 2006 the Vice-Head of the unit.