



# The Tenth Plasma Biotechnology Meeting (2017)

St Georges Bay, Malta  
May 15 - 19, 2017

Keynote

## **Darwin's Medicine: How Business Models are Evolving in the Life Sciences Industry"**

Professor Brian D Smith

*Pragmedic, United Kingdom*

## **Session 1 Manufacturing Perspectives**

*Chair: Geoffrey Pot, Shire, Belgium*

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### **Impact of Filter Membrane Orientation on Depth Filter Performance During Commercial Production of Plasma Derived Products: A Case Study**

Nicolas Szalkiewicz, Pascaline Deffontaine, Alexandra Delfosse, Julien Hastir, François Luc, Christophe Van Ryckeghem and Gert Verheyden \*

*Shire, Lessines, Belgium*

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### **Optimizing Automated Buffer Management in Plasma Fractionation**

Joakim Lundkvist\*, Debora Otero, Enrique Carredano, Karolina Busson

*GE Healthcare, Uppsala, Sweden*

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### **Improving the Purity of Plasma Proteins**

Ben Beacom, Elena Sirbu, Jim Pearson, Chris Sadler, Patrick V. Gurgel, Steve Burton\*

*Prometic Bioseparations Ltd.*

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### **Affinity Chromatography, a Robust Technology for the Purification of a rhFVIIa Coagulation Factor**

Damien Bataille\*, Sandrine De Marco, Alain Lejars, Caroline Goussen, Monique Ollivier, Sami Chtourou, Ludovic Burlot, Michel Nogre

*LFB Biotechnologies, Les Ulis, France*

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### **Analytical Refractometry for Protein Determination: Evaluation of Manual and automated Instruments and Procedures for Process Analytical and Quality Control Application**

Heinz Anderle\*, Alfred Weber, Karin Herbinger, Stefan Zlabinger

*Shire Pharmaceuticals, Process Development and Technical Services, Analytical Development, Industriestrasse 67, A-1220 Wien/Vienna, Austria*

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### **Development of a Single Pass Tangential Flow Filtration (SPTFF) Method for the Concentration of an Ig G Solution from 10% to 20% in 1 Simple Filtration Step**

Christophe Carnawal, Sylvie Defrere, Thorsten Bisschop and Eric Youseff

*Shire*

## **Session 2 Quality and Regulatory Affairs**

*Chair: Albert Farrugia, Kedrion Biopharma, Italy*

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### **The German Experience in Policy Evolution for Haemophilia Therapies – From IQWIG to AMNOG to ACCESS**

Uwe Schlenkrich, Publisher Haemophilia News, Leipzig Germany

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### **Evolution of National Self-sufficiency in Haemotherapies in Malta – From Aspiration to Achievement**

Alex Aquilina, Director, Maltese National Blood Transfusion Service

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### **Improved Concept for Process Validation Stage 1 (Process Design)**

Lars Sejergaard, Thomas B. Hansen, and Ernst B. Hansen

*Novo Nordisk A/S, Brudelysvej 17-19, DK-2880 Bagsværd, Denmark*



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## **Technology Transfer and Change Management – Case Studies**

Darnon Estelle\*, Bajon Anne

*LFB Biomedicaments, Industrial Process Direction, Les Ulis, France*

## **Session 3 Pathogen Safety**

*Chair: Albrecht Gröner, Pathoguard Consulting, Germany*

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## **Source Plasma Safety**

George B Schreiber

*Plasma Protein Therapeutics Association Annapolis, MD USA*

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## **Epidemiology of New Emerging Viruses and Impact on Pathogen Safety of Plasma Derived Products**

Albrecht Gröner

*PathoGuard Consult*

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## **Confirmation of Effective Virus Clearance of Emerging Pathogens**

Nathan J Roth\*, Wolfram Schaefer, Thomas Novak, Birgit Popp, Martin Stucki, Eleonora Widmer, Connie Broumis, David Eakins, Randel Fang

*CSL Behring - Bern Switzerland, Marburg Germany, & Broadmeadows Australia*

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## **Understanding Virus Filtration Mechanisms and Designing Robust Virus Filtration Processes**

Tomoko Hongo-Hirasaki

*Asahi Kasei Medical Co., Ltd., Nobeoka-city, Miyazaki, Japan*

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## **Diagnostic assays for variant Creutzfeldt-Jakob disease—challenges facing appropriate selection criteria**

Jillian K Cooper

*NIBSC, South Mimms, Hertfordshire, United Kingdom*

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## **Pharmacovigilance in Blood / Plasma derived Biologics / Business as usual or what? / Experiences from ~5 years working under the revised EUPV legislation**

Rainer Schmeidl

*Vice President Corporate Drug Safety / EU QPPV, Biotest AG, Dreieich, Germany*

## **Session 4 Applications of Plasma Products and Clinical Developments**

*Chair: Salvador Grancha, Instituto Grifols S.A., Spain*

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## **Biochemical Properties and Stability of CUVITRU, a Launched 20% Subcutaneously Administrable Immunoglobulin Preparation from Human Plasma**

Harald Arno Butterweck, Ursula Mais-Paul, Lucia Gnauer, Alfred Weber and Wolfgang Teschner

*Shire, Vienna, Austria*

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## **Development of a Novel Polyclonal Antibody Preparation for the Treatment of Patients with Severe Community-acquired Pneumonia**

Benjamin Dälken, Matthias Germer\*, Andrea Wartenberg-Demand, Imke Schulz, Jörg Schüttrumpf

*Biotest AG, Dreieich, Germany*



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## **Feasibility to Nebulize and to Topically Apply Human Plasma-derived Immunoglobulins into the Lungs**

Marius Loetscher,<sup>1</sup> Marlies Illi,<sup>1</sup> Alain Kropf,<sup>1</sup> Karin Steinfuehrer,<sup>2</sup> Ulrich Baumann,<sup>3</sup> Sylvia Miescher,<sup>1</sup> Martin Spycher,<sup>1</sup> Adrian W. Marius Loetscher,<sup>1</sup> Marlies Illi,<sup>1</sup> Alain Kropf,<sup>1</sup> Karin Steinfuehrer,<sup>2</sup> Ulrich Baumann,<sup>3</sup> Sylvia Miescher,<sup>1</sup> Martin Spycher,<sup>1</sup> Adrian W. Zuercher,<sup>1</sup> & Cedric Vonarburg<sup>1\*</sup>

1. Department of Research, CSL Behring AG, Bern, Switzerland 2. PARI Pharma GmbH, Gräfelting, Germany 3. Medizinische Hochschule Hannover, Hannover, Germany

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## **"Development of Inter-alpha Inhibitors as A Novel Neuroprotective Agent in Hypoxic-Ischemic Brain Injury"**

Yow-Pin Lim\*

ProThera Biologics, Inc. 593 Eddy Street, Providence, RI 02903, USA

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## **IVIG-Inspired Drugs for Improved Therapy in Autoimmune Diseases**

Carlos J. Bosques

Senior Director of Research, Momenta Pharmaceuticals, Cambridge MA, USA

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## **Use of SOMAscan as an Analytical Tool for the Plasma Fractionation Industry**

Karl McCann\*, Pushpa Kotharu, Vladimir Gurevich, Joseph Bertolini

CSL Behring Australia, Broadmeadows, Australia

## **Session 5 Markets, Policies and Strategy**

Chair: [John Curling](#), John Curling Consulting AB, Sweden

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## **The World Needs Plasma: From The USA And Other Countries**

Jan M Bult

Plasma Protein Therapeutics Association

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## **The Nordic Market: Is the Supply of Plasma Products Secured?**

Leni von Bonsdorff\*

Sanquin Oy, Hevosenkenkä 3, 02600 Espoo, Finland

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## **Local fractionation – An African Model**

David Stubbings

National Bioproducts Institute, Pinetown, South Africa

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## **The Successes, and the Failures, of the Plasma Fractionation Industry**

Albert Farrugia

Kedrion Biopharma, Lucca, Italy

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## **Plasma Protein Fractionation, a Leading Example for Ecological Footprint Awareness?**

Groenewegen et.al. <sup>\*)</sup>, van der Laan et.al. <sup>\*\*)</sup>

<sup>\*)</sup> Proxycys b.v. Nw-Amsterdam, NL; <sup>\*\*)</sup> Delft University, Delft, NL.

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## **Global Manufacturing Technology Transfer: the R&D Contribution**

Robert Forrest\*, Karl McCann and Joe Bertolini.

CSL Behring (Australia) Pty Ltd, Melbourne, Australia



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## Session 6 New Products & Innovations in Plasma Processing

Chair: *Sami Chtourou, LFB Biotechnologies, France*

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### **Fc Multimers as IVIG Mimetics — Potential Next Generation Biologics**

Fabian Käsermann\*, Rolf Spirig, Adriana Baz Morelli and Adrian Zuercher  
*CSL Behring, Research, Bern, Switzerland*

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### **Generation and characterization of a Novel Thrombin-activable Factor X Correcting Factor VIII, Factor IX and Factor XI Deficiencies**

Jean-Luc Plantier\*, Toufik Abache, Alexandre Fontayne, Virginie Beghin, Céline Bourdon, Anne-Sophie Dezetter, Dominique Grenier, Emilie Jacque, Alain Longue, Béatrice Souilliant, Guillaume Chevreux, Damien Bataille, Sami Chtourou  
*LFB Biotechnologies, Loos, France*

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### **In Vivo Efficacy of an Innovative Biological Fibrin Glue Containing Fibrinogen and Activated Factor VII (FVIIa)**

Louise Pasquesoone<sup>1</sup>§, Fanny Bonhomme<sup>2</sup>§, Véronique Duret<sup>3</sup>, Jean-Luc Plantier<sup>3</sup>, Sami Chtourou<sup>3</sup>, Philippe Mondon<sup>3</sup>\*  
*1, Department of Plastic Surgery, Burn Center, University Hospital of Lille, Roger Salengro Hospital, rue Emile Laine 59037 Lille, France 2, Hopitaux Universitaires de Genève, Genève, Suisse 3, Direction of Innovative Therapeutic, LFB Biotechnologies, Loos, France §, Both authors contribute equally to the work \*, corresponding author ; mondonp@lfb.fr*

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### **Eshmuno® P anti-A and anti-B: Affinity Resins for Removal of Anti-A and Anti-B Isoagglutinins**

Santosh B. Rahane\*, Matthew Turiano, Lloyd Gottlieb  
*EMD Millipore Corp. 80 Ashby Rd., Bedford, MA 01730, USA Email: santosh.rahane@emdmillipore.com*

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### **Streamlined Quantification and Identification Analysis in Plasma Fractionation using Surface Plasmon Resonance**

Fredrik Sundberg\*, Åsa Frostell, Anna Mattsson, Åsa Eriksson, Elisabeth Wallby, Johan Kärnhall, Nina B. Illarionova, Camilla Estmer Nilsson  
*GE Healthcare Bio-Sciences AB, Björkgatan 30, SE-751 84 Uppsala, Sweden*

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### **Sensitive and Specific Measurement of Low Avidity Natural Occurring Immunoglobulin G Antibodies**

Andrea Engelmaier, Eva Minibeck, Alfred Weber\*  
*Shire, Vienna, Austria*

## Poster Session

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### **Establishment of a Competitive Enzyme-linked Immunosorbent Assay for the Measurement of Heparin in Plasma Products**

Andrea Engelmaier, Alfred Weber\*  
*Shire, Vienna, Austria*

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### **An Improved Fc Function Assay Incorporating CMV Antigen-coated Red Blood Cells Generated using the KODE Technology**

Thanae Malinas, Owen Tatford\* and Joe Bertolini  
*CSL Behring Australia Pty. Ltd., Broadmeadows, Australia*

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### **Removal of Isoagglutinins from IVIG and Plasma using Affinity Chromatography**

Bastiaan Lobbezoo, Lucy Pepperell, Patrick V. Gurgel\*, Steve Burton  
*Prometic Bioseparations Ltd.*



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## **Continuous Process Robustness Improvement with Regard to the Process Parameter pH– An Approach beyond DoE and QbD**

Harald Arno Butterweck  
*Shire*

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## **Removal of Isoagglutinins at Large Scale using an Innovative & Patented Oligosaccharides Production Process**

Bernard Mandard - Henri Sors  
*GlycoBAR - Meylan - France*

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## **Innovative Hydrophobic Interaction Chromatography (HIC) Resins for Next Generation Molecule Challenges**

Ingeborg van Gemeren \*1, Moira Lynch 2, Jinsong Liu 2, James Molinari 2, Dave Thomas 2, John Li 2, Kelly Flook 2, Andy Tomlinson 2 and Shelly Parra 2  
*1 Thermo Fisher Scientific J.H. Oortweg 21, Leiden, The Netherlands and 2 Thermo Fisher Scientific Bedford, MA, USA*

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## **Enabling Custom Solutions for Downstream Processing**

Ingeborg van Gemeren\*1, Pim Hermans1, Orjana Terova2, Jing Zhu2, Andy Tomlinson2  
*1 Thermo Fisher Scientific, J.H. Oortweg 21, Leiden, The Netherlands and 2 Thermo Fisher Scientific, 35 Wiggins Ave, Bedford MA, USA*

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## **Purification of Plasma Derived Proteins by Novel Column chromatography Resins**

Hironobu Shirataki  
*Asahi Kasei Medical, Tokyo, Japan*

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## **Robustness Studies for Albumin Fractionation Process Based on Design of Experiment (DoE)**

\*Seohyeon Kim, Hyojin Kim, Gunsul Lee, Taehyun Ban, Jaehak Seol, Sookwang Kim  
*Green Cross Corp., Yongin, Korea*

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## **Measles Neutralizing Antibodies in Patients Receiving IGIV**

Martyn Paddick\*, Vatsala Thirunavukkarasu, Sally Leung  
*Bio Products Laboratory Elstree UK*

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## **High Viscosity Tangential Flow Filtration (TFF) Applications in IgG**

Dana KinzImaier, Elizabeth Goodrich, \*Craig Jackson\*  
*Merck Life Science*