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Sunday, May 6, 2018

- 12:30 – 17:30 Conference Registration (Royal Palm Foyer)
- 15:00 – 15:15 **Opening Remarks**
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA
- Session 1: Views from the Younger Generation (and the Young at Heart)**
Session Chairs: Neil Templeton, Merck & Co., Inc, USA
Josh Leonard, Northwestern University, USA
Derrick Scott, Delaware State University, USA
- 15:15 – 15:20 **Introduction**
Neil Templeton, Merck & Co., Inc., USA
Josh Leonard, Northwestern University, USA
Derrick Scott, Delaware State University, USA
- 15:20 – 16:50 Short Poster Highlights
- 16:50 – 17:30 Break and Networking time
- 17:30 – 18:15 **Keynote**
The human protein atlas: Implications for human biology, drug development, and precision medicine.....1
Mathias Uhlén, KTH Royal Institute of Technology and Karolinska Institute, Sweden
- 18:30 – 20:30 Dinner (Key West Buffet in Commons Area)
- 20:30 – 22:30 **Poster Session** and Reception (*sponsored by MilliporeSigma*)
(Authors of even-numbered posters are asked to stay with their posters)
- Poster Chairs:
Anthony Grippe, Merck & Co., Inc., USA
Weiwei Hu, Celgene, USA
Devesh Radhakrishnan, BioMarin, USA
Nicholas Sandoval, Tulane University, USA

Monday, May 7, 2018

06:30 – 08:00 Breakfast
Organizing Committee Breakfast Meeting

08:00 – 08:10 **Opening Remarks**
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA

Session 2: Towards Other Cell Lines and Systems: Opportunities and Challenges Beyond CHO *(sponsored by Lonza)*

Session Chairs: Véronique Chotteau, KTH Royal Institute of Technology, Sweden
Rashmi Kshirsagar, Biogen, USA

08:20 – 08:45 **Moving Beyond CHO: Alternative host systems may be the future of biotherapeutics2**
Christina Alves, Biogen, USA

08:45 – 09:10 **Insect cell platforms for production of pseudo-typed VLPs for drug and vaccine development3**
Antonio Roldao, iBET - Instituto de Biologia Experimental e Tecnológica, Portugal

09:10 – 09:35 **Production of biopharmaceuticals in an intensified perfusion process of HEK 293 cells4**
Johan Rockberg, KTH Royal Institute of Technology, Sweden

09:35 – 10:00 **Beyond CHO cells: Cell-free protein synthesis for biotherapeutics5**
Bob Kiss, Sutro Biopharma, USA

10:00 – 10:30 Coffee Break

Session 3: Impact of Novel Gene Editing Approaches to Engineering and Developing Cell Lines *(sponsored by Genentech)*

Session Chairs: Kris Chan, Michigan State University, USA
Karin Anderson, Pfizer, USA

10:40 – 11:05 **Engineering CHO cells for the production of "Hard-To-Produce" proteins6**
Bjørn Voldborg, Technical University of Denmark, Denmark

11:05 – 11:30 **CRISPR/Cas9 mediated knockout of microRNAs for precise cell engineering7**
Kerstin Otte, University of Applied Sciences Biberach, Germany

11:30 – 11:55 **miR-CATCH identifies biologically active miRNA regulators of the pro-survival gene XIAP, in Chinese hamster ovary cells8**
Paul Kelly, National Institute for Bioprocessing Research and Training(NIBRT), Ireland

11:55 – 12:20 **Glycoengineering of CHO cells for production of recombinant therapeutics with enhanced efficacy20**
Zhiwei Song, A*STAR Bioprocessing Technology Institute, Singapore

Monday, May 7, 2018 (continued)

- 12:20 – 12:45 **Elimination of the “Essential” Warburg effect in CHO cells through a multiplex genome engineering strategy21**
Nate Lewis, University of California, San Diego, USA
- 12:45 – 14:00 Lunch
- 14:00 – 15:30 **Workshops (Four concurrent)**
- Increasing Speed to the Clinic and Market B** (Lagoon Pavilion)N/A
(Sponsored by Amgen and Bristol-Myers Squibb)
Facilitators: Kevin Smith (Janssen R&D), Matt Croughan (Keck Graduate Institute), Inn Yuk (Genentech)
- Advances and Challenges with Tech Transfer, Scale-up, and Comparability**
(Pegasus South)N/A
(Sponsored by Celgene, GE Healthcare and Novo Nordisk)
Facilitators: Anurag Khetan (BMS), Kara Calhoun (Genentech)
- Opportunities and challenges of adopting decades of cell culture knowledge for cell and gene therapy development** (Royal Palm East 1-3)N/A
(Sponsored by BioMarin, Gilead Sciences and Irvine Scientific)
Facilitators: Chapman Wright (Biogen), Amine Kamen (McGill University), John Pierciey (bluebird bio)
- How can interactions within the ‘biomanufacturing ecosystem’ deliver value?**
(Pegasus Ballroom East)N/A
(Sponsored by Janssen R&D and NIIMBL)
Facilitators: Tim Charlebois (Pfizer), Mike Betenbaugh (Johns Hopkins University)
- 15:30 – 16:00 Coffee Break
- Session 4: Regulatory Strategies and Concerns in Current and Emerging Therapies**
Session Chairs: Chris Frye, Eli Lilly, USA
 Bill Bentley, University of Maryland, USA
 Pranhitha Reddy, Gene-to-BLA, USA
- 16:05– 16:30 **Limitations of subcloning as a tool to characterize homogeneity of a cell population22**
Jennitte Stevens, Amgen, USA
- 16:30 – 16:55 **Registration enabling campaign for accelerated development: A PPQ strategy with minimal early investments to enable fast to market development for a promising monoclonal antibody23**
Jessica Wu, Genentech, USA
- 16:55 – 17:20 **Derivation of process control strategy for biosimilar: Is it different from the way a control strategy is derived for a novel biologic?24**
Dinesh Baskar, Biocon Research Limited, India
- 17:20 – 17:45 **Confronting the Analytical Challenges of Chimeric Antigen Receptor T Cell25**
Heidi Zhang, Juno Therapeutics, USA

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Large scale production and characterization of exosomes26
Konstantin Konstantinov, Codiak BioSciences, USA
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- 20:30 – 22:30 **Poster Session** and Reception (*sponsored by Roche and Solentim*)
(Authors of odd-numbered posters are asked to stay with their posters)

Tuesday, May 8, 2018

- 06:30 – 08:00 Breakfast
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- 08:00 – 08:05 **Opening Remarks**
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA
- 08:05 – 08:50 **Keynote**
Cell Culture Bioprocess Learnings: Past successes and future challenges27
Günter Jagschies, GE Healthcare Life Sciences, Germany
- Session 5: Pushing the Limits on Process Intensification: 10 g/L and Beyond**
Session Chairs: Greg Hiller, Pfizer, USA
Marcella Yu, Boehringer Ingelheim, USA
- 09:00 – 09:30 **Intensification of a multi-product perfusion platform – managing growth characteristics at high cell density for maximized volumetric productivity32**
Shawn Barrett, Sanofi, USA
- 09:30 – 10:00 **Evolution of TFF-based perfusion: A path towards non product sieving and direct chromatography integration33**
Nuno D. S. Pinto, Merck & Co., Inc., USA
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Laurel Zhang, Genentech, USA
- 11:00 – 11:30 **Development of a novel automated perfusion mini-bioreactor ambr® 250 perfusion.....35**
Barney Zoro, Sartorius, UK
- 11:30 – 12:00 **Intensified cell culture using a linked bioreactor system36**
Matthew Gagnon, Pfizer, USA
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Tuesday, May 8, 2018 (continued)

- 13:30 – 15:00 **Workshops (Four concurrent)**
- Increasing Global Access to Biotherapeutics: What Role Does Upstream Play?**
(Lagoon Pavilion)N/A
(Sponsored by Boehringer Ingelheim, MedImmune and Shire)
Facilitators: Brian Kelley (Vir), Jeff McGrew (Just Biotherapeutics)
- Advances in Cell Line Engineering and Protein Expression Strategies** (Pegasus South).....37
(Sponsored by Eli Lilly and Company and Merck and Co., Inc.)
Facilitators: Steven Lang (Genentech), Diane Hatton (MedImmune)
- Applications of ‘Omics Tools in Cell Culture** (Royal Palm East 1-3)N/A
(Sponsored by AbbVie and Biogen)
Facilitators: Mike Laird (Genentech), Nate Lewis (University of California, San Diego), Bhanu Mulukutla (Pfizer)
- PAT Implementation: Key Challenges and Opportunities** (Pegasus Ballroom East)N/A
(Sponsored by Eppendorf AG, GlaxoSmithKline and Sartorius Stedim Biotech)
Facilitators: Kelly Wiltberger (Biogen), Stephen Goldrick (University College London)
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CAR T Cell Therapy: Fifteen years of academic driving43
Isabelle Rivière, Memorial Sloan Kettering Cancer Center, USA
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Session Chairs: Greg Russotti, Celgene Corporation, USA
Eleftherios T Papoutsakis, University of Delaware, USA
- 16:25 – 16:50 **Engineered CAR T cell therapy for solid tumors**44
Juan F Vera, Center for Cell and Gene Therapy, Baylor College of Medicine, Texas Children’s Hospital, USA
- 16:50 – 17:15 **iPSC-derived neurospheroids recapitulate development and pathological signatures of human brain microenvironment**45
Catarina Brito, iBET - Instituto de Biologia Experimental e Tecnológica, Portugal
- 17:15 – 17:40 **Biomufacturing of platelet-like cells and cell microparticles for cell therapy applications**57
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Thomas Brieva, Celgene, USA
- 18:05 – 18:30 **Development of a large scale GMP compliant suspension cell culture system for the manufacturing of allogenic Exosome-based biotherapeutics**59
Scott Estes, Codiak BioSciences, USA
- 18:30 – 20:30 Dinner on your own

Tuesday, May 8, 2018 (continued)

20:30 – 22:30

Poster Session and Reception (*sponsored by Wuxi Biologics*)
(Authors of even-numbered posters are asked to stay with their posters)

Wednesday, May 9, 2018

06:30 – 08:00 Breakfast

11:00 – 12:00 Grab 'n Go lunches (in Foyer)

08:00 – 12:30 Networking Time

Session 7 - Process Scale Up/Down, Characterization and Control Strategy

Definition (sponsored by Kerry)

Session Chairs: Shailen Singh, Merck and Co., Inc., USA

Gary Lye, University College London, UK

12:35 – 13:00 **Probing lactate metabolism variations in large-scale bioreactors60**

Sen Xu, Merck and Co., Inc., USA

13:00 – 13:25 **Medium development strategies and scale down models for a high density high productivity cell line61**

Amy Johnson, Regeneron, USA

13:25 – 13:50 **Process scale up and characterization of an intensified perfusion process62**

Jiuyi Lu, Sanofi, USA

13:50 – 14:15 **Leveraging a technical partnership to deliver high titer biologics manufacturing63**

Haofan (Eric) Peng, Biogen, USA

14:15 – 14:40 **Efficient technology transfers to increase agility, flexibility, and productivity64**

Kara Calhoun, Genentech, USA

14:40 – 15:05 **Towards advanced understanding of scale-up: From computational fluid dynamics to systems biotechnology approaches65**

Jochen Schaub, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

15:05 – 15:45 **Martin Sinacore Award Lecture**

Understanding and improving cell culture processes through omics technologies.....66

Amanda Lewis, Bristol-Myers Squibb, USA

15:45 – 16:15 Coffee Break

Session 8: Computational Strategies to Enhance Bioprocess Performance

Session Chairs: Amanda Lewis, Bristol-Myers Squibb, USA

Colin Clarke, National Institute for Bioprocessing Research and

Training (NIBRT), Ireland

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Rashmi Kshirsagar, Biogen, USA

16:50 – 17:15 **Multivariate data analysis enabling improved clone selection68**

Stephen Goldrick, University College London/MedImmune, UK

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Ioscani Jimenez del Val, University College Dublin, Ireland

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- 17:40 – 18:05 **More accurate process understanding from process characterization studies using Monte Carlo simulation, regularized regression, and classification models70**
Cary Opel, Gilead Sciences, USA
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Tom Mistretta, Amgen, USA
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William M. Miller, Northwestern University, USA
- 19:00 – 20:30 Dinner (Poolside A)
- 20:30 – 22:30 **Poster Session** and Reception
(Authors of odd-numbered posters are asked to stay with their posters)

Thursday, May 10, 2018

06:30 – 08:00 Breakfast
Steering Committee Breakfast Meeting

08:00 – 08:05 **Opening Remarks**
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA

Session 9: Advanced Cell Culture Processes with an Emphasis on New Analytical and Computational Technology

Session Chairs: Arthi Narayanan, Genentech, USA
Cleo Kontoravdi, Imperial College London, UK

08:20 – 08:45 **Automated and enhanced clone screening using a fully automated microtiter plate-based system for suspension cell culture88**
Sven Markert, Roche Diagnostics GmbH, Germany

08:45 – 09:10 **Systems biology approach in the development of chemically-defined media for production of protein therapeutics in Chinese hamster ovary cells89**
Wai Lam Ling, Merck and Co., Inc., USA

09:10 – 09:35 **Feedback control of lactate using Raman spectroscopy90**
Peter Slade, Pfizer, USA

09:35 – 10:05 Coffee Break

10:05 – 10:30 **An energy-based modelling tool for culture medium design and biomanufacturing optimization91**
Athanasios Mantalaris, Imperial College London, UK

10:30 – 10:55 **Novel modeling methodology to predict product quality and cell culture performance in fed-batch and perfusion cultures92**
Bassem Ben Yahia, UCB Pharma S.A., Belgium

10:55 – 11:45 **Keynote**
From bioreactors for protein therapeutic production to bioreactors for testing efficacy and safety of protein therapeutics93
Linda Griffith, Massachusetts Institute of Technology, USA

11:45 – 13:15 Lunch

Session 10: Advances In Cell Culture Control of Product Quality Attributes

(sponsored by Regeneron Pharmaceuticals, Inc.)

Session Chairs: Martin Gawlitzek, Genentech, USA
Seongkyu Yoon, University of Massachusetts, Lowell, USA

13:20 – 13:45 **Tailoring antibody glycosylation via integrating genome and protein engineering to generate preferred glycoforms on the Fc region94**
Mike Betenbaugh, Johns Hopkins University, USA

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Michael Handlogten, MedImmune, USA
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Brian Mickus, Gilead Sciences, USA
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Wei-Shou Hu, University of Minnesota, USA
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Session Chairs: Weichang Zhou, WuXi Biologics, China
 Wei-Shou Hu, University of Minnesota, USA
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Peter Zandstra, University of British Columbia, Canada
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- 18:30 – 19:30 Reception
- 19:30 – 21:00 Banquet (Pegasus Ballroom)
(sponsored by Genentech)

Friday, May 11, 2018

06:30 – 10:00 Networking Breakfast and Departure

Poster Presentations

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