SESSIONS

DAY ONE: COMPLEX MOLECULES & MONOCLONALITY - 02/04/2019

Registration Opens

08:30 - 09:10

Chairperson's Opening Remarks

09:10 - 09:20

Overcoming the Challenges of Cell Line Development and Engineering for Difficult to Express Proteins

09:20 - 09:50
Cell Line Development for Novel Modalities and Difficult to Express Proteins

Participants

Kerensa Klottrup-Rees - Scientist II, Cell Culture and Fermentation Sciences, MedImmune

Cell Line Development Strategies for Bispecific and Multi-Specific Proteins

09:50 - 10:20
Cell Line Development for Novel Modalities and Difficult to Express Proteins

Participants

Valentina Ciccarone - Principal Scientist, Cell Line Development, MacroGenics, Inc.

Spotlight Presentation

10:20 - 10:50
Cell Line Development for Novel Modalities and Difficult to Express Proteins

Participants

A Representative from ALS , ALS

Morning Coffee Break

10:50 - 11:30
Cell Line Development for Novel Modalities and Difficult to Express Proteins

Process Development of a Biosimilar Project

11:30 - 12:00
Cell Line Development for Novel Modalities and Difficult to Express Proteins

Participants

Martin Bertschinger - Deputy Director Cell Sciences, Glenmark Pharmaceuticals SA.

High Titre Stable Suspension Lentiviral Vector Producer Cell Lines Using Bacterial Artificial Chromosome (BAC)

12:00 - 12:30
Cell Line Development for Novel Modalities and Difficult to Express Proteins

Lentiviral vectors are showing success as delivery vehicles for gene therapy, however, suppling sufficient quantities of clinical grade vectors remains challenging. To overcome some of the limitations of current 4 plasmids transient transfections GSK has established a technology to produce stable lentiviral vector producer cell lines from a single large BAC construct, and manufacture in suspension culture in large bioreactors.

Participants

Mark (Mao Xiang) Chen - Manager, Cell Line Development, Cell and Gene Therapy CMC,, GlaxoSmithKline R&D

Rapid HeLa based Producer Cell Line Development for Scalable rAAV Production

12:30 - 13:00
Cell Line Development for Novel Modalities and Difficult to Express Proteins

One challenge for cell line development in industry is to generate highly productive stable cell lines within the shortest time frame possible. This presentation will cover lessons learned over three years in establishing a robust, high throughput HeLa suspension screening platform to generate stable monoclonal producer cell lines suitable for Phase III clinical trial/commercial rAAV production.

Participants

Aubrey R Tiernan - Senior Scientist, Head of Cell Line Development, Ultragenyx Pharmaceuticals, Inc

Novel Approaches and Technology Implementation to Demonstrate Assurance of Clonality

13:00 - 13:30
Assuring and Proving Monoclonality

Participants

A Representative from Cytena - -, Cytena

Lunch

13:30 - 14:45
Assuring and Proving Monoclonality

Accelerating Cell Line Development using Transposase-Mediated Integration and Verified In-Situ Plate Seeding

14:45 - 15:15
Assuring and Proving Monoclonality

The Janssen R&D Cell Line Development group has partnered with ATUM to evaluate their transposase-mediated integration system, which allows us to generate higher producing transfection pools and limit the need for downstream screening. We have also partnered with Solentim to evaluate their Verified In-Situ Plate Seeding (VIPS) system, which allows us to seed and image single cells in microtiter plates to assure monoclonality in a single imaging step. These additions have resulted in a more efficient and accelerated cell line development process.

Participants

Angela Tuckowski - Associate Scientist, Janssen R&D Cell & Developability Sciences Group

Panel Discussion: Strategies to Evaluate and Improve Cell Line Stability

15:15 - 16:15
Evaluating and Predicting Cell Line Stability

- What things affect cell line and clone stability?
- How to use information on genome stability to produce more stable cell lines?
- Strategies to evaluate long term cell line stability
- Development of predictive models for cell line stability assessment in early stage development
- New technologies to predict clone stability

Opening of Exhibition Hall & Networking Drinks

16:15 - 17:45
Evaluating and Predicting Cell Line Stability

SCHEDULE

DAY ONE: COMPLEX MOLECULES & MONOCLONALITY - 02/04/2019

TIME	ASSURING AND PROVING MONOCLONALITY	CELL LINE DEVELOPMENT FOR NOVEL MODALITIES AND DIFFICULT TO EXPRESS PROTEINS	EVALUATING AND PREDICTING CELL LINE STABILITY
08:00	**08:30** - Registration Opens	**08:30** - Registration Opens	**08:30** - Registration Opens
09:00	**09:10** - Chairperson's Opening Remarks	**09:10** - Chairperson's Opening Remarks **09:20** - Overcoming the Challenges of Cell Line Development and Engineering for Difficult to Express Proteins **09:50** - Cell Line Development Strategies for Bispecific and Multi-Specific Proteins	**09:10** - Chairperson's Opening Remarks
10:00		**10:20** - Spotlight Presentation **10:50** - Morning Coffee Break	
11:00		**11:30** - Process Development of a Biosimilar Project	
12:00		**12:00** - High Titre Stable Suspension Lentiviral Vector Producer Cell Lines Using Bacterial Artificial Chromosome (BAC) **12:30** - Rapid HeLa based Producer Cell Line Development for Scalable rAAV Production	
13:00	**13:00** - Novel Approaches and Technology Implementation to Demonstrate Assurance of Clonality **13:30** - Lunch		
14:00	**14:45** - Accelerating Cell Line Development using Transposase-Mediated Integration and Verified In-Situ Plate Seeding		
15:00			**15:15** - Panel Discussion: Strategies to Evaluate and Improve Cell Line Stability
16:00			**16:15** - Opening of Exhibition Hall & Networking Drinks

SESSIONS

DAY TWO: ACCELERATION & AUTOMATION - 03/04/2019

Registration

07:30 - 08:50

Chairperson's Opening Remarks

08:50 - 09:00

Adapting Cell Line and Clone Selection Methods and Workflows for Continuous Manufacturing

09:00 - 09:30
Continuous Manufacturing Cell Line and Clone Selection Strategies

Participants

Christine DeMaria - Director, Cell Line Development, Sanofi

Streamlining Early Cell Line Development to Increase Speed and Efficiency

09:30 - 10:00
Accelerating Cell Line Development

Participants

Thomas Jostock, PhD - Science and Technology Lead / Principal Fellow, Novartis

Spotlight Presentation

10:00 - 10:30
Accelerating Cell Line Development

Participants

A Representative from Lonza - *, Lonza, Switzerland

Morning Coffee & Networking

10:30 - 11:30
Accelerating Cell Line Development

Case Study from Amgen: Accelerating Cell Line Development

11:30 - 12:00
Accelerating Cell Line Development

Participants

Christopher Tan - Scientist, Amgen

The BEST of Both Worlds – Targeted Integration and Multiple Copies: How Can This Go Together For Improved Cell Line Development?

12:00 - 12:30
Accelerating Cell Line Development

Targeted Hot Spot integration and multiplication of independent expression units – can this go together and even speed up cell line development? By targeting the Rosa26 Hot Spot in vitro we generated BAC-based expression vectors, which integrated in multiple copies into the CHO host cell chromatin and acted as independent expression units. This allowed us to adapt the selection process and developed long-term stable high-yield production cell lines at an unprecedented speed.

Participants

Anton Bauer - Senior Scientist, Medical University of Vienna

Spotlight Presentation

12:30 - 12:45
Accelerating Cell Line Development

Participants

A representative from Valitacell - -, Valitacell

Spotlight Presentation

12:45 - 13:00
Accelerating Cell Line Development

Participants

A Representative from Batavia Biosciences - -, Batavia Biosciences

Lunch In The Exhibition Hall

13:00 - 13:30
Accelerating Cell Line Development

Live Labs

13:30 - 14:15
Accelerating Cell Line Development

End-to-end Workflow Platform to Speed Up Cell Line Development at Highest Quality Standards

14:15 - 14:45
Accelerating Cell Line Development

We have developed an E2E platform that supports the entire bioprocess development workflow by automating cell line development and managing upstream process (USP), downstream process (DSP), analytical and formulation development. The system directly integrates with instruments and enables informed decision-making via its query and reporting infrastructure. We present efficiency and quality gains obtained using the cell line and upstream process development modules of the platform.

Participants

Christoph Freiberg - Senior Scientific Consultant, Biologics, Genedata

Reducing Cell Line Development Timelines and Increasing Speed to Clinic

14:45 - 15:15
Accelerating Cell Line Development

Participants

Eva Rubio-Marrero - Scientist I, CLD, Drug Substance-Biologics, Celgene Corp

Scalable, Helper Virus-Free AAV Production in Suspension

15:15 - 15:45
New Technologies for Faster and Easier Clone Production and Selection

CEVEC has developed a helper virus-free suspension AAV production platform on the basis of the CAP-GT cells. These human suspension cell lines grow to high density in serum free conditions and allow reproducible and high titer production of viral vectors. CEVEC's stable AAV packaging/producer cell lines enables a consistent quality production of AAV vectors that abolishes the need for transient transfection or helper-virus transduction.

Participants

Silke Wissing - Vice President R&D, CEVEC

Afternoon Coffee & Networking

15:45 - 16:15
New Technologies for Faster and Easier Clone Production and Selection

Making the Most Out of the Data Collected along the CLD Process

16:15 - 16:45
New Technologies for Faster and Easier Clone Production and Selection

High titers and good product quality are the key features a final production cell line needs to have. Besides many other quality attributes a consistent track record and data integrity are essential to launch the cell line for production. Furthermore, the availability of screening data during cell line development allows for fast analysis and the selection of the best clones. We will present Bayer's way for tracking and analysis of clone selection data.

Participants

Anke Mayer-Bartschmid, - Cell and Protein Sciences, Pharmaceuticals Division, , Bayer Pharma

Rapid Development of Cell Lines Suitable for Commercial Manufacturing

16:45 - 17:15
New Technologies for Faster and Easier Clone Production and Selection

Cell line development to support early phase clinical programs is often performed on rapid timelines, recognizing that it may be necessary to develop a new cell line to support commercialization if the programs advances to that stage. This presentation will focus on technologies and strategies that enable the most rapid development of an early phase cell line that is also suitable for commercial manufacturing (single cycle cell line development).

Participants

Martin Allen - Senior Director, Cell Line Development, Pfizer

KEYNOTE: Engineering Complex Traits in CHO Cells through Multiplex Genome Editing

17:15 - 17:45
New Technologies for Faster and Easier Clone Production and Selection

CHO remains the primary host cell for producing most biotherapeutics. However, there remain many traits that could be improved in the cells. Here, I will discuss recent work in our lab were we utilized systems biology approaches to identify genes to target for host cell engineering to improve cell line and bioprocess quality.

Participants

Nathan Lewis - Assistant Professor, University of California, San Diego

End of Conference Day Two and Evening Party

17:45 - 19:15

SCHEDULE

DAY TWO: ACCELERATION & AUTOMATION - 03/04/2019

TIME	ACCELERATING CELL LINE DEVELOPMENT	CONTINUOUS MANUFACTURING CELL LINE AND CLONE SELECTION STRATEGIES	NEW TECHNOLOGIES FOR FASTER AND EASIER CLONE PRODUCTION AND SELECTION
07:00	**07:30** - Registration	**07:30** - Registration	**07:30** - Registration
08:00	**08:50** - Chairperson's Opening Remarks	**08:50** - Chairperson's Opening Remarks	**08:50** - Chairperson's Opening Remarks
09:00	**09:30** - Streamlining Early Cell Line Development to Increase Speed and Efficiency	**09:00** - Adapting Cell Line and Clone Selection Methods and Workflows for Continuous Manufacturing	
10:00	**10:00** - Spotlight Presentation **10:30** - Morning Coffee & Networking		
11:00	**11:30** - Case Study from Amgen: Accelerating Cell Line Development		
12:00	**12:00** - The BEST of Both Worlds – Targeted Integration and Multiple Copies: How Can This Go Together For Improved Cell Line Development? **12:30** - Spotlight Presentation **12:45** - Spotlight Presentation		
13:00	**13:00** - Lunch In The Exhibition Hall **13:30** - Live Labs		
14:00	**14:15** - End-to-end Workflow Platform to Speed Up Cell Line Development at Highest Quality Standards **14:45** - Reducing Cell Line Development Timelines and Increasing Speed to Clinic		
15:00			**15:15** - Scalable, Helper Virus-Free AAV Production in Suspension **15:45** - Afternoon Coffee & Networking
16:00			**16:15** - Making the Most Out of the Data Collected along the CLD Process **16:45** - Rapid Development of Cell Lines Suitable for Commercial Manufacturing
17:00	**17:45** - End of Conference Day Two and Evening Party	**17:45** - End of Conference Day Two and Evening Party	**17:15** - KEYNOTE: Engineering Complex Traits in CHO Cells through Multiplex Genome Editing **17:45** - End of Conference Day Two and Evening Party

SESSIONS

DAY THREE: CELL LINE & HOST CELL ENGINEERING - 04/04/2019

Chairperson's Opening Remarks

08:20 - 08:30

Genome Scale Science For CHO: From Chasing The High Productivity Miracle Gene To Exquisite Phenotype Control

08:30 - 09:00
New Technologies: Cell Line and Host Cell Engineering

Traditionally in cell line development and engineering, there was a quest for individual genes which, if overexpressed or knocked out, would enhance performance, with very limited success. However, high level performance is more likely to be the result of the perfect combination of expression level of multiple genes. Today, with detailed knowledge of genomes, transcriptomes and the regulatory mechanisms that define the later, and with new tools available to manipulate these, the exquisite control of phenotypes starts to become a realistic target.

Participants

Nicole Borth - Professor, BOKU University and ACIB

Technology Toolbox for Cell Line Development

09:00 - 09:30
New Technologies: Cell Line and Host Cell Engineering

Chinese Hamster Ovary cells are widely used for large-scale production of recombinant biopharmaceuticals. We will present that applying transcriptomics derived approaches supported the identification of the root cause of cell growth inhibition and low productivity of a difficult to express therapeutic protein and how state of the art cell line engineering tools enabled the high expression of this therapeutic protein. Especially the combination of the recently published CHO genome with screening methods and cell line engineering tools has enabled the development of superior CHO cell lines.

Participants

Holger Laux - Fellow, Novartis Cell Line Develeopment

Spotlight Presentation

09:30 - 10:00
New Technologies: Cell Line and Host Cell Engineering

Morning Coffee & Poster Tour 1

10:00 - 10:45
New Technologies: Cell Line and Host Cell Engineering

Use of Circular RNAs as a Basis for Recombinant Protein Production

10:45 - 11:15
New Technologies: Cell Line and Host Cell Engineering

Participants

Niall Barron, PhD - Director, National Institute for Cellular Biotechnology

Application on CRISPR Cas9 to Accelerate Cell Line Development and Engineering

11:15 - 11:45
CRISPR and Genome Editing Technologies

If you are interested in presenting on this topic please contact: catherine.marshall@knect365.com

Spotlight Presentation

11:45 - 12:00
CRISPR and Genome Editing Technologies

Participants

A Representative from Polyplus - -, Polyplus

Novel Technologies for Cell Line Development and Engineering

12:00 - 12:15
CRISPR and Genome Editing Technologies

Participants

A Representative from Selexis - -, Selexis

Lunch and Live Labs

12:15 - 13:30
CRISPR and Genome Editing Technologies

Engineering Strategies to Suppress Viral Particle Release from CHO Cells

13:30 - 14:00
CRISPR and Genome Editing Technologies

CHO cells are known to express endogenous viral elements embedded in their genome, and to release retroviral-like particles in the culture supernatant. This complicates the detection of potential contamination by viral adventitious agents, and, despite the lack of evidence of infectivity of these particles, raises safety and regulatory concerns. Using Next generation sequencing approaches, we characterized several families of endogenous retroviral elements (ERVs) present in CHO-K1 cell genome. We focused on one highly conserved ERV group of the Gammaretrovirus gender, as it was potentially functional. Transcriptome and viral particle analysis validated the functionality of ERVs from this group, and it further indicated that the mRNA and viral genome may be expressed from few (approximately 3) ERV sequences. Using CRISPR-Cas9-mediated CHO genome engineering, we mutagenized the conserved ERV sequence group. Comparison of genomic and viral particle sequences allowed the identification of one ERV that encodes the viral genome of corresponding retroviral particles. We show that particular mutations within this ERV suffice to decrease the release of viral genome-loaded particles below detection limits.

Participants

Nicolas Mermod - Professor, Director, Institute of Biotechnology, University of Lausanne, Switzerland

SESSIONS

DAY THREE: CELL LINE & HOST CELL ENGINEERING - 04/04/2019

Characterizing Clone Performance: A Union of Structure and Sequencing

14:00 - 14:30
Omics and Big Data Integration in Cell Line Development and Engineering

- Higher order chromatin territories and chromatin features within CHOK1 chromosomes
- High resolution 3D FISH combined with nuclear architecture to characterize transgenic loci
- High resolution chromatin architecture interfaced with recombinant DNA
- Epigenetic characterization of transgenes
- Genetic characterization of clones using next-generation sequencing platforms
- Differences in rDNA integration between linear and integrase treated

The generation of a recombinant CHO lineage relies on the integration of a transgene into the donor genome, an approach which results in transgenic heterogeneity. Requirements for predictable transgene expression demands higher level knowledge of the interplay behaviour of recombinant DNA and the CHO genome. Here, we map higher level chromatin features to the CHO genome and develop a contiguous, CHO chromosome specific epigenome map. We also utilize super-resolution confocal microscopy and FISH to characterize the interplay of chromatin and chromatin territories with recombinant DNA. We utilize this data in conjunction with whole genome and transcriptome sequencing to predict clone performance.

Participants

Steven Huhn - Senior Scientist, Merck

Putting The Horse Before The Cart: Designing Gene Expression Constructs For CHO Cell Engineering

14:30 - 15:00
Systems and Synthetic Biology Applications

Manufacture of non-natural, engineered protein formats will require purpose-built designer cell factories. While a great deal of effort has been devoted to identifying target genes for CHO cell engineering, relatively little has been spent figuring out to optimally express them. This presentation discusses design rules for creating plasmid vectors encoding complex gene combinations, describing how genetic component compositions can be designed and configured in order to optimize the performance of engineered cell factories.

Participants

Adam Brown, Ph.D. - Lecturer of DNA Engineering, University of Sheffield

Spotlight Presentation

15:00 - 15:30
Systems and Synthetic Biology Applications

Participants

A Representative from Sartorius - -, Sartorius

Afternoon Coffee and Poster Tour 2

15:30 - 16:00
Systems and Synthetic Biology Applications

The Relevance Of Cell Size In A CHO Fed Batch Process: Metabolic And Transcriptomic Characterization

16:00 - 16:30
Systems and Synthetic Biology Applications

In a fed-batch process, using a commercially available media system a switch is observed from a cell proliferation phase to a phase where cell division is arrested and cell growth continues in the form of a threefold increase in cell size and dry weight. Metabolic flux and transcriptome analysis is applied to better understand the biological mechanisms associated with this switch.

Participants

Dirk E. Martens - Associate Professor, Bioprocess Engineering, Wageningen University

Panel Discussion: Integrating New Engineering and Cell Line Development Technologies into Established Workflows

16:30 - 17:00
Systems and Synthetic Biology Applications

- What new technologies have been adopted by industry and used routinely in cell line development?
- Success rates and realities of engineering tools? e.g. genomics, genome editing, CRISPR, NGS, targeted integration
- What is the industry status on CRISPR adoption?
- Are titres and timelines better with new technologies compared to standard approaches?
- Specific site integration vs. random integration: What is the impact on expression level and expression stability?
- What are the best, efficient and smart ways to use cell line engineering in a workflow?
- Where and how are industry incorporating new technologies and engineering for clinical and pipeline products when timelines are critical?
- Feasibility of cell line engineering: Are people doing customised cell line engineering for individual projects and is this feasible?
- Industry opinions on engineering: Engineer the host or look for replacements?

End of Cell Line Development & Engineering 2019

17:00 - 17:05

SCHEDULE

DAY THREE: CELL LINE & HOST CELL ENGINEERING - 04/04/2019

TIME	CRISPR AND GENOME EDITING TECHNOLOGIES	NEW TECHNOLOGIES: CELL LINE AND HOST CELL ENGINEERING	OMICS AND BIG DATA INTEGRATION IN CELL LINE DEVELOPMENT AND ENGINEERING	SYSTEMS AND SYNTHETIC BIOLOGY APPLICATIONS
08:00	**08:20** - Chairperson's Opening Remarks	**08:20** - Chairperson's Opening Remarks **08:30** - Genome Scale Science For CHO: From Chasing The High Productivity Miracle Gene To Exquisite Phenotype Control	**08:20** - Chairperson's Opening Remarks	**08:20** - Chairperson's Opening Remarks
09:00		**09:00** - Technology Toolbox for Cell Line Development **09:30** - Spotlight Presentation		
10:00		**10:00** - Morning Coffee & Poster Tour 1 **10:45** - Use of Circular RNAs as a Basis for Recombinant Protein Production		
11:00	**11:15** - Application on CRISPR Cas9 to Accelerate Cell Line Development and Engineering **11:45** - Spotlight Presentation			
12:00	**12:00** - Novel Technologies for Cell Line Development and Engineering **12:15** - Lunch and Live Labs			
13:00	**13:30** - Engineering Strategies to Suppress Viral Particle Release from CHO Cells			
14:00			**14:00** - Characterizing Clone Performance: A Union of Structure and Sequencing	**14:30** - Putting The Horse Before The Cart: Designing Gene Expression Constructs For CHO Cell Engineering
15:00				**15:00** - Spotlight Presentation **15:30** - Afternoon Coffee and Poster Tour 2

SCHEDULE

DAY THREE: CELL LINE & HOST CELL ENGINEERING - 04/04/2019

TIME	CRISPR AND GENOME EDITING TECHNOLOGIES	NEW TECHNOLOGIES: CELL LINE AND HOST CELL ENGINEERING	OMICS AND BIG DATA INTEGRATION IN CELL LINE DEVELOPMENT AND ENGINEERING	SYSTEMS AND SYNTHETIC BIOLOGY APPLICATIONS
16:00				**16:00** - The Relevance Of Cell Size In A CHO Fed Batch Process: Metabolic And Transcriptomic Characterization **16:30** - Panel Discussion: Integrating New Engineering and Cell Line Development Technologies into Established Workflows
17:00	**17:00** - End of Cell Line Development & Engineering 2019	**17:00** - End of Cell Line Development & Engineering 2019	**17:00** - End of Cell Line Development & Engineering 2019	**17:00** - End of Cell Line Development & Engineering 2019