

A JOURNEY INTO THE NEW AGE OF ADVANCED THERAPY MEDICINES

CELL + GENE THERAPY FOCUSED FULL DAY CLASS

APRIL 25, 2019 | GILEAD SCIENCES | OCEANSIDE, CALIFORNIA

EVENT REGISTRATION INFORMATION AVAILABLE ONLINE AT
WWW.ATDEVENTS.NET



Lei Shi
Vice President, Global Manufacturing

KITE PHARMA

Xiao-Ping Dai, PhD
VP, C> Process Development

WUXI ADVANCED THERAPIES



Peter Walters
ATMP Subject Matter Expert

CRB



Joan Habb
Site Head, Gene Therapy Operations

MILLIPORESIGMA



Emilie Pellitier
USA Managing Partner

LAPORTE CONSULTANTS



Erin Rasch, MS
Senior Director

BE THE MATCH BIOTHERAPIES



PANEL DISCUSSION

Moderator: Noel Maestre, Biotech Team Lead, CRB

Leo Castaneda, President/CEO, AES, Ken Rando, Clinical Team Leader, BioSpherix Medical, Fred Koller, Executive VP, Miltenyi Biotec, Eytan Abraham, VP of Personalized Medicine, Lonza



ISPE San Diego Chapter

A Journey into the New Age of Advanced Therapy Medicines: Cell and Gene Therapy Full Day Class

Thursday, April 25, 2019
7:00 am - 6:00 pm

Sponsored By:



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Location:

Gilead Sciences, Inc., Building B600, 4100 Avenida De La Plata, Oceanside, CA 92056

Synopsis:

The way we deliver medicine is changing faster than ever before. With more than 900 Advanced Therapy Medicinal Products (ATMP) companies worldwide innovating new products, this wave of personalized medicine is about to make landfall and disrupt an industry built on mass production and scale-up capabilities. This forum will share real time information about what's going on in the industry, including the latest technologies, standards, industry guidelines, and case studies of those leading the way in this space.

Target audience:

All Levels. Whether you are new to the industry and want to gain an understanding of ATMPs, or a seasoned professional, this will be an exciting forum with the latest information on this very hot topic.

Program Facilitator: Dr. Anthony Davies, Founder & CEO, Dark Horse Consulting Inc.

Program Manager: Nicki Lange, Director of Business Development, CRB

Speakers:

Lei Shi, VP Global Manufacturing, Kite Pharma, a Gilead

Xiao-Ping Dai, PhD, VP, C> Process Development, Chief Technologist, WuXi Advanced Therapies

Joan Haab, Site Head, Gene Therapy Operations, MilliporeSigma

Peter Walters, ATMP Subject Matter Expert, CRB

Emilie Pelletier, USA Managing Partner, LAPORTE Consultants Corp

Erin Rasch, MS, Senior Director, Be The Match BioTherapies®

Panelists:

Noel Maestre, Biotech Team Lead, CRB (Moderator)

Leo Castaneda, President/CEO, AES (Automation Engineering Systems)

Ken Rando, Director of Business Development, BioSpherix Medical

Fred Koller, Executive VP, Miltenyi Biotec

Eytan Abraham, VP of Personalized Medicine, Lonza

David Keggan, Sales Engineer, Comecer

Additional Sponsorships Available!

A Journey into the New Age of Advanced Therapy Medicines: Cell and Gene Therapy Full Day Class

Thursday, April 25, 2019

Working Schedule:

7:00-8:00AM Registration / Networking and Continental Breakfast

**8:00-8:30AM Advanced Therapy Medicinal Products (ATMP) Overview
Peter Walters, ATMP Subject Matter Expert, CRB**

This discussion will provide a basic overview of current technologies and a look ahead in the marketplace.

Takeaways:

- Define ATMP types - gene therapy, cell therapy, regenerative therapy, and genetically modified cell therapy
- Overview of the global landscape and progress for ATMPs
- Regulatory / Guidance primer specific to ATMPs
- Submarket manufacturing considerations and challenges faced by the industry

**8:30-9:30AM Case Study: Yescarta - Insights and Challenges in Commercializing a Personalized Cell Therapy Product
Lei Shi, VP Global Manufacturing, Kite Pharma, a Gilead Company**

YESCARTA™ is a First-in-Class, CD19-directed genetically modified autologous T cell immunotherapy with a CD3ζ/CD28-based signaling that recognizes and eliminates CD19-expressing cells on normal and malignant cells. Recently published 2 year data demonstrated an overall response rate of 83 percent, with 58% of patients having achieved a complete response after a single infusion in Refractory Large B-Cell Lymphoma setting. Commercialization of YESCARTA™ met many unprecedented challenges not faced in traditional pharmaceutical operations such as unique starting material per patient, requiring continuous processing to shorten the lead time, establishing make-to-order supply chain, expanded quality system from vein-to vein, and offering business solutions for health center and patient for easy access. Kite is able to achieve a cycle time of 16-18 days from apheresis to product infusion. Kite is now focusing on the next generation of cell therapy technology platforms and process automation to support a growing pipeline.

**9:30-10:30AM Case Study: WuXi - Innovating Advanced Therapies Through Technology Development
Xiao-Ping Dai, PhD, VP, Cell & Gene Therapy Process, Chief Technologist, WuXi Advanced Therapies**

Translating genomic insights into innovative advanced therapies is one of our greatest opportunities to dramatically improve patients' lives. In this talk, we will discuss our recent technical advancement on cell and gene therapies. From Leukapheresis to diverse cell therapy treatments, and from transduction to suspension culture of HEK293 cells to produce viral vector, a series of progress were implemented to advance our platform development.

Takeaways:

- Process development for robust scale up or scale out
- The importance of cell lines for suspension culture
- The importance of closing process and automation in cell therapy process

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A Journey into the New Age of Advanced Therapy Medicines: Cell and Gene Therapy Full Day Class **Thursday, April 25, 2019**

Working Schedule:

10:30-10:45AM BREAK

10:45AM-Noon PANEL DISCUSSION: Closing Down the Process - The Future of Cell and Gene Therapy Manufacturing

Moderators: Noel Maestre, Biotech Team Lead, CRB

Dr. Anthony Davies, Founder & CEO, Dark Horse Consulting Inc.

Panelists: Leo Castaneda, President/CEO, AES (Automation Engineering Systems)

Ken Rando, Director of Business Development, BioSpherix Medical

Fred Koller, Executive VP, Miltenyi Biotec

Eytan Abraham, VP of Personalized Medicine, Lonza

David Keggan, Sales Engineer, Comecer

Automating a production process reduces cost, reduces risk, decreases implementation time, and maintains flexibility. The race to effectively design the “closed” process for ATMP production and increasing automation to ultimately increase product quality and reduce or eliminate the human-error factor for patients is ongoing. In a panel format, hear from industry vendors about the challenges and hurdles that they have discovered in the process, and how they are solving these challenges.

Noon-1:00PM LUNCH

1:00-2:00 pm “Millipore Sigma Viral Vector Manufacturing: Path to Commercialization”

Joan Haab, Site Head, Gene Therapy Operations, MilliporeSigma

As the only viral vector contract manufacturing organization with multiple products approved for commercial sale, Millipore Sigma has a unique perspective on the path to regulatory approval & commercial production. In this talk, we'll focus on some of the key lessons learned and our strategy for supporting out customers as they progress down this path. We'll discuss the use of a risk management approach to successfully prepare for pre-license inspections as well as ongoing GMP production, including utilizing a phase gate process to ensure comprehensive decision-making around requirements and prerequisites for all stages of development.

2:00 - 2:45PM Dark Horse Consulting – more information coming

2:45-3:00PM BREAK

3:00-4:15PM Cell and Gene Therapy Lab to GMP Production Workshop

Emilie Pelletier, USA Managing Partner, LAPORTE Consultants Corp

In this workshop session, participants will learn how a lab scale cell therapy process can be scaled-up to CGMP manufacturing. Participants will break into small groups of and each group will be given product information, a lab scale process description, and a volume of dose per year for CGMP product production. Each team will create the identified high-level deliverables that are typically required from a user requirements perspective. A short presentation will be given by the session leaders on each topic before the teams break-out to work on the deliverables. Each team will present to the group what they have developed. Whole group discussions will be encouraged.

4:15-4:45PM Techniques for Navigating the Cell Therapy Supply Chain When Exceptions are the Norm

Erin Rasch, MS, Senior Director, Be The Match BioTherapies®

With the introduction of many new cell and gene therapies to market, commercial strategies for supply chain management remain critical to the successful delivery of these therapies to patients in need. In this session, hear evidence-based strategies for mitigating risk throughout the cell therapy supply chain and how key systems and processes, including ongoing training, dedicated patient and therapy management staff, and the support of end-to-end supply chain management software can build efficiencies and help to ensure successful product delivery. Additional discussion will focus on the importance of implementing standardized processes across the industry to minimize the burden on the cell therapy infrastructure and support the increased demand for cell therapy clinical trials and the projected advancement to commercialization.

4:45-6:00PM Networking Happy Hour with Appetizers



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Registration Instructions
A Journey into the New Age of
Advanced Therapy Medicines: *Cell and Gene Therapy Full Day Class*
Thursday, April 25, 2019

Sponsorships Available

To Register and Receive an immediate receipt, use our on-line registration: <http://atdevents.net/register.php>

ISPE LA, SD, SF Members: If you are an ISPE Member in California, please do not set up a new account, you should already be in our system. Please email Rob Fleming for assistance with your username and/or password.

ISPE Members of other Chapters: You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below. To update your account to a Member account, please forward your confirmation email from ISPE or ISPE Membership Card to Rob Fleming. We need your Chapter name, your ISPE Member number and expiration date. You can get your Membership card once logged onto the ISPE website (see bottom left side of the screen).

Non Members: If you do not have an account on our system, you can set one up on the site using letters (not numbers) as your username.

****Students:** The Student Rate is for individuals who are enrolled full time in a related academic program at an accredited institution. The Student Rate does not apply to working professionals taking one or two courses on the side. To verify your status as a student, we may ask you to supply your student ID and copy of current class schedule. Final eligibility determined by ISPE SD.

Registrations can also be faxed. Complete the form and fax to 949-266-8461.

If paying by check, please mail your check made payable to: ISPE San Diego Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612. Tel: 949-387-9046. Tax ID#33-0551783.

Registration Fee Includes lunch and free parking

\$250 ISPE Member

\$315 Non-Member

\$50 Student

Sponsors \$500 (includes one attendee)

Note: If you are between jobs or your company does not support your registration fees, please contact Kimberly Syre (ksyre@cox.net) for reduced fee options or sponsorship opportunities.

Registration or Online Questions? Contact Rob Fleming: rob.fleming@yahoo.com
Name Badges will be given at the event.

Cancellations must be received via email to: rob.fleming@yahoo.com by April 15, 2019 for refund. After the cancellation date if you have reserved a space but do not attend, your payment **MUST** be remitted, however, an alternate person may attend in your place. If the alternate is not a member, they will need to pay the additional amount for non-members. Name badges will be given at the on-site registration desk.



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Registration Form

A Journey into the New Age of

Advanced Therapy Medicines: Cell and Gene Therapy Full Day Class
Thursday, April 25, 2019

REGISTRATION RATES

_____ \$250 ISPE Members

_____ \$315 Non-Members

_____ ~~Free~~ *Free for First 10 Gilead Employees **SOLD OUT**

_____ \$50 *Gilead Employees (after first 10)

_____ \$100 ISPE YP (Young Professional) Members

_____ \$50 Students Student Members

_____ \$500 Sponsors (includes a table top at the meeting and one attendee)
Additional attendees can attend at the ISPE Member rate

Please list the name of your attendee: _____

*** Special rates for Gilead Employees does not extend to contractors working at the company.**

CREDIT CARD PAYMENT - Please Indicate Type of Credit Card

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Company: _____

Address: _____

City: _____ State: _____ Zip: _____

E-Mail: _____

Phone: _____ Cell: _____

Driving Directions:

Gilead Sciences, Inc. - Building B600

4100 Avenida de la Plata, Oceanside, CA 92056

From San Diego

Take Interstate I-5 North.

Exit at Hwy CA-78 East.

Exit at El Camino Real.

Turn left/North (over the freeway).

Make a right on Oceanside Blvd.

Make a left on Corporate Centre Drive.

Turn right onto Avenida de la Plata.

Head to 4100 Avenida de la Plata.

From Los Angeles

Take Interstate I-405 South toward Long Beach.

Merge onto I-5 South.

Merge onto CA-78 East.

Exit at El Camino Real.

Turn left/North (over the freeway).

Make a right on Oceanside Blvd.

Make a left on Corporate Centre Drive.

Turn right onto Avenida de la Plata.

Head to 4100 Avenida de la Plata.

It is recommended that you look up directions from your starting point to make sure you have the best driving directions.