ISPE San Diego Chapter

Advanced Therapy Medicinal Products Forum

Cell and Gene Therapy Focused

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

Sponsored By:

Location: Gilead Sciences, Inc., Building 600, 4100 Avenida de la Plata, Oceanside, CA 92056

Synopsis: The way we deliver medicine is changing faster than ever before. With more than 900 ATMP companies worldwide innovating new products, this wave of personalized medicine is about to make landfall and disrupt an industry built on mass 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 Advanced Therapy Medicinal Products (ATMP), or a seasoned professional, this will be an exciting forum with the latest information available on this very hot topic.

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

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

Speakers:
- Xiao-Ping Dai, PhD, VP, Cell and Gene Therapy Process Development, Chief Technologist WuXi Advanced Therapies
- Daniel Pratt, Director of Engineering and PM, Technical Operations, Takeda Pharmaceuticals
- Erin Rasch, MS, Senior Director, Be The Match BioTherapies®
- Lei Shi, VP, Global Manufacturing, Kite Pharma (a Gilead Company)
- Peter Walters, Process Engineer, ATMP Subject Matter Expert, CRB
- TBD – Dark Horse Consulting

Panelists:
- Noel Maestre, Biotech Team Lead, CRB (Moderator)
- Leo Castaneda, President/CEO, AES (Automation Engineering Systems)
- Ken Rando, Clinical Team Leader, BioSpherix Medical

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Advanced Therapy Medicinal Products Forum:
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Morning Schedule:

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

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

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

Lessons Learned:
• 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

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

Lessons Learned:
• 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

10:30-10:45AM  BREAK

10:45AM-Noon  PANEL DISCUSSION: Closing Down the Process - The Future of Cell and Gene Therapy Manufacturing
Moderator: Noel Maestre, Biotech Team Lead, CRB
Panelists: Leo Castaneda, President/CEO, AES (Automation Engineering Systems)
Ken Rando, Clinical Team Leader, BioSpherix Medical
TBD - Comecer
Additional Panelists TBA

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
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Afternoon Schedule:

1:00-2:00PM  TBD

2:00-2:45PM  Dark Horse Consulting - Speaker TBD

2:45-3:00PM  BREAK

3:00-4:15PM  Cell and Gene Therapy Lab to GMP Production Workshop
  Daniel Pratt, Director of Engineering and PM, Technical Operations, Takeda Pharmaceuticals

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®

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

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
Any other Questions, Contact Kimberly Syre: ksyre@cox.net
Name Badges will be given at the event.

Cancellations must be received via email to: rob.fleming@yahoo.com by April 18 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.
# Registration Form

## Advanced Therapy Medicinal Products Forum: *Cell and Gene Therapy Focused*

**Thursday, April 25, 2019**

### REGISTRATION RATES

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<th>Description</th>
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<tr>
<td>$250</td>
<td>ISPE Members</td>
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<td>$315</td>
<td>Non-Members</td>
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<td>Free</td>
<td>*Free for First 10 Gilead Employees</td>
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<td>*Gilead Employees (after first 10)</td>
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<td>ISPE YP (Young Professional) Members</td>
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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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Credit Card #: ____________________________ Exp Date: _________

### YOUR CONTACT INFORMATION:

First and Last Name: ____________________________________________

Title: ____________________________________________

Company: ____________________________________________

Address: ____________________________________________

City: ____________________________________________ State: _____ Zip: ______

E-Mail: ____________________________________________

Phone: ____________________________________________ Cell: __________________
Driving Directions:

Gilead Sciences, Inc. - Building 600

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.
Make a right into the Gilead parking lot at 4049 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.
Make a right into the Gilead parking lot at 4049 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.