



# THE EVOLUTION OF IMMUNOTHERAPY

FROM DEVELOPMENT TO UTILIZATION

SEPTEMBER 18, 2019  
4-7PM

Hosted by Dendreon in Seal Beach  
Includes Tour of Dendreon

At



**SPEAKERS:**

**Bruce Johnson, Site Director, Dendreon**

**Will Junker, Sr. Director Quality Engineering, Kite Pharma, Inc.**

**Nadeem Sheikh, PhD, VP Research & Manufacturing Sciences  
Dendreon**

**Christina Yi, Chief Operations Officer, Dendreon**

<http://atdevents.net/register.php>





**ISPE**®

Greater Los Angeles  
Area Chapter

# Cell & Gene Therapy

The Evolution of Immunotherapy From Development to Utilization by Dendreon  
Lessons Learned Yescarta by Kite Pharma

Wednesday, September 18, 2019  
4:00 – 7:00 pm

Registration Limited to 70 Attendees  
Sponsorships Available

Location: Dendreon, 1700 Saturn Way, Seal Beach, CA 90740

Host: Bruce Johnson, Site Director, Dendreon

**Speakers:**

Bruce Johnson, Site Director, Dendreon  
Will Junker, Sr. Director Quality Engineering, Kite Pharma, Inc  
Nadeem Sheikh, PhD, Vice President Research & Manufacturing Sciences, Dendreon  
Christina Yi, Chief Operations Officer, Dendreon

**Program Managers:**

Paul Crissman, Principal, Biotechnical Solutions  
Merritt Postma, Director Western Region, SKAN US

**Schedule and Topics:**

- 4:00 – 4:45pm Registration and Networking with Appetizers
- 4:45 – 5:15 pm The Evolution of Immunotherapy – from Development to Utilization  
Dendreon Presentation on their flagship product, PROVENGE, a unique kind of cancer immunotherapy
- 5:15 – 5:45 pm Lessons Learned Yescarta by Kite Pharma
- 5:45 – 6:00 pm Q&A
- 6:00 – 7:00 pm Tour of Dendreon

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## About the Speakers

### **Bruce Johnson, Site Director, Dendreon**

An accomplished leader, Bruce has more than 25 years of experience defining and implementing world-class manufacturing (biologics and biotech) strategies that support business success. As head of Dendreon's West Coast Immunotherapy Manufacturing Facility (IMF), Bruce leads a high-performing team of 125 and is accountable for manufacturing operations at the 180,000 facility, which produces the world's first autologous active cellular therapy (personalized medicine) for the treatment of advanced prostate cancer. Equally versed in clinical and commercial GMP environments, Bruce's core competencies include: manufacturing, supply chain, engineering and facilities management. He also is technically skilled in the areas of protein fermentation / purification, sterilization, employee health & safety, and business continuity / risk management protocols.

### **Will Junker, Sr. Director Quality Engineering, Kite Pharma, Inc.**

Will Junker is a biotechnology and pharmaceutical leader with a career spanning 33+ years. He started this career at Aventis in Frankfurt, Germany supporting their Insulin franchise for 15 years with process development, new facility design, process automation and all areas of validation. Upon migration to the US, Will managed computer validation for Baxter's BioScience division in Southern California before moving to the East Coast. For over 12 years with MedImmune/AstraZeneca he served in various leadership roles like site validation, corporate validation, new facilities design, construction and CQV, process/facility automation and IT. At Kite since 2017, Will is building a global QE function to serve as technical core of quality and drive next generation quality concept introduction.

A member of ASQ, ISPE and PDA, he holds an advanced degree in Chemical Engineering from the University of Applied Sciences in Darmstadt, Germany.

### **Nadeem Sheikh, PhD, Vice President of Research & Manufacturing Sciences, Dendreon**

Nadeem heads Research & Manufacturing Sciences (R&MS), which represents the biologic and scientific foundation for Dendreon. R&MS maintains the scientific integrity of Dendreon's active cellular immunotherapy platform, furthering its development and generating and analyzing clinical data to strengthen the therapeutic understanding of PROVENGE: Analytical Sciences, Antigen Sciences, Biometrics, Clinical Affairs, Clinical Immunology, Process Sciences, and Process monitoring.

After working on therapeutic vaccine approaches for malaria and HIV, Nadeem joined Dendreon in 2004 as a scientist in the vaccine development group to work on sipuleucel-T, an innovative cell-based cancer immunotherapy for prostate cancer that would eventually become PROVENGE® (sipuleucel-T). He worked on CMC (chemistry, manufacturing and controls) aspects, a critically important process in drug development. Nadeem and the vaccine process team outlined the manufacturing steps and ensured control of the product every step of the way – from receipt of the cell collection (or leukapheresis) to final PROVENGE product. As a cellular immunologist, Nadeem has an extensive publication record in the immunology and mechanisms of action of adjuvants and vaccines; this knowledge has been applied to studies by R&MS demonstrating the immunological basis for the efficacy of sipuleucel-T.

### **Christina Yi, Chief Operations Officer, Dendreon**

With more than 20 years of industry experience, Christina has a proven track record of success across various aspects of pharmaceutical operations. Leveraging modern operational approaches and data to deliver consistent, high-impact results, she has successfully brought innovative products to market through strategic planning, efficient process design and regulatory compliance. At Dendreon, Christina is responsible for manufacturing, quality, sourcing and procurement, technical operations, apheresis operations and project management.



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**Cell & Gene Therapy**  
**Wednesday, September 18, 2019**  
**REGISTRATION FORM and INSTRUCTIONS**

For an immediate receipt, please use the Chapter's online processing system: <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, as 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 ([rob.fleming@yahoo.com](mailto:rob.fleming@yahoo.com)). We need your Chapter name, your ISPE Member number and expiration date. You can get your Membership card once logged onto the ISPE website. (Go to "Account/My Account" then "Print Your Membership Card" on left side of the screen towards the bottom).

**Non Members:** If you do not have an account on our system, you can set one up on the site using all letters (no numbers) for your username.

**Fax Registration:** Complete the Registration Form with a credit card payment and Fax to (949) 266-8461.

**Pay by Check:** If paying by check, please register online to hold your spot. Then mail your check no later than one week prior to the meeting to ensure it is received in time. **Make checks payable to:** ISPE Greater Los Angeles Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612. Tax ID#95-4452996.

**Registration Help, setting up your account, having problems with online registration, need to reset your password, questions regarding registration or receipts? Email Rob Fleming ([rob.fleming@yahoo.com](mailto:rob.fleming@yahoo.com)).**

*Cancellations must be received in writing via fax or email to Rob Fleming by September 10, 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 event.**

- \_\_\_\_\_ \$85 ISPE Members      \_\_\_\_\_ \$115 Non-Members      \_\_\_\_\_ \$50 YP Members
- \_\_\_\_\_ Free ISPE Student Members (Help at Registration table and during the event is Required)
- \_\_\_\_\_ Free for first 20 Dendreon Employees (does not apply to contractors working at the site, presenters not included in 20)
- \_\_\_\_\_ \$40 Government, Non ISPE Students and Additional Dendreon Employees
- \_\_\_\_\_ \$500 Event Sponsor (includes table at event and 2 attendees)

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## **Driving Directions and Check In Instructions**

### **Dendreon**

1700 Saturn Way, Seal Beach, CA 90740

### **From LAX**

Take 405 Freeway South.

Exit at Seal Beach Blvd.

Turn Left onto Seal Beach Blvd.

Turn Right onto Apollo Dr.

Apollo Dr. turns left and becomes Saturn Way.

Dendreon will be on the Right Hand Side.

### **From San Diego**

Take 5 Freeway North to 405 Freeway North.

Exit at Westminster Ave. W. and merge onto Westminster Blvd.

Turn Left onto Seal Beach Blvd.

Turn Right onto Apollo Dr.

Apollo Dr. turns left and becomes Saturn Way.

Dendreon will be on the Right Hand Side.

### **Check In**

Please park in a Visitors or Employee parking spot.

Go to the main entrance to check in.

*Please look up driving directions from your own starting point.*