PROGRAM ANNOUNCEMENT

Wednesday, 18 September 2019

Monthly Program

Global Trends in Clinical Drug Development: Fast to Market in the US and China

Program Speaker:

Lei Zhang, Ph.D.,
VP of Global Clinical Development & Operations and Regulatory Affairs, Zensun USA, Inc.

Event Agenda:

Date: **Wednesday, 18 September 2019**

Time*:

5:15 – 6:00 PM	Registration, Snacks, & Networking
6:00 – 6:05 PM	Welcome and Announcements
6:05 – 7:05 PM	Program Presentation
7:05 – 7:30 PM	Q & A

*Times are approximate.

Program Topic:

It has become a global mission to control costs, improve efficiency, and successfully bring more life-saving & life-changing drugs to market. How much progress has been made? How do we continue to accomplish this mission? How do we get the drug to market faster? How do we make therapy more affordable for patients? Where are the opportunities? To answer these questions, this presentation will first take you on a quick journey to the US and China to see the remarkable progress achieved through a series of reforms in the last four years. Then, it will provide a top-down view on how to leverage regulations in both countries to shorten the time to market (e.g., parallel IND or NDA application, international multicenter clinical trial). The presentation will also discuss key factors impacting clinical drug development beyond regulatory submission, point out barriers to clinical trials, and share practical strategies and solutions.

Highlights for the US will cover:

- Drug approvals in 2018
- Acceleration in the gene therapy sector
- Disease specific guidance documents for gene therapy

Highlights for China will cover:

- China's reform of the regulatory system for medical products
- Exponential growth in new approvals
- How China's activities can be effectively integrated into the global drug development program for faster time to market.

Speaker Biography:

Dr. Lei Zhang has 24 years of experience spanning across the biotech/biopharma, medical device, and diagnostic industries. Her breadth and depth of expertise globally in both clinical and regulatory spaces include drugs, biologics, IVDs, cell & gene therapies, cancer vaccines, and combination products. She has contributed to both pre- and post-market regulatory submissions in the US (CDER, CBER, CDRH), EU, and China.

Dr. Zhang currently serves as VP of Global Clinical Development & Operations and Regulatory Affairs at Zensun USA, overseeing the clinical and regulatory programs for a 'first-in-class' biologic compound (Neucardin) in late stage clinical development. Prior to Zensun, Dr. Zhang held various management positions in clinical & medical affairs and drug delivery development at Alere (now Abbott), Inovio Pharmaceutics, Halozyme Therapeutics, and Cytori Therapeutics.

Dr. Zhang received a B.S. from Nankai Univ. and a M.S. from Beijing Medical Univ.; a Ph.D. in Biophysics from Friedrich-Shiller Univ. in Germany; completed her postdoctoral research in Neuroscience at the Massachusetts Institute of Technology (MIT). Dr. Zhang has 30+ peer-reviewed publications, is a co-inventor of 20+ patents and has given over 20 invited podium presentations at multidisciplinary international conferences. Dr. Zhang was the Board Director and VP of Programs SDRAN in 2016 & 2017; served as a co-Chair of Medical Device & Diagnostics Committee for Sino-America Biotechnology and Pharmaceutical Professional Association (SABPA) from 2014 to 2016.

Location: Hologic Inc.
10210 Genetic Center Drive
San Diego, CA 92121

To register for the meeting, click here to access the SDRAN registration system (123Signup) for this event.

* **Please make your reservation early. The pre-registration due date is *Monday, 16 September 2019*. Advanced registration is appreciated to assist in event planning.**

** ***Space is limited for our monthly programs. Registration is capped at 100 participants. Register today to ensure your seat. Once our limit is reached, registration will close. Events with closed registration will not allow walk-ins.***

Online registration (through Monday 16 September 2019):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@SDRAN.org

Directions to Hologic:

From the North I-5 and I-805

I-5 South toward San Diego
Exit toward I-805 S
Exit toward Mira Mesa Blvd
Turn left onto Sequence Dr
Turn right to the facility

From the South I-805

I-805 North toward Sorrento Valley
Exit toward Mira Mesa Blvd
Turn left onto Sequence Dr
Turn right to the facility