



PROGRAM ANNOUNCEMENT

Wednesday, 19 June 2019

Monthly Program

Using Legos and Pyramids to Explain Biosimilars: Updates, Challenges and Opportunities

Program Speaker:

Hubert C. Chen, MD

Chief Medical Officer, Metacrine
Medical & Scientific Advisor, Pfenex

Event Agenda:

Date: **Wednesday, 19 June 2019**

Time*:

5:15 – 6:00 PM Registration, Snacks, & Networking

5:30 – 5:55 PM *Speed 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:

For more than a decade now, biotech and pharmaceutical companies have brought a new class of treatments – biosimilars – to markets around the world. Biosimilars, also known as biological products that are demonstrated to be “biologically similar” to or interchangeable with an FDA-approved biological product, offer cost savings for some of the most expensive medicines. However, even today after decades of companies starting their quests to develop biosimilars, they are only just beginning to see widespread adoption.

Currently, there are more than 150 reference products for biosimilars which offer promise of new, cost-saving competition despite the many manufacturing and approval challenges. From the regulatory perspective, a number of agencies have adopted principles from the US and/or the EU biosimilar guidances. However, specific guidelines are yet to be established for some major markets. A global development strategy is still evolving and, in time, it will determine how biosimilars will be regulated and marketed globally.

Key topics covered will include:

- Introduction to biosimilars
- Review of regulatory and commercial experience: Comparing/contrasting US vs EU

- Case study: a biosimilar/therapeutic equivalent candidate referencing Forteo for the treatment of osteoporosis
- Challenges & opportunities with developing biosimilar products

Speaker Biography:

Hubert C. Chen, MD, is the Chief Medical Officer of Metacrine and Medical & Scientific Advisor at Pfenex. He previously served as Chief Scientific and Medical Officer of Pfenex, where he oversaw the research and development of biosimilar programs and led multiple interactions with the US FDA, EMA, Health Canada and Japan's PMDA.

Location: Pfizer Inc.
 10770 Science Center Drive (visitors center)
 Conference Room #1110
 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, 17 June 2019. Advanced registration is appreciated to assist in event planning.**
- ** **A photo ID is required to sign in at the venue.**
- *** **Space is limited for our monthly programs. Registration is capped at 85 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 17 June 2019):

\$15 SDRAN Member	\$25 Non-Member
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Onsite Registration:

\$25 SDRAN Member	\$35 Non-Member
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For Questions Email: programs@SDRAN.org

Directions to Pfizer:

From the North

I-5 South toward San Diego
 Take Exit 29, turn left into Genesee Ave
 Turn right onto Science Center Dr
 CB2 Visitors Center is located at the end of the cul-de-sac

From the South

I-5 North toward Downtown
 Take Exit 29, turn right into Genesee Ave
 Turn right onto Science Center Dr
 CB2 Visitors Center is located at the end of the cul-de-sac