



PROGRAM ANNOUNCEMENT

Wednesday, July 19, 2017

Monthly Program:

A Case Study on NDA Preparation - What It Means to a Small Company

Program Speaker:

Malcolm Lloyd-Smith, MS
Chief Regulatory Officer
Neurocrine Biosciences, Inc.

Event Agenda:

Date: Wednesday, July 19, 2017

Time: 5:15 – 6:00 PM Registration & Snacks
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:00 PM Program Presentation

Old Location: BD (former CareFusion) (directions on last page of this flyer)
3770 Torrey View Court
San Diego, CA 92130

Program Speaker: Malcolm Lloyd-Smith, MS

Program Topic:

It is well known that drug development from lab to clinical trials and commercialization is very costly, time consuming and unpredictable. After adequate clinical data are collected, drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing through submitting the New Drug Application (NDA) to the agency. Because the odd of NDA success is rare, especially for small biopharmaceutical companies, we are excited to have Malcom Lloyd-Smith (Chief Regulatory Officer) to share his extensive experiences through a case study on what to be considered for a successful NDA submission and approval.

Program Summary:

When a company is planning to submit its first NDA in many years there is much to be done to ensure that not only is the NDA prepared in a good comprehensive manner, but that the whole company is aware of the project and is supportive of what needs to be done "behind the scenes".

Using the example of the recent approval of the breakthrough product INGREZZA (valbenazine) indicated for the treatment of adults with tardive dyskinesia, Malcolm will discuss:

- The building up of a Quality organization, preparation for an FDA Sponsor inspection, including mock audits and inspections, creating a common approach to NDA document preparation and QC, and use of standardized templates across the organization.
- The process of establishing good and efficient communications with the review Division, pre-NDA interactions with the Agency and establishing credibility will be discussed, as will the various post-NDA submission interactions with the Division through to NDA approval.

Speaker Biography:

Malcolm Lloyd-Smith currently works at Neurocrine Biosciences as Chief Regulatory Officer with responsibility for regulatory affairs, project management, QA and medical writing. Prior to that, he held positions in Quality and Regulatory Affairs at Cadence Pharmaceuticals in San Diego, and Elan Pharmaceuticals in the UK. Previously, Mr. Lloyd-Smith served in various positions of increasing responsibility with DuPont Pharmaceuticals in Germany, Switzerland, USA and UK.

During his career Malcolm has built top performing regulatory teams both in the US and Europe and has successfully filed and obtained approval for more than 12 BLA's, NDA's or MAA's for both small and large molecules in the psychiatry, pain, addiction, cardiovascular, radiopharmaceutical, CNS and HIV therapeutic areas. Neurocrine obtained FDA approval in April 2017 for INGREZZA (valbenazine), the first approved treatment for tardive dyskinesia.

Malcolm has an honors bachelor degree in pharmacology from the University of Leeds and a master degree in pharmacological biochemistry from the University of Hatfield, both in the UK.

To register for the meeting, click on the link below to access the SDRAN registration system (123Signup) for this event:

<https://www.123signup.com/register?id=hfdhz>

Please make your reservation early. The online registration due date is Monday July 17, 2017. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday July 17, 2017):

\$15 SDRAN Member

\$25 Non-Member

Onsite Registration:

\$25 SDRAN Member

\$35 Non-Member

For Questions Email: jodyuro@hotmail.com

Directions to BD (former CareFusion):

❖ NOTE – BACK TO PREVIOUS LOCATION

From the North I-5

I-5 South toward San Diego
Exit toward Carmel Mountain Rd
Left onto Carmel Mountain Rd
Left onto Torrey View Court
Facility is on the right

From the South I-5

I-5 North toward Del Mar
Merge onto I-5 local Bypass
Take Carmel Mountain Rd exit (32)
Turn right onto Carmel Mountain Rd
Turn left onto Torrey View Court
Facility is on the right