THE 29TH ANNUAL





BALTIMORE MARRIOTT WATERFRONT • BALTIMORE, MARYLAND • SEPTEMBER 15 - 17, 2019

GENERAL SESSION ANNOUNCEMENT

Diana M. Yoon, PhD

Biomedical Engineer, Senior Scientific Reviewer

Office of Combination Products (OCP)

U.S. Food & Drug Administration

Regulatory Challenges for Combination Products

The Sharing Alliance™ is pleased to welcome Dr. Diana Yoon from FDA's Office of Combination Products.

The Sharing Conference™ continues to expand the learning and sharing for our attendees and in this general session you'll hear about the responsibilities of the Office of Combination Products surrounding the regulatory life cycle of combination products. Dr. Yoon will focus on the challenges to regulate combination products, including classification and jurisdiction, pre-market and post-market regulations. She will also discuss current ongoing efforts to aid in better understanding the expectations of combination products to the industry as well as inside FDA.

Whether you're from a pharmaceutical or medical device company, or a company that has both; whether you currently have a combination product, or just want to be prepared if your company gets one; or even if you are just curious to know more about the regulatory challenges for combination products, there will be plenty of valuable take-aways to bring back to the office.

Attendees will also have the opportunity to send questions for Dr. Yoon to the Alliance prior to the conference, should they prefer to pose questions anonymously. Details on submitting questions will be coming in August.

LEARN MORE ABOUT THE CONFERENCE

Register today for the Sharing Conference!

REGISTER HERE

Take advantage of the team discount!

When three people from the same pharmaceutical, medical device or biotech company attend, one more may attend for FREE. Forward this email to a colleague and get your team on board!

Email: mail@sharingalliance.org for details.



This year's conference theme – Connecting Commercial Operations with Compliance – was created to address the relationship between commercial operations activities and the compliance factor.

We invite you to take a look at how compliance connects with many aspects of commercial operations, including Data Management, Transparency, Free Goods and PAP, and more!









