DIA/FDA Oligonucleotide-Based Therapeutics Conference

Conference | October 28-30

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Overview

The DIA/FDA *Oligonucleotide-Based Therapeutics Conference* brings together leading experts to inform, educate, and share advancements in oligonucleotide-based therapeutic product development. Developed collaboratively by regulators, industry professionals, and academics, the program covers a wide range of topics from the nonclinical, CMC, and clinical areas, including emerging CMC guidance and considerations, learnings from recent regulatory filings, extra-hepatic and CNS delivery of oligonucleotides, toxicology testing, gene editing, and safety assessments. The conference offers a unique three-day experience with multiple perspectives presented, and the opportunity to interface with regulators from around the globe.

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Analyze the latest strategies for clinical use of oligonucleotide therapies and explain the specific challenges of developing RNA-based therapeutics
- Describe the chemistry, manufacturing, and controls challenges associated with the development of oligonucleotides, including formulation and specification issues
- Describe the technology landscape, CMC challenges, and regulatory considerations associated with novel oligonucleotide delivery approaches
- Explain the latest global regulatory updates in oligonucleotide therapeutic developments

Why You Can't Miss It

- Learn about the latest advancements, regulatory updates, and emerging trends in oligonucleotide therapies directly from leading industry experts and global regulators
- Our three tracks (Clinical, Nonclinical, and CMC) will comprehensively cover a wide range of aspects of oligonucleotide therapeutics—from development to regulatory collaboration—and provide practical insights into current challenges and successful strategies for overcoming hurdles in clinical use, safety assessments, and CMC
- This conference offers a networking opportunity to engage with peers, innovators, and regulators in sessions designed to foster meaningful collaboration and knowledge exchange.
- The final session, a Grand Question & Answer panel, will encourage discussion between the audience and an esteemed panel of experts, allowing participants to ask any remaining questions and contribute to conversations on key developments shaping the future of this field

Who Should Attend

Professionals involved in the following areas of oligonucleotide science:

- Drug Discovery
- Clinical
- Quality Assurance
- Vaccines
- Delivery Technologies
- Safety and Toxicology
- Diagnostics
- Preclinical
- CMC
- RNAi
- Biotechnology
- Clinical Pharmacology/Research
- Regulatory

Track Descriptions

Track 1: Clinical
There are more than a dozen oligonucleotide based products approved for therapeutic use and nearly 100 currently in clinical testing. Track 1 will explore the lessons learned and the ongoing challenges to clinical use of oligonucleotide therapies.

Track 2: Nonclinical
As oligonucleotide-based therapeutics advance, understanding their nonclinical development and safety is critical for their success in clinical and commercial stages. This track offers an in-depth look at the latest safety assessments, preclinical models, and regulatory expectations for nonclinical data.

Track 3: CMC
This track provides a collaborative forum for innovators and regulators to present and discuss cutting edge topics in oligonucleotide chemistry, manufacturing, and controls (CMC). Emphasizing emerging topics that require ongoing global regulatory collaboration, attendees will gain a deeper understanding of key insights into current challenges and successful strategies for navigating this evolving field.

Schedule At-A-Glance (All times listed are Eastern Time)

DAY ONE | MONDAY, OCTOBER 28		ROOM
8:30AM-4:45PM	Registration	Capital Terrace
9:15-9:30 AM	Welcome and Opening Remarks	Presidential Ballroom
9:30-10:30AM	Session 1: Keynote Address	Presidential Ballroom
10:30-11:00AM	Refreshment and Networking Break	Capital Terrace
11:00AM-12:30PM	Session 2 Track 1: Extra-Hepatic Delivery – Clinical Experience: Emerging Track 2: Pro-Arrhythmic Risk of Oligonucleotide Therapeutics: Is New Guidance Needed? Track 3: Commercial/Clinical Case Studies – Synthetic Oligos	South American AB Presidential Ballroom Federal AB
12:30-1:30PM	Networking Luncheon	Capital Terrace
1:30-3:00PM	Session 3 Track 1: Safety Observations in Late Clinic Development and Early Commercial Surveillance Track 2: Translatability of CNS Safety and Pharmacology Track 3: Emerging Oligonucleotide CMC Guidance	South American AB Presidential Ballroom Federal AB
3:00-3:30PM	Refreshment and Networking Break	Capital Terrace
3:30-5:00PM	Session 4 Track 1 and 2: Applying Toxicology Testing to the Clinic Track 3: Demonstrating Comparability for Oligonucleotides Therapeutics	Presidential Ballroom Federal AB
5:00-6:00PM	Networking and Poster Reception	Capital Terrace
DAY TWO | TUESDAY, OCTOBER 29		**ROOM**
8:00AM-4:15PM	Registration	Capital Terrace
8:00-8:30AM	Networking Breakfast	Capital Terrace
8:30-9:30AM	Welcome to Day Two and Session 5: Plenary Session: CRISPR Cures	Presidential Ballroom
9:30-10:00AM	Refreshment and Networking Break	Capital Terrace
10:00-11:30AM	Session 6 Track 1: Extra Hepatic Delivery – Clinical Experience in CNS Track 2: Off Target Safety Assessment Track 3: CMC Considerations in Development of mRNA-based Therapeutics	South American AB Presidential Ballroom Federal AB

11:30AM-12:45PM	Networking Luncheon featuring Roundtable Discussions	Congressional & Senate
12:45-2:15PM	Session 7 Track 1 and 2: Gene Editing Track 3: Challenges Around Oligonucleotides Control Strategies	Presidential Ballroom Federal AB
2:15-2:45PM	Refreshment and Networking Break	Capital Terrace
2:45-4:15PM	Session 8: Hot Topics	Presidential Ballroom
4:15-5:15PM	Oligonucleotide Safety Working Group (OSWG) – Open Meeting	Presidential Ballroom

DAY THREE | WEDNESDAY, OCTOBER 28		ROOM
7:30AM-12:40PM	Registration	Capital Terrace
7:30-8:00 AM	Networking Breakfast	Capital Terrace
8:00-9:15AM	Session 9 Track 1: Advantages & Challenges of Early Phase Clinical Studies with Oligos Track 2: Extra/Non-Hepatic Delivery Track 3: Innovative Manufacturing Approaches and Regulatory Implications	South American AB Presidential Ballroom Federal AB
9:25-10:40AM	Session 10 Track 1: Clinical Pharmacology of Oligonucleotides Track 2: Non-Clinical Safety Assessment of Oligonucleotides Track 3: Streamlining Oligonucleotide Development with Platform Approaches Roundtable	South American AB Presidential Ballroom Federal AB
10:40-11:10AM	Refreshment and Networking Break	Capital Terrace
11:10AM-12:40PM	Session 11: Grand Q&A Panel	Presidential Ballroom
12:25-12:40PM	Closing Remarks	Presidential Ballroom
12:40PM	Conference Adjourns	Presidential Ballroom

Continuing Education Credit Allocation

This program is eligible for Attendance Credit. No Continuing Education will be offered.

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Disclosure statements are included with each speaker's biographical sketch.

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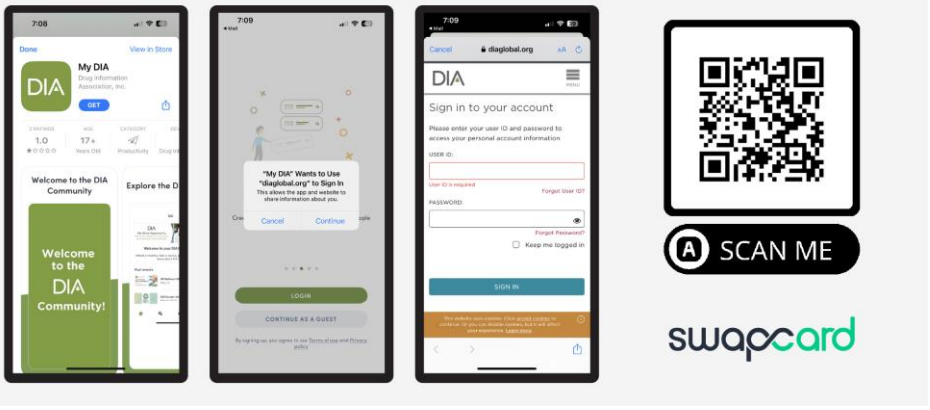

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