Online Workshop

Monday December 08, 2025 8:30 am-12:05 pm PT and Tuesday December 09, 2025, 8:30 am-12:10 pm PT

Bioanalysis of Oligonucleotides:

Strategies, Applications, and Regulatory Considerations

Organizers: Stephanie Pasas-Farmer, PhD (BioData Solutions); Shichang Miao, PhD (PBSS)







Stephanie Pasas-Farmer, PhD
President and Founder,
BioData Solutions

- Introduction to Oligos
- Regulatory Considerations for Oligonucleotides and Impact on Bioanalysis - PK Bioanalysis



An Zhao, PhD Associate Director, Regeneron

 Immunogenicity Assessment for Oligonucleotide Therapeutics



Aaron Anderson, MS
Associate Scientist,
Avidity Biosciences, Inc.

 Integrated Bioanalysis Strategies for Antibody-Oligonucleotide Conjugates (AOCs)



Joleen T. White, PhD
Senior Advisor,
BioData Solutions

 Regulatory Considerations for the Oligonucleotides Immunogenicty Assessment



Kelly Colleti, PhD, MBA

Director, Preclinical Bioanalytics, **Beam Therapeutics**

- Approaches to PK Bioanalysis of Oligonucleotides - bDNA, qPCR or dPCR
- Further Advances in Oligonucleotide Modalities and Impact on Bioanalysis -Advances in delivery (LNP, etc.)



Maral Llewellyn, PhD

Director of Bioanalytical Science, **Ionis Pharmaceutical**

- Approaches to PK Bioanalysis of Oligonucleotides
 - LBA
 - LC-MS/MS



Steven Louie, MS

Principal, Louie BioPharma Consulting

 Approaches to PK Bioanalysis of Oligonucleotides - Metabolism

PBSS Gold Sponsor WILSON SONSINI

Major Event Sponsor: Sponsorship Opportunities Available



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Bioanalysis of Oligonucleotides: Strategies, Applications, and Regulatory Considerations





Organizers: Stephanie Pasas-Farmer, PhD (BioData Solutions); Shichang Miao, PhD (PBSS)

Day 1: December 08, 2025

Time (PST)	Topic	Presenter(s)
8:30-8:45 AM	PBSS Welcome and Introductions	PBSS
08:45 - 09:15 AM	Introduction to Oligos	Stephanie Pasas-Farmer, PhD, President and Founder, BioData Solutions
09:15 - 09:45 AM	Approaches to PK Bioanalysis of Oligonucleotides - LBA	Maral Llewellyn, PhD, Director of Bioanalytical Science, Ionis Pharmaceutical
09:45 - 10:15 AM	Approaches to PK Bioanalysis of Oligonucleotides –LC-MS/MS	Maral Llewellyn, PhD, Director of Bioanalytical Science, Ionis Pharmaceutical
10:15 - 10:25 AM	Sponor(s) Presentation	-
10:25 - 10:35 AM	Break	
10:35 - 11:05 AM	Approaches to PK Bioanalysis of Oligonucleotides – bDNA, qPCR or dPCR	Kelly Colleti, PhD, MBA, Director, Preclinical Bioanalytics, Beam Therapeutics
11:05 - 11:35 AM	Approaches to PK Bioanalysis of Oligonucleotides – Metabolism	Steven Louie, MS, Principal, Louie BioPharma Consulting
11:35 AM - 12:05 PM	Panel discussion	All presenters

Day 2: December 09, 2025

Time (PST)	Topic	Presenter(s)
8:30-8:40 am	Welcome and recap of Day 1	Stephanie Pasas-Farmer, PhD, President and Founder, BioData Solutions
08:40-09:10 am	Immunogenicity Assessment for Oligonucleotide Therapeutics	An Zhao, PhD, Associate Director, Regeneron
09:10-09:55 am	Further Advances in Oligonucleotide Modalities and Impact on Bioanalysis - Advances in delivery (LNP, etc.)	Kelly Colleti, PhD, MBA, Director, Preclinical Bioanalytics, Beam Therapeutics
09:55-10:40 am	Integrated Bioanalysis Strategies for Antibody–Oligonucleotide Conjugates (AOCs)	Aaron Anderson, MS, Associate Scientist, Avidity Biosciences, Inc.
10:40-10:50 am	Sponor(s) Presentation	-
10:50-11:00 am	Break	
11:00-11:20 am	Regulatory Considerations for Oligonucleotides the Immunogenicty Assessment	Joleen T. White, PhD, Senior Advisor, BioData Solutions
11:20 -11:40 am	Regulatory Considerations for Oligonucleotides and Impact on Bioanalysis - PK Bioanalysis	Stephanie Pasas-Farmer, PhD, President and Founder, BioData Solutions
11:40 AM - 12:10 PM	Panel discussion	All presenters

