MARC ROY, PhD

Head of Nonclinical Safety | PhD Toxicologist | Oligonucleotide, siRNA & Genetic Medicines | INDs Cleared Without Preclinical Inquiries | GLP/Non-GLP & CRO Oversight | FDA Representation

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Professional Summary

Nonclinical safety leader with over 15 years advancing oligonucleotide and genetic-medicine programs from lead optimization through IND submission and early clinical development. Cleared multiple INDs including exon-skipping oligonucleotide and antibody-oligonucleotide conjugate programs without preclinical inquiries. Directs outsourced GLP and non-GLP toxicology, interprets CRO deliverables against regulatory standards, and authors the nonclinical submission sections that clear review. Led a seven-person nonclinical safety function overseeing a $25M portfolio and represented preclinical safety in FDA interactions.

Core Competencies

- siRNA and oligonucleotide toxicology
- Outsourced GLP and non-GLP study design and oversight
- IND and NDA nonclinical authorship (cleared without preclinical inquiries)
- Toxicological risk assessment and program de-risking
- Nonclinical safety team building and management
- Nonclinical safety strategy from lead optimization through IND
- CRO management and data interpretation
- FDA and global regulatory representation
- Cross-functional leadership across discovery, CMC, clinical, and regulatory
- Antibody-oligonucleotide conjugate, AAV, and LNP-mRNA modalities

Professional Experience

Toxicologist, Nonclinical Safety, *Sarepta Therapeutics* 10/2024 – 07/2025

- Directed nonclinical safety programs for siRNA candidates SRP-1001 and SRP-1003 and AAV gene-therapy program SRP-9010, covering study design through data interpretation.
- Authored preclinical safety sections supporting the regulatory advancement of SRP-9010.
- Reviewed CRO pharmacology and toxicology reports, resolving data gaps to keep programs on timeline.
- Coordinated outsourced study execution across oligonucleotide and gene-therapy programs to maintain regulatory-grade deliverables.

Senior Director, Nonclinical Safety, *Strand Therapeutics* 06/2023 – 04/2024

- Led nonclinical safety for lipid-nanoparticle mRNA delivery programs STX-001, STX-003, STX-004, and STX-005.
- Conducted GLP and non-GLP preclinical studies aligned to program objectives and regulatory standards.
- Authored regulatory documents supporting IND submissions and on-time filings.
- Directed cross-functional teams and built operational frameworks that streamlined R&D execution.

Senior Director, Nonclinical Safety, *Design Therapeutics* 05/2022 – 05/2023

- Cleared the DT-168 IND with no preclinical inquiries.
- Managed safety and pharmacology for DT-216, DT-168, and additional preclinical programs built on novel DNA trinucleotide-repeat-binding polyamide constructs.
- Designed and executed studies across internal and CRO resources to meet regulatory standards.
- Interpreted toxicology data to de-risk programs ahead of IND-enabling work.

Senior Director, Preclinical Development, *Dyne Therapeutics* 08/2021 – 05/2022

- Cleared the IND for DYNE-251, a dystrophin-targeted antibody-oligonucleotide conjugate, through timely completion of safety-substantiating nonclinical studies.
- Authored the preclinical safety sections of DYNE-251 regulatory documents for compliant, on-time filing.
- Applied antibody-oligonucleotide-conjugate toxicology expertise across a complex oligonucleotide modality.

Director, Preclinical Safety (Project Team Lead), *Novartis Institutes for BioMedical Research* 12/2020 – 08/2021

- Designed and executed GLP and non-GLP studies, coordinating internal and external resources for compliance and quality.
- Authored preclinical safety sections across multiple gene-therapy programs.
- Represented preclinical safety in collaborations and development programs, aligning stakeholders.
- Contributed to gene-therapy programs targeting neurological disease.

Senior Director, Head of Nonclinical Safety, *Sarepta Therapeutics* 03/2019 – 11/2020

- Led a seven-person nonclinical safety function (five toxicologists, two immunologists) across a $25M portfolio of exon-skipping oligonucleotide and AAV programs.
- Prepared nonclinical sections of INDs, NDAs, and investigator brochures supporting successful regulatory submissions.
- Authored and reviewed responses to global regulatory inquiries.
- Set nonclinical safety strategy focused on de-risking oligonucleotide and AAV delivery approaches.

Molecular Pathology & Investigative Toxicology (Senior Principal Scientist to Director), *Pfizer, Inc.* 2008 – 2019

- Served as molecular pathology lead for the global DSRD investigative antibody-drug conjugate (ADC) team, developing and validating patient-selection assays.
- Authored four lab-developed-test reports submitted to the FDA as IND amendments for phase 1b trials.
- Built target-expression characterization workflows (western blot, qRT-PCR, ISH, IHC; RNAscope automation) that informed program go/no-go decisions.
- Developed strategies to mitigate toxicities in gene-therapy platforms and evaluated GLP and carcinogenicity study designs.

🎓 Education

Ph.D., Chemical Biology, *Boston College, Graduate School of Arts and Sciences*

B.A., Chemistry, *Assumption College*