# MARC ROY, PhD

Nonclinical Safety & Preclinical Development Leader, PhD | Oligonucleotides, ADCs, AAV & LNP-mRNA | IND-Enabling Strategy | GLP Toxicology & CRO Oversight | Molecular Pathology | 15+ Years Pharma & Biotech


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## Professional Summary


Preclinical development and nonclinical safety leader whose career spans large-pharma drug safety research and venture-backed genetic medicine companies. Fifteen-plus years covering the full arc from mechanistic investigative toxicology and molecular pathology through safety strategy, IND-enabling packages, and regulatory defense. Track record includes INDs filed without preclinical inquiries, four lab-developed-test reports accepted by the FDA as IND amendments, and a $25M safety portfolio supported by a seven-person team. Modality breadth covers oligonucleotides, antibody-oligonucleotide conjugates, antibody-drug conjugates, AAV gene therapy, LNP-delivered mRNA, and small molecules.


## Core Competencies

- Preclinical development leadership and safety strategy
- GLP and non-GLP toxicology study design, monitoring, and interpretation
- Nonclinical authorship: INDs, NDAs, investigator brochures, health-authority responses
- Investigative and mechanistic toxicology
- Translational biomarker and patient-selection assay development
- Cross-functional partnership with discovery, CMC, clinical, and regulatory
- IND-enabling program design and regulatory defense
- CRO sourcing, contracting, oversight, and report review
- FDA and international regulatory representation
- Molecular pathology: IHC, ISH, RNAscope, qRT-PCR, western blot, RNA sequencing
- Team leadership, hiring, and functional management
- Portfolio and budget management

## Professional Experience

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

- Held nonclinical safety ownership across a mixed-modality portfolio spanning two siRNA candidates (SRP-1001, SRP-1003) and an AAV gene therapy program (SRP-9010).
- Shaped study strategy and endpoint selection for each program, then carried that work through to data interpretation and internal risk positions.
- Wrote the preclinical safety content underpinning SRP-9010's regulatory progression.
- Scrutinized incoming pharmacology and toxicology reports from contract laboratories, challenging findings and closing gaps that would otherwise have surfaced during health-authority review.
- Kept outsourced work synchronized across modalities so that deliverables arrived at submission quality rather than requiring rework.

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

- Owned the nonclinical safety agenda for a lipid-nanoparticle mRNA platform, covering four development candidates: STX-001, STX-003, STX-004, and STX-005.
- Planned and delivered the GLP and non-GLP study programme behind those candidates, matching design choices to both scientific questions and regulatory expectation.
- Produced the regulatory documentation supporting IND filings and kept submissions to schedule.
- Ran cross-functional teams spanning discovery, development, and regulatory, translating safety findings into decisions the wider organization could act on.
- Introduced operational frameworks and prioritization processes that reduced friction in R&D execution and sharpened resource allocation against research priorities.

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

- Took DT-168 through IND filing with no preclinical inquiries raised by the agency.
- Held safety and pharmacology accountability for DT-216, DT-168, and an additional preclinical portfolio built on novel DNA trinucleotide-repeat-binding polyamide constructs — a modality with no established regulatory precedent to draw on.
- Built study designs and protocols across a mix of internal capability and external laboratories, holding both to the same regulatory standard.
- Read toxicology data early enough to influence candidate direction, surfacing liabilities before they became sunk investment.

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

- Delivered IND clearance for DYNE-251, a dystrophin-targeted antibody-oligonucleotide conjugate, by completing the nonclinical package that substantiated its safety on the timeline the programme required.
- Authored the preclinical safety sections of the submission, structured for clarity under reviewer scrutiny.
- Applied conjugate-specific toxicology judgement to a modality where antibody and oligonucleotide liabilities interact rather than sit independently.

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

- Led preclinical safety as project team representative across gene therapy programmes directed at neurological disease.
- Designed and executed GLP and non-GLP studies, coordinating internal laboratories alongside external providers while holding compliance and data quality constant across both.
- Wrote preclinical safety sections spanning multiple programmes at differing stages of maturity.
- Acted as the preclinical voice in partnerships and development programmes, keeping scientific, clinical, and regulatory stakeholders aligned on safety position.

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

- Headed the nonclinical safety function with full accountability for a $25M portfolio centred on exon-skipping oligonucleotides and AAV delivery.
- Managed a team of seven — five toxicologists and two immunologists covering hiring, development, and workload allocation across concurrent programmes.
- Set the safety strategy that determined which liabilities were investigated, which were monitored, and which warranted programme-level escalation.
- Prepared nonclinical sections of INDs, NDAs, and investigator brochures feeding successful regulatory submissions.
- Authored and reviewed responses to global regulatory inquiries, defending safety positions to health authorities across jurisdictions.

**Director, Investigative Toxicology,** Pfizer 10/2017 – 01/2019

- Provided molecular pathology and toxicology expertise into therapeutic development decisions across the portfolio.
- Devised scientific strategies to mitigate toxicities arising in gene therapy platforms, improving the safety profile of assets that would otherwise have stalled.
- Designed nonclinical studies purpose-built to support clinical development rather than to satisfy checklists.
- Evaluated and endorsed GLP and carcinogenicity study designs, holding regulatory compliance and scientific integrity as joint criteria.
- Worked mechanistically, pursuing why a toxicity occurred, not only whether it did — which is the discipline that distinguishes investigative toxicology from routine screening.

**Global Molecular Pathology Lead,** Pfizer 02/2017 – 10/2017

- Defined RNA sequencing methodology for mechanistic investigation, extending what the organisation could ask of its safety data.
- Coordinated molecular pathology support across multiple research units, aligning independent project goals into shared capability.
- Maintained regulatory compliance across Investigative Molecular Pathology Laboratory operations.

**Senior Principal Scientist,** Pfizer, Inc. 01/2012 – 02/2017

- Managed the Investigative Molecular Pathology Laboratory within Drug Safety Research and Development, overseeing the safety assessments that fed programme decisions.
- Served as molecular pathology lead to the global DSRD investigative antibody-drug conjugate team.
- Led development and validation of patient-selection assays for ADC programmes, authoring four lab-developed-test reports submitted to the FDA as IND amendments supporting phase 1b trials.
- Established a target-expression characterization process in primary tumors using western blot, qRT-PCR, ISH, and IHC, validating the cell-surface proteins ADC programmes were built on.
- Characterized expression of two oncology targets in primary tumors; the confirmed absence of expression led to programme termination, redirecting investment before clinical spend.
- Built in vitro models predicting organ damage and toxicity, reducing reliance on exploratory in vivo work.
- Partnered with Advanced Cell Diagnostics to implement the RNAscope assay on automated staining instruments, shortening validation timelines for immunohistochemical assays.
- Investigated the mechanism of kinase-inhibitor-induced hyperglycaemia across a six-month rat toxicity study.

**Principal Scientist / Senior Principal Scientist,** Pfizer 05/2008 – 12/2011

- Led early development of patient-selection assays for ADC programmes, establishing the compliance protocols those assays were later validated under.
- Developed in vitro models that improved prediction of organ damage and reduced the volume of exploratory study work required.
- Coordinated practice network members across sites, streamlining shared operational processes.

## 🎓 Education

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

**B.A., Chemistry,** Assumption College