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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Executive Biography

Marc Roy is a nonclinical safety and preclinical development leader with more than fifteen years spent moving genetic medicines from laboratory concept to cleared regulatory submission. His career has traced the full width of the discipline from mechanistic investigative toxicology inside one of the world's largest pharmaceutical organizations to functional safety leadership at the venture-backed companies defining the next generation of oligonucleotide, gene, and RNA therapeutics.

He is, in practice, the person a development-stage company brings in when a program has to survive contact with a regulator.

Regulatory outcomes, not regulatory activity. Marc has authored and defended the nonclinical foundations of multiple INDs, including filings cleared without preclinical inquiries, an outcome that reflects not luck but the discipline of anticipating what a reviewer will ask before they ask it. At Design Therapeutics he took DT-168 through IND filing with no preclinical questions raised, working on novel DNA trinucleotide-repeat-binding polyamide constructs for which no regulatory precedent existed. At Dyne Therapeutics he delivered IND clearance for DYNE-251, a dystrophin-targeted antibody-oligonucleotide conjugate, assembling the nonclinical package that substantiated its safety on the timeline the program demanded. Earlier, at Pfizer, he authored four lab-developed-test reports accepted by the FDA as IND amendments supporting phase 1b oncology trials.

Modality breadth that is genuinely rare. Marc has held nonclinical safety accountability across siRNA, exon-skipping oligonucleotides, antibody-oligonucleotide conjugates, antibody-drug conjugates, AAV gene therapy, lipid-nanoparticle-delivered mRNA, and small molecules. At Strand Therapeutics he owned the safety agenda for four LNP-mRNA development candidates. At Sarepta he directed programs spanning siRNA candidates and AAV gene therapy simultaneously.

At Novartis Institutes for BioMedical Research he led preclinical safety for gene therapy programs targeting neurological disease. This breadth matters because the toxicology of these modalities does not transfer cleanly between them conjugates, vectors, and delivery systems each fail in their own way, and recognizing which failure mode is in front of you is not something acquired quickly.

Functional leadership and portfolio ownership. As Senior Director and Head of Nonclinical Safety at Sarepta Therapeutics, Marc held full accountability for a $25M safety portfolio built on exon-skipping oligonucleotides and AAV delivery, leading a team of seven — five toxicologists and two immunologists across concurrent programs. He set the strategy that determined which liabilities were investigated, which were monitored, and which warranted escalation to program leadership. He has authored and defended responses to global regulatory inquiries and represented preclinical safety directly in health-authority interactions, without intermediaries.

A foundation in the science itself. Before moving into safety leadership, Marc spent eleven years at Pfizer in molecular pathology and investigative toxicology, ultimately as Director of Investigative Toxicology. He managed the Investigative Molecular Pathology Laboratory within Drug Safety Research and Development and served as molecular pathology lead to the global investigative antibody-drug conjugate team. He built target-expression characterization workflows using western blot, qRT-PCR, ISH, and IHC, and partnered with Advanced Cell Diagnostics to bring the RNAscope assay onto automated staining platforms. In one instance, his characterization work confirmed the absence of target expression in primary tumors and led directly to program termination redirecting investment before clinical spend. That grounding in mechanism, rather than in study administration alone, is what allows him to interpret a CRO dataset rather than merely receive it.

Marc holds a PhD in Chemical Biology from Boston College and a BA in Chemistry from Assumption College.

He is currently open to Head of Nonclinical Safety, VP, and preclinical development leadership roles, and having deliberately unwound his geographic commitments is unconstrained in location for the right organization and the right science.