Dessi McEntee, MS, DABT

BOARD-CERTIFIED TOXICOLOGIST · FRACTIONAL CHIEF DEVELOPMENT OFFICER

Dessi McEntee is a board-certified toxicologist who has spent fifteen years doing one thing: getting molecules safely to the FDA. She is the operator who runs nonclinical development — not the advisor who hands a founder a deck and walks away. For early-stage biotechs with a promising molecule and no development team, she is the person who takes it from candidate to a cleared IND, builds the program so it survives investor diligence, and translates the science into a story that funds the next round.

WHAT SHE DOES

As a fractional Chief Development Officer, McEntee owns the nonclinical development program end to end — the strategy, the studies, the CROs, the regulatory submissions, and the development narrative that ties them together. She sets the program plan and the critical path, designs the toxicology and safety studies, selects and manages the CROs that run them, interprets the data, and authors the regulatory filings that put it all in front of the agency. Founders don't have to assemble a function or ride herd on vendors themselves; she is the single owner who makes the program cohere. And as a board-certified toxicologist, she does not take a CRO's interpretation on faith — she can tell when a study design is wrong, or a finding misread, before it costs a program a year.

WHERE SHE HAS DONE IT

McEntee began at the bench at Pfizer, where she ran in-vivo toxicology, safety pharmacology, and DART studies across species behind some of the company's largest programs. On the Prevnar vaccine franchise — today a multibillion-dollar product — toxicology studies turned up heart lesions in rabbits that threatened the entire program. She designed and ran the control study that proved the lesions were caused by stress rather than the vaccine, developing a new method to measure stress biomarkers in the process. The program continued; she published the method.

She then moved up the development chain. At Instem she standardized nonclinical safety data for regulatory submission, contributing to industry-wide data standards. At Epizyme she led nonclinical safety for small-molecule oncology programs, where she authored the IND for the SETD2 program and redesigned a dose-ranging study in a way that surfaced toxicity a shorter, conventional design would have missed — catching it early enough to protect the pivotal GLP study rather than repeat it. At Q32 Bio, as Associate Director of Toxicology, she oversaw complex biologics programs to IND, owning study design,

protocols, reporting, and regulatory strategy across challenging cases — including a single-species, surrogate-protein program run because the candidate was immunogenic in healthy animals — and helped carry a program into the clinic.

SHE HAS SAT IN THE FOUNDER'S CHAIR

McEntee has also been the founder. She built and led her own venture, Mimicry Solutions, developing an AI-driven computational toxicology platform — raising capital on the strength of the science, filing patents, securing an SBIR funding invitation, owning the equity structure and the strategy, and building collaborations across academia, pharma, and AI/ML. She knows what it is to run development with no team, no time, and investors watching every milestone. For more than six years she has run her own consulting practice, embedding as the development lead across dozens of early-stage biotechs. Today she serves as fractional Chief Development Officer to founders building toward IND, and as Chief Development Officer and a member of the Board of Directors at an early-stage company she helped build from the ground up — giving her a seat in both the development trenches and the boardroom.

RANGE

Small molecules are her core and the bulk of her work, but her program experience spans modalities most development leads never touch in a single career — biologics and fusion proteins, antibody-drug conjugates, vaccines, nanoparticles, and radiopharmaceuticals — across oncology, immunology, pain, rare disease, endocrinology, and cardiovascular indications. Whatever a founder's molecule is, she has very likely built a program around something like it.

TRACK RECORD

Across more than forty client engagements and 750+ nonclinical studies supported over her career, she has authored 8+ INDs and their international equivalents and 10+ pre-INDs and regulatory briefing documents. She has led face-to-face interactions with the FDA, Health Canada, and European regulators across six health authorities, authored and won a fertility-study waiver, and supported venture investors on nonclinical due diligence — with zero clinical holds on nonclinical grounds across the programs she has led. Multiple programs under her leadership have advanced to first-in-human.

WRITING, TEACHING & SPEAKING

McEntee is the author of **Data Is Not Strategy: Why Interpretation, Not Volume, Drives Nonclinical Decisions** (2025), as well as **Thank an Animal** (2024) and **Thank an Animal: Oncology** (2024). She is the founder of Nonclinical Academy, where she has built curriculum for professionals seeking to deepen their nonclinical development expertise, and publishes a weekly newsletter, *The Nonclinical*, read by thousands of scientists. She has delivered invited lectures and panel presentations at leading industry

forums, including panel discussions at the SOT Annual Meeting and a webinar on interim study monitoring and submission-quality SEND datasets for PointCross Life Sciences. The thread through all of it is the same skill that gets programs funded: turning complex science into something non-scientists can act on.

EDUCATION & CREDENTIALS

MS, Pharmacology and Toxicology — Michigan State University · BS, Animal Science — University of Connecticut · Diplomate, American Board of Toxicology (DABT), 2022