PROFESSIONAL DEVELOPMENT JUSTIFICATION DOCUMENT

Confidential

TO:	Manager / HR / Finance / Professional Development Committee
RE:	Professional Development Course Approval — Foundational Tier
COURSE:	The Complete Guide to Nonclinical Development
INVESTMENT:	$399
ACCESS:	1-Year Access

Purpose of This Document

This document has been prepared to support the approval of a professional development investment in **The Complete Guide to Nonclinical Development**, an expert-led online course designed for pharmaceutical and drug development professionals. It outlines the course credentials, learning outcomes, business value, and relevance to the employee's professional growth within the organization.

About the Course

The Complete Guide to Nonclinical Development is the most comprehensive nonclinical and toxicology course available to drug development professionals. Delivered as a self-paced online program, the course spans 500+ slides across 14 modules and 2 bonus modules, covering the full nonclinical development landscape — from study design and GLP principles to regulatory strategy, toxicology interpretation, and IND preparation.

The course is designed for professionals across all functions in drug development — including regulatory affairs, clinical development, CMC, project management, and chemistry — who need a comprehensive understanding of nonclinical development to be more effective in their roles and more competitive in their careers.

Instructor Credentials

This course was developed and is taught by **Dessi McEntee, DABT** — one of the most trusted nonclinical development experts in the pharmaceutical industry.

- Board-Certified Toxicologist (DABT) with 15+ years hands-on experience in drug development
- Founder, Toxistrategy — providing fractional nonclinical leadership to IND-bound biotech teams
- Board of Directors and Chief Development Officer, Immugen BioPharma
- Author of Data Is Not Strategy: Why Interpretation, Not Volume, Drives Nonclinical Decisions
- Trusted by 30+ biotech and pharma companies across oncology, immunology, rare disease, and more
- Multiple drug programs successfully advanced to FIH clinical trials under her nonclinical leadership
- Flawless regulatory track record across IND submissions and nonclinical safety programs

The expertise behind this course is not academic — it is the direct result of 15+ years of real-world nonclinical leadership at the highest levels of drug development. Students are learning from someone who has done the work, not just studied it.

Course Inclusions — Foundational Tier

- ✓ Full course access — all 12 modules + 2 bonus modules with real-world case studies, 1-year access
- ✓ Downloadable workbooks for structured learning and reference
- ✓ Module quizzes to reinforce and assess knowledge retention
- ✓ Lesson forum access — community of pharmaceutical and drug development professionals

Professional Learning Outcomes

Upon completion of this course the employee will be equipped to:

- Understand how nonclinical development fits into the full drug development pipeline and IND pathway
- Interpret toxicology study results and their clinical, strategic, and regulatory implications
- Communicate confidently and effectively with nonclinical teams, CROs, and regulatory agencies
- Apply nonclinical strategy to program decisions with greater confidence and reduced risk
- Identify gaps and risks in nonclinical programs before they result in costly delays or regulatory setbacks
- Navigate key regulatory guidance documents and understand their practical application
- Contribute more meaningfully to cross-functional teams and nonclinical discussions

Business Value to the Organization

Investment in nonclinical development knowledge directly supports organizational goals in drug development. Professionals with a strong nonclinical foundation contribute to:

- Faster, more informed decision-making across the drug development team
- Reduced risk of costly nonclinical program errors and regulatory delays
- More effective cross-functional collaboration between nonclinical, clinical, regulatory, and CMC teams
- Stronger IND packages and more confident regulatory interactions
- Reduced reliance on external consultants for foundational nonclinical knowledge

The Foundational tier includes one year of access which provides ample time to complete the full course and build a strong nonclinical foundation. At $399, this tier represents an accessible entry point to expert-level nonclinical knowledge that would otherwise take years of on-the-job experience to accumulate.

Professional Development Reimbursement: This course qualifies as professional development and is eligible for company education, training, or professional development budgets. A receipt will be provided at checkout for reimbursement and record-keeping purposes. The course is self-paced and can be completed outside of working hours at the employee's discretion.