CERTARA

FACT SHEET

Nonclinical Development Science Services

Strategic Preclinical Support for First-in-Human Readiness

How well-informed is your pre-clinical drug development program?

Early drug development is complex, but the right expertise ensures efficiency. Certara's Non-Clinical Drug Development Services provide integrated regulatory strategies from hit-to-lead identification through first-in-human (FIH) studies. Our experts support ADME, bioanalysis, toxicology, drug safety, and CMC for both small and large molecules—maximizing success from the start.

Certara's Nonclinical Drug Development Services

Early drug development/Preclinical drug development support for Investigational New Drug (IND) Application

Expert Discovery & Nonclinical DMPK Support
Certara designs and manages bioanalytical method development, nonclinical PK/TK, ADME studies (in vitro & in vivo), radiolabeled studies, metabolite profiling (MIST), enzyme phenotyping, and transporter interaction studies.

Comprehensive Toxicology & Drug Safety Support
From regulatory strategy to study execution, Certara provides CRO management, protocol development, study oversight, and data integration for regulatory submissions.

End-to-end CMC Support
Certara supports CMC from preclinical to post-launch for small & large molecules across diverse administration routes.

Why Choose Certara?

We're expert drug developers who know how to advise on your most critical decisions. Our success is your success – we guide and design FIH-enabling programs without conflicts of interest. We sit on the same side of the table as our clients and partner with them to develop and deploy efficient and effective best practice strategies.

125+ Years combined scientific experience

15+ Marketed drugs supported in the last 30 years

130+ Successful first in human packages

Meet the Experts | Expert guidance for efficient studies

Nathalie Roux, PhD
Vice President, Head of DMPK

Nathalie provides strategic DMPK & ADME discovery services, nonclinical DMPK, clinical pharmacology, and regulatory sciences for several biotechnology companies. She is also a Core Team Member of the Center of Excellence in Drug Interaction Science.

Deven Shah, BPharm, PhD
Sr. Director, Integrated Drug Development

Deven Shah is Certara's Chemistry, Manufacturing & Controls (CMC) lead helping clients with their drug development CMC needs. Deven also supports the Certara Global Health practice area spending a significant amount of time attending to the Bill & Melinda Gates Foundation work.

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Learn more: certara.com/services/nonclinical-development-science-services/

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 66 countries. For more information visit certara.com