

Early Drug Development Center of Excellence

Developing Customized Solutions for Drug Product Development

Early Drug Development is a key service area within NGT, created specifically with biotech companies in mind and designed to help clients advance their drug candidates, rapidly and efficiently, to the next important development milestone.



Talk to NGT BioPharma Consultants about creating a customized solution for your early development pipeline candidates.



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A FIT-FOR-PURPOSE APPROACH

- NGT utilizes a **bespoke consulting model**: Services are developed in collaboration with the client and centered around their product's unique requirements and challenges while complementing the clients internal and third party competencies and capabilities
- Whether it is an individual subject matter expert or a cross-functional team, NGT provides **the expertise and resources you need, when you need them**

EARLY DRUG DEVELOPMENT FUNCTIONAL EXPERTISE

- Our consultants are **seasoned pharmaceutical experts** whose experiences encompass the full range of early drug development technical, regulatory and quality disciplines; their extensive experience and depth of expertise are meticulously configured to address your explicit product and development challenges
- NGT's consultancy offerings span **all the essential, interdependent early development functions**:
 - CMC, including API chemistry, material sciences, drug product, analytical, and clinical supply
 - Regulatory strategy and global application preparation
 - Quality/GXP strategy and operational compliance
 - Nonclinical strategies and experimental approaches
 - Phase 1/First-in-Human clinical strategies and study oversight
 - CDMO/CRO selection and qualification as well as coordinating or providing operational oversight
- NGT prides itself on maintaining a deep, diverse workforce of **subject matter experts** who can quickly be **matched to our client's needs** to achieve their objectives

PRODUCT LEADERSHIP AND PROJECT MANAGEMENT

- NGT complements our technical, regulatory and quality consultants with **veteran project leaders and/or project managers** – CMC professionals who are experienced in leading matrixed early development cross-functional teams, and who understand the criticality of logistical support activities to operational efficiency and effectiveness
- Working together with the client and NGT's consultants, our project leaders/managers create customized pre-clinical and clinical development strategies and implementation plans addressing project challenges to **accelerate project milestone timelines**, enabling the avoidance of common pitfalls that often lead to costly delays in reaching critical milestones and the ultimate achievement of market success