

Consulting Services

FACTSHEET



Drug Development Services

Development of new therapeutic entities can be a complex process requiring the development of a sound strategy and a detailed project plan. These are essential for progression of a compound through the different phases of preclinical and clinical testing in a timely and cost-effective manner.

Aptuit Consulting is an independent group of scientists with expertise across all areas of the drug development process. We have both internal and affiliated consultants located in the US and Europe who can provide local support and advice in the following areas:

Strategic drug development consulting

We offer a team approach with our clients to prepare a development plan based on a thorough understanding of regulatory strategy, commercial considerations and in-depth scientific knowledge. We also prepare “Gap Analysis” of existing preclinical packages for support or change in indication, route or geographic region for regulatory submission.

Preclinical study design, review and implementation

Design of safety and ADME studies including species selection, identification and qualification of service providers, implementation of studies at service provider(s), and monitoring of progress and conclusions. We also offer expert review of preclinical study reports.

Regulatory submissions

In addition to strategic regulatory planning, our regulatory specialists can oversee, manage and maintain regulatory submissions in the US and EU as well as represent clients with these regulatory authorities. Creation of eCTD's is a speciality.

Phase I safety and Phase I/II proof-of-concept studies

Creation of Phase I and II study designs, identification of clinical study centers based on therapeutic area, special population requirements, and experience with class of compound. Design and implementation of Phase 0 and exploratory IND studies are emphasized.

API/Pharmaceutical Development

Advice on API manufacture and formulation of drug product together with supporting analytical chemistry from preclinical through to commercialization.

Specialist consulting areas include:

- **Strategic** – Drug development strategy and management services
- **CMC** – Drug substance/drug product development; pharmaceutical sciences
- **Preclinical** – Safety assessment, metabolism/PK, and discovery support
- **Clinical** – Clinical studies to achieve evaluation of safety/proof of concept; clinical trial supply logistics
- **Regulatory** – Regulatory strategy and submissions

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit consulting services, please call one of our offices or email:

+1 781 778 0418 North America

+44 1506 813333 Europe

email: consultinginfo@aptuit.com

or visit our website: www.aptuitconsulting.com

Engineering a better drug development process.