

## Consulting Services

### FACTSHEET



## Regulatory Strategy/Submissions Services

Regulatory Affairs is a key area of pharmaceutical consulting which touches all other disciplines (eg, chemistry, manufacturing, and controls; preclinical; and clinical). Knowledgeable in the FDA, HPFB, and EMEA regulatory requirements for clinical testing and marketing approval and serving as a conduit to regulatory authorities, Aptuit Consulting provides a cohesiveness to the drug development continuum that is critical to achieving approvable drug submissions.

Aptuit Consulting can provide independent regulatory specialists with strategic expertise as well as operational expertise to assist with regulatory strategy and integration of technical information into regulatory dossiers. Aptuit Consulting can assist our clients in the following areas:

- Regulatory strategy development, implementation and management
- Regulatory compliance gap analysis of product development plans and submissions
- Regulatory authority liaison and meetings, including meeting information packages
- INDs, IMPDs, and CTAs or individual dossier components
- NDAs, ANDAs, NDSs, and MAAs, including CTD format, or individual dossier components
- CMC-Specific: IND, IMPD, NDA, ANDA, NDS, MAA, DMF/EDMF, European Pharmacopeia Certificate of Suitability
- Preparation of regulatory submission technical sections and summaries such as Investigator Brochures, protocols, nonclinical sections, clinical sections, etc
- Orphan drug designation applications
- Regulatory dossier maintenance activities such as annual reports, amendments, safety reports, supplements, etc.
- Publishing of regulatory documents and submissions
- US Agent services for US-based regulatory submissions

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:

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**Engineering a better drug development process.**