

Consulting Services

FACTSHEET



Regulatory Strategy and Submissions Services

Aptuit Consulting's regulatory affairs team provides expertise across a broad range of therapeutic drug classes including critical guidance for strategy and support on individual projects or as part of the integrated drug development plan. Our regulatory strategy experience combined with our knowledge of the eCTD publishing requirements enable us to guide and help you complete successful submissions on time.

Regulatory Strategy

Aptuit Consulting experts are knowledgeable in the regulatory requirements of the FDA, HPB, and EMA for clinical testing and marketing approval of new drugs and devices and serve as a conduit to regulatory authorities for pre-IND and other face-to-face meetings. Our regulatory experts offer strategic and operational expertise to assist with product development and the integration of technical information into regulatory dossiers.

Aptuit Consulting provides:

- 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, including Investigator Brochures, protocols, nonclinical sections and clinical sections
- Orphan drug designation applications
- Regulatory dossier maintenance activities, including annual reports, amendments, safety reports, and supplements
- US Agent and EU Legal Representative services for foreign firms seeking US-based or EU-based regulatory submissions

Submission Services

Aptuit Consulting is experienced in electronic submissions (eCTD). Our submission services are delivered by publishing experts who understand the publishing process, and content requirements to produce high quality regulatory submissions. We offer advanced publishing activities that extend the capabilities of your own organization.

Aptuit Consulting provides:

- Regulatory publishing expertise
- Regulatory publishing submission management
- Submission-level publishing in CTD/eCTD formats
- Bookmarking and hyperlinking, including case report forms
- Document formatting
- Legacy document conversion

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 further information about Aptuit Consulting Regulatory Affairs Services, please contact:

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Engineering a better drug development process through scientific excellence.