

Pharmaceutical Development Services Ltd is an integrated drug development consulting service. We manage the development, supply and regulatory control of new and existing pharmaceutical products. Our regulatory expertise includes pharmaceuticals, biotechnology products, orphan drugs, biologicals, diagnostics, medical devices, alternative and herbal medicines, nutraceuticals, health foods, food supplements and cosmetics.

Expertise:

- Regulatory strategy and management for reports and submissions in Europe and USA
- CTD pharmaceutical, preclinical or clinical overviews
- Compilation of e-CTDs
- Preparation of response documents or appeals on behalf of the applicant
- Briefing documents for pre-NDA or EMEA scientific meetings
- Development strategies to address products with specific difficulties
- Pharmacovigilance

Services:

- Due Diligence
- Strategic Regulatory Consultancy
- Clinical Trial Regulatory Affairs
- Submissions
- Responses to Regulatory Decisions
- Safety including pharmacovigilance
- Post approval maintenance
- Preparation of, or conversion to, eCTD