Regulatory Strategy & Advice						
Pharmaceuticals, Radiopharmaceuticals, Biologics, Biosimilars & Combination Products				**Medical Devices & Diagnostics**	**NHPs Dietary Supplements**	**Cosmetics**
Pre-Submission Meetings with Agencies						
Canada: Health Canada	United States: Food & Drug Administration (FDA)	Europe/UK: European Medicines Agency (EMA) / Medicines and Healthcare Products Regulatory Agency (MHRA)	Australia: Therapeutic Goods Administration (TGA)	All Application Types	In exceptional cases	In exceptional cases
Pre-clinical & Clinical Trials Management						
CTA CTA-A	IND	CTA	CTN CTX	ITA IDE HDE	CTA	Not applicable

Submissions/Dossiers						
NDS, SNDS CMC ANDS SANDS DINS	MF NDA BLA SNDA ANDS	DMF Original Variations MAA-CP DCP, MRP	DMF NCEs Generics Variations	PMA 510(k) Class II-IV Technical File Design Dossier CE Marking	PLA NPN SLA QAR NDI	VCRP Cosmetic Notifications

Other Services

- Product Quality Assurance Coordination during Registration/Licensing
- Product Promotional & Labeling Reviews (LA/SA)
- Agency Query Management
- **Direct, Online & Publishing Services (eCTD, NeeS, Conversions, Paper)**
- Establishment Registrations, Licenses & Listing
- Annual Product/Facility Renewal Services
- Application Fee Management

Contact us at **info@axsource.com**