Regulatory Services

Consulting, e-Publishing, Labeling, Submission

The Regulatory Services Team at Piramal Pharma Solutions is your one-stop shop for complete regulatory support including global submissions, CMC consulting, e-Publishing and electronic submissions, and product labeling and artwork. With almost 300 years of collective experience ranging from analytical to formulation development and manufacturing, the team has expertise in every aspect of regulatory submissions and are well-seasoned in communicating with USFDA and other regulatory agencies.

Services

Global Submissions

- INDs, IMPD, CTAs
- NDAs, ANDAs, MAs
- DMFs, CEP, ASMFs
- Dossiers for ROW markets
- Site and company registrations
- DCGI submissions as Indian agents
- Biological applications (ADCs)

CMC Consulting

- QbD compliance as per ICH Q 8, 9, 10, & 11
- Support for identification of KSM/RSM, reference standard characterization report
- Quality checks for validity and consistency of CMC documentation
- Gap analysis exercise for regulatory & strategic recommendations
- Genotoxic impurity evaluation and strategies for limits

e-Publishing & Submissions

- Turn-key services: document sharing, document review & quality check, uploading & publishing, final submission
- PDF files for compliance for eCTD filing like bookmarks, hyperlinking, page layouts, inherent zoom, OCR
- eCTD software to comply with latest FDA requirements for compliance to technical rejection criteria for study data

Labeling & Artwork

- Product labels: authoring, tracking & distribution
- Clinical & non-clinical overviews
- Authoring, SmPC & PIL
- Artwork management
- SPL management

Achievements

Our team has successfully filed numerous NCEs (INDs, CTAs, IMPDs); EU MAAs; Canada ANDSs; dossiers to ROW countries; DMFs (USA, HC, ASMFs, CEPs, JDMFs, NMPA-China, ANVISA-Brazil, WHO, and ROW); and 200+ ANDAs with more than 100+ approvals to credit.

IND/Clinical Trial Application (CTA)

IND/CTA filing experience in US, Europe (France, Hungary, Czech, Netherlands), Australia, New Zealand, Argentina, and India

- **23 total INDs/CTAs compiled (different Phases I, II, III)**
- **2 Orphan drug designation applications**
- **Experience in CMC review and compilation from Phase I to NDA**
- Pre-IND meeting package to USFDA
- Three herbal products in Phase-II/III clinical trials
- New Medical Device Application submitted to DCGI India
- No clinical hold for any submissions

Generic & other Regulatory Applications for Formulations

Piramal & customer applications done in USA, Europe, Canada, Australia, Asia Pacific, GCC, and semi-regulated countries

1. Experience in review and compilation of toxicology, pharmacology and clinical sections (Modules 4 & 5)
2. ANDA development & filing generic application paragraphs II, III & IV
3. **32 ANDAs submitted out of which 24 are approved**
4. Lifecycle management of these done by Piramal including AR, post-approval supplements

Experience of filing dosage forms

Immediate/modified released solid dosage forms, parenteral (liquid, lyo), fixed dose combination, ophthalmic

API Applications

About 167 DMFs, ASMFs, JDMFs, and CEPs submitted in USA, Europe, Canada, Japan, China, Brazil, and ROW for supplying APIs

Site Registrations

DUNS and establishment registration, self identification facilities for drugs and devices

Food facility registration under Bioterrorism Act

e-Submissions and Publishing

eCTD submissions successfully done for EU and US

ASMFs submitted with all European countries in support of CP, DCP, NP, MRP, and work sharing procedures through Syncplicity/CESP gateway

ANDAs submitted electronically – 21 applications

Establishment/drug SPL submissions – 1,100

NDC labels, GDUFA identification submitted to FDA through SPL

SPOR database management

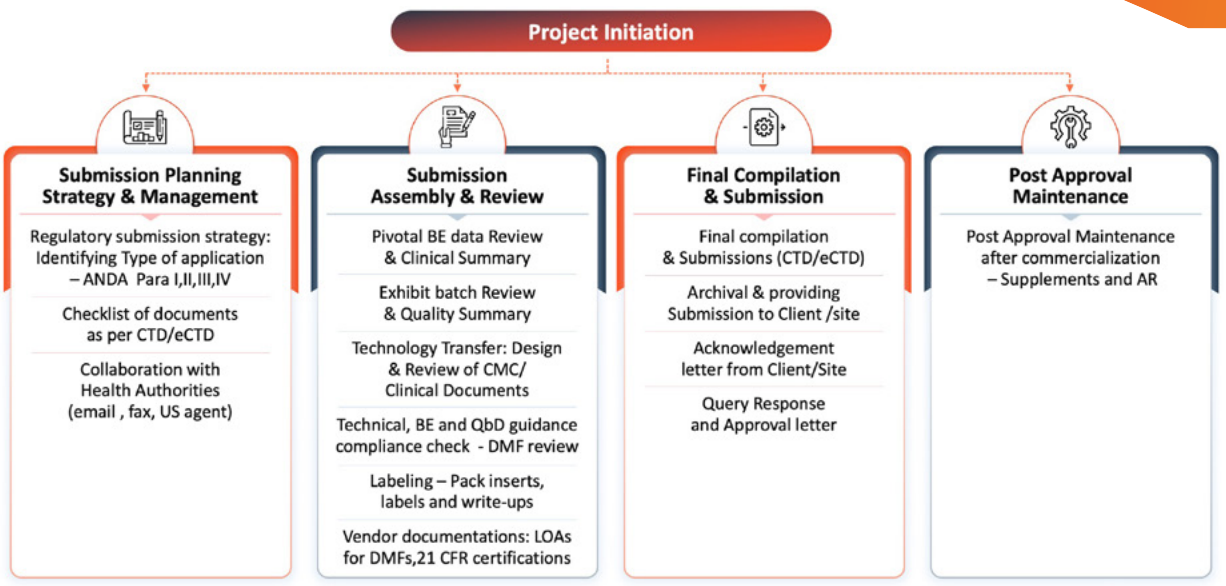
Labeling Artwork

Artwork management through Harmony Artwork Management (recorded artworks & repository of the artworks)

Harmony eProofing software usage

Worked on and finalized around 4,600 artworks

Life Cycle Management (e.g. ANDA Submission)



Electronic Data Systems

The Regulatory Services Team utilizes key software systems through the course of its work, with expertise in these applications:

- eCTD software "PharmaReady" from Navitas LifeSciences
- SPL software from Navitas LifeSciences
- Lorenz eValidator
- Artwork management system "Harmony Artwork Management" from Greatfour Technologies
- Artwork verification tool "Harmony" from Greatfour Technologies
- Use of Electronic Submission Gateway (ESG)

Get in touch with us
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