2021

The Gnomon Group
Regulatory Affairs Consulting Group
and
Triangle Regulatory Publishing
Document Publishing and eSubmssion Company

equals

Alliance eSubmission Group, LLC

The Gnomon Group Regulatory Consultants

- Over 200 years of combined pharmaceutical development experience in large and small companies, CROs, and as consultants
- Provided regulatory support for over 15 compounds from early development to approved NDA, and for over 150 INDs
- US and International regulatory experience

Core Regulatory Services

- Regulatory strategy development (All Phases)
- US regulatory authority liaison and advisor for drugs, biologics and medical devices
- All Phase FDA Meetings
- Regulatory project team member
- Post-marketing approval regulatory support
- Drug safety experience

Expanded TGG Project Team Capability With Over 15 Experienced Dedicated Associates

- CMC development strategy support including vendor inspection
- GMP, GLP, and GCP support
- Stats, DM and Medical Writing
- DSMB support
- Clinical operations
- Clinical and nonclinical pharmacokinetics
- Pharmacology/toxicology
- Medical Writing
- Medical monitor and drug safety consulting
- Project management

Triangle Regulatory Publishing (TRP)

- Over 75 years of combined Regulatory Operations experience
- Small, Medium and Large Pharmaceutical/Biotech experience
- Proven Track Record in all phases of regulatory document production and submission
- Electronically submitted hundreds of NDAs, INDs, Supplements, Safety Reports and other supporting submissions
- Paper to electronic conversion consultants

TRP Core Regulatory Operation Services

- eSubmissions
- Document formatting (Word/Case Report Forms/PDF Navigation)
- eCTD readiness, granularity, naming conventions, establish gateway including pilot submissions
- Document publishing electronic Common Technical Document (eCTD) format
- Templates
- Document management best practices

Alliance eSubmission Group, LLC.

- Strategic Partnership between TRP and TGG
- Jointly own eSubmission software
- Lorenz Docubridge Model Software
  - Includes content planning, publishing, compilation and distribution
  - Submission manger
  - Document publisher
  - Reviewer
- Industry Validated Publishing System
- Compliant with Global Regulatory Standards
- Versatile and Customizable to client needs

Benefits of strategic partnership

- Enhanced project control with integrated support and billing for all services
- Time and cost efficiencies reduces the time and cost from final documentation to eSubmission (established document and eSubmission management processes and low infrastructure overhead)
- Leverages insights and experience from both Companies
- Integrates regulatory advice/support with data management/stats, medical writing, document formatting, and eSubmission

Examples of Current Projects

- Multiple eSubmission filings including INDs, amendments, DMFs, BLA, ANDA, NDAs and supplements
- eSubmission consultants for over 50 companies
- Multiple medical writing projects (6 medical writer associates)
- Ongoing regulatory support for over 35 project teams
- Multiple FDA meetings
- FDA IND agent for ex-US companies and maintain IND
- Regulatory support for marketed drug
- Regulatory support for investigational and marketed medical devices
- Due Diligence Projects