PARAGON
POWERING BUSINESS TRANSFORMATION

REGULATORY OPTIMIZATION SERVICES

Managing Electronic Submissions in a Global Environment

A rapidly changing environment is a challenge for any organization. For the pharmaceutical/biologic industry, it means keeping up with regulatory requirements for health authorities around the world. In addition to daily submission activities, regulatory operations groups must find a way to stay abreast of the regulations and implement them through development and maintenance of processes, standards, training, and adoption. These added tasks and responsibilities can tax regulatory groups already stressed with the preparation and delivery of submissions and registration management for health authorities around the world. Paragon can help your organization navigate this fluid environment and get the most out of your investments with our subject matter expertise and expansive experience across regulatory functions.

Regulatory Operations Optimization Services Include:

- **Process Development** – Identify gaps in processes, drafting / editing policies, implementing best practices, and training personnel
- **Template Support** - Development, review, use, and training
- **Systems Support** – Non-biased support for vendor tool selection process, software implementation, validation, and migration activities
- **Regulatory Intelligence** - Guidance interpretation, implementation, and training
- **Electronic Submission Support** – eCTD compliance Assessments and global dossier planning
- **Electronic Submission Preparation** – Requirement analysis, evaluation, implementation, and training
- **Advertising and Promotion (Ad/Promo) Submission Transition** - Training and best practices
- **Regulatory Operations Harmonization** – Process and data standardization across all electronic submission systems and tools
- **Training** – Development and delivery across all electronic submission systems and tools
- **Electronic Submission Strategy** – Forge a plan to expand electronic submissions into new markets and plan for technology changes
- **System Gap Analysis** – Evaluation and reporting on opportunities for maximizing value of current systems and tools

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Paragon's Regulatory Optimization Practice

Paragon has expertise crossing all areas of product development and post marketing activities: Regulatory, Clinical, Supply Chain and Manufacturing, Labeling, and Information Management. As a non-software client services organization, Paragon operates with complete non-bias in process development, system implementations, and vendor selection processes. During IDMP evaluations, we provide services as necessary for the organizations in which we are working.

DELIVERING MATURITY ACROSS THE REGULATORY SPECTRUM

About Paragon

Paragon is a consulting firm that helps health and life sciences companies become high-performing, compliant, and digitally connected. Paragon powers business transformation and delivers better business outcomes by providing valuable consulting services as a trusted partner to our clients. We do this by building long-term client relationships based on our domain expertise, creative ideas, pragmatic consulting services, and quality delivery of solutions.

For more information, visit us online at www.consultparagon.com, or call 1.800.462.5582.

Paragon Client Roster

Our client roster includes life science industry leaders such as:

- **AbbVie**
- **AstraZeneca**
- **Bausch & Lomb**
- **Bayer**
- **Bristol-Myers Squibb**
- **Celgene**
- **CSL Behring**
- **Daiichi-Sankyo**
- **GSK**
- **Lilly**
- **MedImmune**
- **Merck**
- **Novo Nordisk**
- **Otsuka**
- **Roche**
- **Shire**
- **Chiltern**
- **inVentiv Health**
- **Worldwide Clinical Trials**
- **Regeneron**