PAREXEL®
YOUR JOURNEY. OUR MISSION.®

PAREXEL® CONSULTING

REGULATORY, DEVELOPMENT & COMMERCIAL EXPERTISE. OPERATIONAL EXCELLENCE. ONE SOURCE.

Your therapy is your asset, and the market is your destination. From product profile and regulatory strategy definition to compliance and submission, commercialization planning and ongoing lifecycle management support, no team of experts accelerates your journey better than PAREXEL.

PAREXEL Consulting has defined advisory excellence and innovation for more than 35 years. With over 1000 regulatory, commercialization and operations experts covering 110 countries, we can help you plan earlier to extract greater value from your clinical trial data, and convert end-to-end clinical development, and commercialization expertise into actions that deliver your therapy to the patients that need it sooner.

1000+ regulatory professionals covering **110+** countries

50+ former Regulators from global agencies

REGULATORY PERSONNEL

155+
Doctoral-level professionals

OUR CUSTOMERS

Developed and marketed **191** out of the top **200** drugs

Source: EvaluatePharma® (WW sales) Top 200 drugs ranked in 2012.

At any given time, PAREXEL is working with over 200 unique clients on 1,300 ongoing projects. These range from single product projects related to a specific mission critical submission, to long term, multi-year functional outsourcing partnerships for companies of all sizes.

REGULATORY EXPERIENCE — ANNUAL VOLUME

INDS, CTAS

- 100+ Investigational New Drug Applications (IND)/Investigational Medicinal Product Dossiers (IMPD) – complete and partial dossiers; amendments and maintenance activities
- >1,500 Clinical Trial Applications (initial)
- >12,000 Clinical Trial Application amendments/updates

MARKETING APPLICATIONS AND SUBMISSIONS

- NDA, BLA, MAA, NDS, JNDA – 10+ complete submissions and 100+ partial sections written per year in extensive range of therapeutic areas across all geographies
- 5+ ANDAs per year
- 5 510(k) Premarket Notifications (medical devices) per year

SPECIAL DESIGNATIONS AND INDICATIONS

- Develop regulatory strategies to gain Orphan Drug designations in multiple therapeutic areas
- Multiple Pediatric Indications and Waivers
- Accelerated review designations, breakthrough designations, etc.

HEALTH AUTHORITY MEETINGS

(INCLUDING SUPPORT, MEETING REQUESTS, RESPONSES, ETC.)

- Pre-IND, EOP1/2, Pre-NDA/BLA, Advisory Committee, Scientific Advice, etc.
- 15+ Pre-IND meetings per year
- 5+ Pre-NDA meetings per year
- 50+ Regulatory Authority meetings per year in EU (local and EMA)
- 10+ scientific pre-consultations and consultations with PMDA (Japan) per year
- 3+ Medical Device regulatory authority meetings per year

GLOBAL DEVELOPMENT PLANS

- 5+ per year detailed full strategic product development plans
- 10+ per year "high-level" plans or detailed clinical development plans for all global regions

ANNUAL PRODUCT REVIEWS AND ANNUAL REPORTS

- 750+ Annual product reviews across a wide range of therapeutic areas written and submitted per year
- 600+ Annual reports written and submitted per year

REGULATORY MAINTENANCE ACTIVITIES

- 3,000+ CMC variations completed per year
- 250+ CMC labeling variations per year
- 4,200 clinical supply labels in 100+ countries and 50 languages
- 200+ Marketing authorisation holder transfers per year
- 200+ PSUR and DSUR safety reports per year
- 20+ DMFs and related submissions per year
- +15,000 administrative notifications (agent transfers, product information updates, etc.) per year across a wide range of countries globally

LET OUR 35 YEARS OF REGULATORY EXPERIENCE AUGMENT YOURS.

For more information, email regulatory.portal@PAREXEL.com or visit regulatory.PAREXEL.com

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