

## PRA REGULATORY AFFAIRS

### *Your Goal Is Our Goal—Successful Product Approvals*

Let PRA's Regulatory Affairs services help you navigate through your product's life cycle, from early development to post-approval requirements.

### *Our Expertise and Experience — Charting the Shortest, Quickest Route to Market*

Our Regulatory experts know the regional regulatory requirements in depth across the globe—bringing you a clear advantage for competitive product development plans, rapid study start-up and effective submissions strategies. Our senior regulatory team averages 20 years' experience in drug development and regulatory affairs.

### *We Provide:*

- Strategic regulatory consultation—preclinical to post-marketing
- Global regulatory submissions management—including electronic submission of new drug applications for marketing authorization
- Strategic and tactical support for Agency meetings and interactions
- Regulatory support to global clinical trials—from Phase I “first in human” to Phase IV

*Contact Us to Talk about  
How PRA's Global Regulatory Affairs Team Can Help You*



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## *Regulatory Services from PRA International:*



### *Regulatory strategic consultation:*

- Global consultation for Pharmaceuticals, Biologics and Devices
- Regulatory Consultation for approval/registration requirements
- Regulatory Strategic Plan Development
- Agency Meetings coordination and representation
- Gap analyses and Assessments of Scientific & Technical Data for various submissions/applications
- Due Diligence assessments
- Labeling support: Target labeling—physician and patient text
- Consultation and support for Orphan Drug, Fast Track and Pediatric Applications
- Consultation and support for Marketing Applications including CTD format
- Liaison services to Regulatory Agencies

### *Clinical trial support for New Drug / Clinical Trial Applications:*

PRA regulatory professionals around the globe provide strategic and tactical consultation for Clinical Trials Applications and associated reporting requirements.

- Study start-up consultation
- Preparation and coordination of Clinical Trial Applications, INDs
- Clinical supplies labeling consultation
- Import License Applications
- Maintenance of applications

### *Submissions publishing and coordination:*

PRA's Regulatory operations group provides a full spectrum of regulatory services to more effectively partner with our clients—ranging from rapid production of paper-based submissions to expertise in electronic submissions publishing.

- Marketing applications worldwide (i.e. MAA/NDA)
- Amendments, Supplements, Variations, Notifications and Renewals
- Annual Reports
- Updating and Consolidating Registration Files.
- Capabilities for publishing CSRs, INDs, NDAs, MAA, BLA in CTD format paper and electronic: Core Dossier TM, ISI Toolbox TM and Docutech technologies
- Quality control assurances