HPA INC
HEALTH POLICY ASSOCIATES INC

REGULATORY EXPERTISE FOR US FDA & OUS SUBMISSIONS

HPA provides solutions to regulatory challenges that confront the healthcare industry from FDA and other worldwide regulatory agencies. By working constructively with regulatory authorities, we seek solutions for our clients that resolve regulatory and compliance issues.

WORLDWIDE REGULATORY CONSULTING SERVICES

Regulatory Strategy

- Identifying device, drug, biologics, or combination product status and the appropriate regulatory classification and pre-market submission pathway in jurisdictions where the product will be marketed
- Identifying data requirements to support marketing applications, including any clinical data requirements
- Input and guidance regarding regulatory implications of desired claims and indications, including assessment of anticipated time and cost to approval and market, improving the probability of success
- Strategic interactions with regulatory authorities to confirm the planned approach and assumptions

Regulatory Representation

- FDA establishment registration / device listing activities
- FDA US agent for foreign establishments
- EU authorized representative for CE marked devices
- European medical device trial support

Submission Preparation and Support

- Pre-submission / Pre-IDE meeting involvement and support, comprehensive literature search and analysis
- Review of package prior to submission to regulatory authorities, assistance addressing agency questions, and interacting with regulatory authorities to resolve issues
- 510(k) pre-market notifications
- Investigational Device Exemption applications (IDEs)
- Premarket Approval Applications (PMAs)
- Biologic License Applications (BLAs)
- Technical files / design dossiers / clinical evaluation reports for CE mark
- Canadian license applications
- Applications in Australia, India, China, Brazil, Japan and other global markets

Post-Market Advertising, Promotion and Renewals

- Guidance and assistance with regulatory review of advertising and promotional materials
- Renewal applications in markets requiring periodic license renewals, such as China and Brazil

ABOUT HPA

Health Policy Associates has spent more than 20 years providing high quality consulting services to the medical device and biotech community, helping companies bring their innovations to market. As specialists in regulatory compliance and clinical consulting, HPA helps medical and biotech manufacturers optimize their product development processes while avoiding potential pitfalls.

From clinical trial strategy and design to precision data analysis, HPA's team of industry experts has guided leading manufacturers around the globe to regulatory success again and again, with unrivaled accuracy and efficiency. HPA enhances the efficiency with which a company executes its product development timeline by: developing strategies and plans that meet regulatory and market needs, evaluating and supplementing company resources, managing clinical and/or regulatory functions, developing and implementing quality system and compliance strategies, and assisting with venture capital financing strategies and valuation milestones.

Because of our experience focusing exclusively on the medical device and biotech industries and dealing with some of the most unique and complex products under development, our clients are assured that HPA consultants can resolve their problems and address their specific needs.

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HPA Services

HPA's goal is to provide practical and highly efficient consulting solutions to companies involved in developing new medical device technologies, pharmaceuticals or biologics. HPA's high-quality consulting services include:

- **Clinical Trial Strategy and Execution:** Protocol development/ Case Report Form design, clinical site identification, management and monitoring, database and EDC creation, data analysis, report writing, regulatory submission preparation.
- **Data Management and Analysis:** Database design and hosting, real-time data access and query resolution, customized data analysis and reporting.
- **Worldwide Regulatory Consulting:** Regulatory strategy development, project plans, FDA submission management including presentations, submissions, reports and filings, development of worldwide regulatory strategies.
- **IRO/Data Integrity Auditing:** AIP services including FDA audits and integrity reports, IRO services including OIG work plans, reviews, reporting and submissions.
- **Quality Systems/Compliance Consulting:** Quality system design, compliance strategy development, internal and supplier GMP auditing, FDA inspection assistance, risk management, medical device reporting, application of corrective/preventive action procedures, product recall support.
- **Venture Capital Investing:** VC identification, project plan and timeline development, valuation milestone development

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