WORKING TO BRING YOUR INNOVATIONS TO MARKET

HPA INC

HEALTH POLICY ASSOCIATES INC

For over 20 years, Health Policy Associates has been providing practical and highly efficient consulting solutions to companies involved in developing new medical device technologies, pharmaceuticals and biologics.

Clinical Trial Strategy and Execution

HPA offers a vast array of clinical trial services, providing a comprehensive approach to developing and implementing strategies that respond to the varied regulatory and marketplace needs of our clients. Experienced analysts guide clinical trials down the necessary path to ensure high quality results.

Data Management and Analysis

HPA provides software development and full database management services, including:

- Customized databases and applications for CAPA management, clinical data and MDR reporting
- QSR workflow analysis and database design
- EDC system and data management
- CDISC-compliant database development in SDTM and ADaM standard formats
- Clinical data entry
- Data and query management
- SAS statistical programming
- Data analysis and creation of table/figure/listing statistical analysis output
- Part 11 compliance gap analysis

Worldwide Regulatory Consulting

HPA provides solutions to regulatory challenges confronting the industry today, whether those challenges arise from FDA or other worldwide regulatory authorities. We consistently seek solutions that work for our clients by constructively working with regulatory authorities and resolving any problems associated with regulatory interactions and compliance.

IRO/Data Integrity Auditing

Because of a deep history in AIP and Consent Decree involvement, HPA has a unique, long-term relationship with the FDA that gives us insight and access into the agency's thinking on important compliance issues. HPA's capabilities in this area include:

AIP Services

- Independent FDA audit plans
- Auditing clinical sites
- Integrity reports and managing FDA communications

IRO Services

- Work plans for Office of Inspector General (OIG)
- Arrangements reviews for Anti-Kickback Statute compliance
- Reporting and submission to OIG

Quality Systems/Compliance Consulting

HPA understands that having a robust quality system in place is key to assuring the safety and effectiveness of new medical devices as they are brought to market. We work with clients of all sizes and types to ensure that their quality systems meet all FDA and regulatory requirements, providing services that run the gamut from designing and implementing new quality systems to bringing existing systems into compliance.

Venture Capital Investing

HPA serves as a valuable bridge between the venture community and companies seeking venture investors, helping VCs identify and manage investment opportunities and helping medical device and biotech companies find and work with investors. Our special relationship with the venture capital community is unique among regulatory and clinical consultants and is a valuable part of HPA's services.

Therapeutic Expertise

HPA's extensive expertise covers a wide range of therapeutic areas, including:

- Wound Care
- Cardiovascular Devices
- Diagnostics/Imaging
- Orthopedic Implants
- Cosmetic Treatments
- Stem Cell Treatments
- General Surgery
- Gene Therapy
- Chemotherapy Delivery Systems
- Ophthalmic Therapies

The HPA Difference

- Strong, successful relationships with the VC community, medical/biotech industry partners, and FDA review and compliance staff
- Uniquely client-focused culture, focused on ensuring client success
- Diverse background covering a wide range of therapeutic areas and project types
- Cross-functional, highly trained operational teams

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Since it was founded in 1992, Health Policy Associates, Inc. has been dedicated to providing high quality consulting services to the medical device and biotech community, helping our clients bring their innovations to market. Originating from an impressive compliance background, HPA has, over the years, expanded its areas of expertise to include clinical consulting and quality assurance, and has developed extensive experience dealing with some of the most unique and complex products under development. From clinical trial strategy to precision data analysis, HPA's team of industry experts has guided medical device and biotech companies around the globe to regulatory success, with unrivaled accuracy and efficiency.

CONNECT WITH HPA

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