HPA INC
HEALTH POLICY ASSOCIATES INC

HELPING BIOLOGIC, CELLULAR AND GENE THERAPY COMPANIES ADVANCE NOVEL THERAPEUTIC TECHNOLOGIES

Recent progress in cell and molecular biology, and improvements in our understanding of both stem and gene cell therapies have delivered us to a whole new frontier in medicine. The challenge is that these products are extremely diverse, each with their own biology and immunologic properties, often times with no predicate to guide regulatory or clinical pathways. HPA can provide expert assistance in overcoming these unique challenges.

WHY HPA? THE HPA DIFFERENCE

For the past 23 years, HPA has been providing regulatory and clinical guidance to biologic, cellular and gene therapy companies through our proven technology development process.

A Truly Client-Driven Culture

- Extremely responsive to client requests.
- Completion of projects within set deadlines is our highest priority.
- Incredibly customizable and flexible.
  - A client's needs and goals are HPA's needs and goals.

Strategies and Pathways Are Critical

HPA has the experience to formulate the best regulatory, quality and clinical strategies for your company and get you on the most efficient regulatory and clinical pathways right away.

Speed to Market

HPA knows that time is money and often the difference between success and failure. So we focus on helping our clients speed up the whole process, providing:

- Mutual planning procedures that ensure quicker client interactions
- Swift familiarization with our clients' processes, culture and capabilities, enabling the alignment of core competencies and eliminating redundancies
- Maximized value to the client, through assembly of the proper team around each project
  - By ensuring ongoing communication and seamless interactions, HPA has established an unparalleled track record of happy, successful clients.
- Reduction in start-up time and costs, by leveraging HPA's broad industry knowledge and experience

Strong Understanding of the Requirements and Expectations of Regulatory Bodies

Because regulating agencies and industry standards continue to evolve, HPA constantly strives to be on the leading edge of those changes.

- Weekly interactions with regulators gives HPA insight and experience in dealing with and understanding these requirements.

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.

Health Policy Associates, Inc.
690 Canton Street, Suite 302
Westwood, MA 02090
+1 (781) 329 2993

Office Locations:
Westwood, MA
Cambridge, MA
Silicon Valley, CA
San Antonio, TX

info@healthpolicyassociates.com
www.healthpolicyassociates.com

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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