HPA INC
HEALTH POLICY ASSOCIATES INC

TIMELY, SUCCESSFUL FDA APPROVALS FOR COSMETIC INDICATIONS

Successfully gaining FDA approval in the highly regulated field of dermal fillers and other cosmetic medical treatments requires expertly executed clinical trials, highly accurate data collection and analysis, and a thorough understanding of the application process. Health Policy Associates (HPA) provides its sponsors with a unique culture, which enables flawless and timely execution that is unrivaled in the industry.

HPA brings an unmatched breadth of expertise guiding medical and biotechnology manufacturers through the end-to-end product development process, with an expertise in cosmetic fillers and neurotoxins for cosmetic indications. HPA satisfies their sponsors' need for speed.

HPA - Guiding the End-to-End Development of Cosmetic Products

For more than twenty years, HPA has been providing consulting expertise to the end-to-end process of bringing innovative new medical devices and biologics to market. HPA's experience includes:

- Supporting clients through FDA PMA general and plastic surgery panel meetings
- Guiding dozens of IDE, 510(k) and PMA applications through the general and plastic surgery branch of FDA
- Executing numerous trials including CRF design, database build, site training, monitoring, data analysis and report writing for a wide variety of indications including:
  - Nasolabial fold correction
  - Brow lift
  - Lip augmentation
  - Glabellar line correction
  - Dorsum of hand correction
  - Cheek augmentation
- Designing customized electronic clinical databases for multiple cosmetic indications
- Designing, hosting and analyzing results of Independent Photo Reviews
- Conducting mock audits and training site staff in preparation for FDA inspections, resulting in 'no findings' inspections
- Successfully submitting SAS coding and analysis for several indications to FDA

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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