HPA INC
HEALTH POLICY ASSOCIATES INC

TIMELY, SUCCESSFUL CE MARK & FDA APPROVALS FOR AESTHETIC INDICATIONS

Successfully gaining CE Mark & 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:

- Full CE Mark Dossier or PMA submission support
- HPA's experience includes multiple successful CE Mark and FDA approvals with several in process
- 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
  - Marionette line correction
  - Lip augmentation
  - Glabellar correction
  - Dorsum of hand correction
  - Cheek augmentation
- Designing customized electronic clinical databases for multiple filler 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 for KOLs
- Successfully submitting SAS coding and analysis for several indications to FDA, focusing on validated effectiveness scales
- Training and qualifying reviewers for quality results with high intra and inter rater kappa scores

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HPA's Capabilities for CE Mark Approval of Aesthetic Technologies

HPA is a full-service consulting firm providing expertise to the end-to-end process of bringing innovative new technologies in the aesthetic space to market. HPA's experience includes:

Dermal Filler CE Mark Experience

- Positioned Radiesse CE Mark Approval for Bioform for multiple indications
- Positioned CE Mark approval for US-based dermal filler company (under active NDA) for multiple applications
- Positioned CE Mark approval for OUS-based dermal filler company (under active NDA)
- Lead author in multiple CE Mark submissions currently pending approval

Overall CE Mark Experience

- Identification of applicable CE Mark Directives
- Devising strategies for assessing and selecting Notified Bodies
- Assessment and assignment of appropriate device classifications
- Full service support for compiling and submitting a CE Mark design dossier/technical file
- Design/implementation of a compliant Quality Management System (QMS) consistent with ISO 13485:2016
- Preparation/review/editing of QMS documentation/SOP's, user manuals and labelling
- Identification of applicable standards and testing requirements/strategies
- Full service CRO for clinical trials in support of CE Mark approval and Post Market Clinical Follow-up (PMCF) Studies
- Implementation or assessment of Post Market Surveillance (PMS) activities, including PMS SOP, device specific PMS Plans, and preparation of Clinical Evaluation Reports (CER's)
- Preparation for Notified Body audits
- Responses to audit or technical file non-conformances issues by Notified Bodies
- Biostatistical expertise with dermal filler
- In-house SAS programmers

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 plans that meet regulatory and market needs, evaluating and supplementing 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
San Antonio, TX
Silicon Valley, CA

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, CE Mark & 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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