HPA INC
HEALTH POLICY ASSOCIATES INC

HELPING ORTHOPEDIC & ORTHOBIOLOGIC COMPANIES ADVANCE NOVEL IMPLANTS & REGENERATIVE THERAPIES

Helping Orthopedic & Orthobiologic Companies Advance Next-Generation Regenerative Technologies

For more than 30 years, HPA has partnered with orthopedic and regenerative medicine companies to successfully navigate the complex regulatory and clinical pathways required for FDA approval.

From first-in-human studies through pivotal IDE clinical trials and PMA, De Novo and 510(k) submissions, HPA provides the regulatory strategy, clinical expertise, and project leadership needed to efficiently move innovative orthopedic technologies from concept to commercialization.

Whether developing cartilage repair implants, bone regeneration technologies, spinal fusion devices, orthopedic biologics, soft tissue repair products, or combination products, HPA serves as a trusted strategic partner committed to reducing development timelines, minimizing regulatory risk, and maximizing the probability of FDA success.

HPA's Orthopedic & Orthobiologic Expertise

HPA has extensive experience supporting companies developing innovative orthopedic and regenerative medicine technologies including:

Orthopedic Implants

- Cartilage repair technologies
- Osteochondral implants
- Meniscus replacement devices
- Joint preservation technologies
- Knee and shoulder implants
- Extremity orthopedic devices
- Fracture fixation systems
- Bone void filler

Orthobiologics & Regenerative Medicine

- Bone graft substitutes
- Cell-based therapies
- Stem cell products
- Placental and amniotic tissue technologies
- Growth factor therapies
- Injectable biologics
- Tissue-engineered implants
- Combination products

Spine Technologies

- Spinal fusion devices
- Interbody fusion systems
- Bone graft materials
- Motion preservation technologies
- Disc regeneration technologies

Sports Medicine

- Soft tissue repair devices
- Tendon and ligament repair
- Arthroscopic technologies
- Suture anchor systems

ABOUT HPA

Health Policy Associates has spent more than 30 years providing high quality consulting services to the biologic 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 biologic 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.
3 Allied Drive, Suite 210
Dedham, MA 02026
+1 (781) 329 2993

Office Locations:
Dedham, MA
Austin, TX
New Jersey

info@healthpolicyassociates.com

www.healthpolicyassociates.com

Regulatory and Clinical Leadership Across the Entire Product Development Lifecycle

- FDA Regulatory Strategy
- Q-Submissions and FDA Meetings
- IDE Applications
- PMA, De Novo and 510(k) Submissions
- Clinical Trial Design
- Risk Management (ISO 14971)
- Clinical Monitoring
- Data Management & Biostatistics
- Imaging Core Lab Coordination (MRI/X-ray/CT)
- Safety Management
- Inspection Readiness
- Global Regulatory Strategy

Orthopedic Clinical Operation

- Surgical site coordination
- Operating room logistics
- Investigational device accountability
- Implant traceability
- Surgeon training programs
- Imaging management (MRI, X-ray, CT)
- Long-term patient follow-up

Data Management & Biostatistics

- EDC development
- Database design
- Data management
- Statistical Analysis Plans
- Clinical Study Reports
- FDA submission datasets

HPA INC
HEALTH POLICY ASSOCIATES INC