

# PINNACLE



## Life Sciences Consulting Services

### Regulatory & Quality Systems

- Global Regulatory Assessments & Submissions
  - Premarket Notification 510(k) and De Novo
  - Investigational Device Exemption (IDE)
  - Premarket Approval (PMA)
  - European Technical Document
  - Presubmissions
- Interface with FDA & Notified Bodies
- Clinical Evaluation Reports & Clinical Protocol Development
- Quality System Remediation, Implementation & Maintenance compliant with 21 CFR 820, ISO 13485, MDSAP & EU MDR
- Support FDA Inspections and Corrective Actions
- Supplier & Internal Audits
- Tissue Auditing, Licensing & Registration
- Due Diligence & Integration Planning

### Valuation (FMV) Services

- HCP/KOL Compensation Fair Market Value Opinions
- HCP/KOL Stratification/Tiering
- Licensing & Royalty Valuations
- Joint Venture, Affiliation, & Collaboration Agreement Design & Valuation
- Business & Capital Asset Valuations
- Intellectual Property, Patents, Trade Secrets, & Trademark/ Tradename Valuations
- Data Acquisition/Licensing Valuations
- Co-Promotion, Marketing, & Distribution Agreement Valuations
- Clinical Research & Clinical Trials Valuations
- Real Estate Valuations

### Strategic Services

- Business Plan Development
- Strategic Planning & Pitchbook Development
- Market Assessments
- Strategic Planning for Multi-Partner Collaborations
- Feasibility Studies
- Evaluation of Licensing Models
- Compliance Program Review/ Restructuring
- Compliance Coaching / Focused Support

Pinnacle provides an array of services to support a variety of life sciences organizations, including medical device, pharmaceutical, biologic, and tissue companies. Our team of experts – including our life science professionals at Pinnacle’s affiliate company MRC Global (MRC) – deliver comprehensive solutions for regulatory, quality, clinical, transactional, physician leadership, and key opinion leader advisory services. MRC is a trusted advisor to US and global life science companies and works in collaboration with Pinnacle’s other service lines to provide an unparalleled range of consulting, valuation, regulatory compliance, and value-based services. We have blended the expertise of MRC’s professionals with the service offerings provided by Pinnacle’s professionals to develop a life science service line that goes beyond regulatory management and extends to valuation, strategy, and other consultative advisory services.

For more information about our services  
visit us online at [AskPHC.com](http://AskPHC.com) or [AskMRCGlobal.com](http://AskMRCGlobal.com)

### Pinnacle Family of Companies

