Lifescience Business Solutions
IMPROVING PATIENTS LIVES

Case Summary

TECHNOLOGY DEVELOPMENT - RENAL CARE

Advisor to CEO and Program Lead

TECHNOLOGY

Bioresorbable collagen-based drug delivery scaffold combination device serving unmet Hemodialysis patient needs with improved vascular access.

COMPANY

Private equity held start up focused on clinical-stage vascular drug-device in renal care.

CHALLENGE

Advance product development program, assets and resources for a pre-market pathway aligned with clinical trials, CMC/GMP regulatory standards, corporate timeline and investor expectations.

ENGAGEMENT

Delivered product development and operational roadmap in support of clinical/regulatory demands and strategic expectations. Specific focus called for evaluation of CMC data requirements supporting stability protocols, pre-NDA activity and remediation of manufacturing process capabilities in line with GMP validation and testing protocols.

Proposed and integrated contract manufacturing (CMO) alliance to enable attainment of clinical supply, regulatory milestones, supply chain readiness and improved P&L economics.

OUTCOMES

- *Enhanced organizational alignment and capability toward critical milestone attainment.*
- *Stabilized product supply in support of clinical demand.*
- *Orchestrated CMC/GMP compliance initiatives including Quality Plan, Process Validation, Stability study.*
- *Executed technology transfer via integrated CMO/Distributor alliance for clinical & commercial readiness.*
- *Improved positioning for pre-NDA regulatory review.*
- *Established economic transparency in support of commercial projections & post launch expectations.*
- *Improved board level visibility and investor confidence.*

LESSONS

- *Identification and fulfillment of core talent needs.*
- *Importance of parallel stakeholder input on CMC/GMP requirements.*
- *Criticality of proper CMO alignment and integration on technical, business and cultural parameters.*
- *Importance of testing go-to-market scenarios, requirements and capabilities.*

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