Accelerating the Commercialization Process

Joint Venture Medical

Joint Venture Medical (JVM) was created to assist emerging medical device and pharmaceutical products companies by providing experience and expertise to support product development and launch, sales and distribution, clinical trials, regulatory plans and submissions, and overall corporate business and finance models.

JVM was founded in 2015, by merging the successful service offerings from four companies: AJW Technology Consultants, Inc. (AJW); ScribeFirst, LLC; Orange MedTech, LLC; and Race Rocks Management Inc. In order to best serve our portfolio companies we have strategically aligned with industry leaders to create an end-to-end solution, from seed to sale. Our markets include the Americas, Asia, Australia, and Europe.

About the Partners
AJW provides regulatory and quality management services to over 400 clients worldwide, providing regulatory and quality management services.

OrangeMedTech specializes in new product and technology launches. It has put together 40+ strategic partnerships and sales channels within several Healthcare sub-specialties to capitalize on markets across the World.

ScribeFirst, provides FDA Support, Agent service, and Clinical Trial services to the global marketplace. ScribeFirst is recognized for its experience and vision with respect to assessment and development of reimbursement coding and strategies.

Race Rocks Management Inc. (RRM) is a management consulting service providing experience and expertise in Business Development, Product Development, Strategic Planning, and Finance.

Joint Venture Medical

Consulting Services

Corporate and Business Planning
Strategic planning services to assist with corporate structure, financing, investors, messaging and overall branding

Reimbursement strategy
Assessment of product categorization, existing codes, and new code applications

Product Development
Product definition and refinement services, software and hardware development, quality system compliant development

Sales and Distribution
Market research, branding, advocacy, new product launch, distribution and sales

Regulatory strategy
Global device registrations, post market surveillance, access to former US FDA staff

Clinical Trial Strategy and Management
Protocol development, statistical analysis, medical writing, clinical evaluation, human factors, trial monitoring, data management

Quality Management
ISO systems structure and registration, FDA Inspection preparation, internal and supplier audits, contract manufacturer selection

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Consulting Services Detailed:

Corporate Strategic Planning • Corporate finance strategy • Business Modeling • Investor pitch • Website design and messaging • Budget creation	**Clinical Trials** • Protocol Development • Human factors (HF) studies • Statistical analysis • Trial data management • Trial management, monitoring, and auditing • Medical writing • Clinical expert • Clinical evaluation (literature review)

Product Development
• Product concept and early stage feasibility
• Product definition and design (visual / concept)
• Risk management
• Software development
• Product development
• Design Engineering
• Design control and design history file
• Biocompatibility evaluations
• Human factors engineering (HFE)
	Regulatory Strategy and Compliance
	• Medical Devices
	  • 510(k) Premarket Notification
	  • Premarket Approval (PMA)
	  • Investigational Device Exemption (IDE)
	  • Automatic Class III Designation (De Novo)
	  • FDA Establishment Registration and Device Listing
	  • In-country representation and associated regulatory submissions

Sales and Distribution Consulting
• Sales Strategy
• Marketing Strategy
• Distribution Strategy
• Market Overview
• Initial Market Interview
• Business Plan
• Direct Sales
• Overview Management for Distribution
• Advocacy Management for Distribution
• Contracting of Key Opinion Leaders
• Test Market Sales
	Regulatory Strategy and Compliance
	• Pharmaceuticals
	  • Investigational New Drug (IND)
	  • New Drug Application (NDA)
	  • Abbreviated New Drug Application (ANDA)
	  • Electronic Common Technical Documentation (eCTD)
	  • Facility Registration and Drug Listing
	  • FDA Labeler Code Acquisition
	  • Drug Master File (DMF)
	  • In-country representation and associated regulatory submissions

Reimbursement Strategy • Reimbursement code identification • Reimbursement code consensus planning with agencies • Gap assessments • Strategy building	**Quality Systems Management** • Gap analysis, internal and supplier audits • Facilitation of FDA inspections • Quality systems management (FDA, ISO, MDD) • Unique device identifier (UDI) • Training and education • Electronic Quality Management System