

PMC Medical

SMART Solutions™ to outsourced
manufacturing of precision
medical components

December 9, 2009



- ✿ Continuous Operation & Ownership Since 1929
- ✿ Privately-Held
- ✿ Financial Strength
 - ✿ Consistently Strong Balance Sheet
 - ✿ Support Customer Growth Through Internal Investment
- ✿ Technical Leadership
 - ✿ Manufacturing Precision Components
 - ✿ Specialty materials
 - ✿ Niche market strategy
- ✿ Emphasis on Operational Excellence
 - ✿ Operator Training
 - ✿ Integrated Plant Maintenance System
 - ✿ Metrics driven operation



Our First Medical Opportunity

- ✿ PMC asked to provide DFM and manufacturing engineering support for OTC Pharmaceutical Device
- ✿ Engineering services contract (6 months)
- ✿ Customer ultimately chose an alternate, non-molded design
- ✿ Opened our eyes to:
 - ✿ Regulatory requirements
 - ✿ Quality system requirements

Our Second Medical Device Opportunity

- High Volume Disposable

- ✿ Excellent feedback from the prospective customer
 - ✿ PMC Systems
 - ✿ Technical capabilities
- ✿ PMC determined that high volume commodity medical business did not fit our core strengths

The Decision to Take the Next Step...2006 into 2007

- ✿ Positive feedback from medical OEMs
- ✿ Encouragement from our external Advisory Board
- ✿ Desire to diversify into a new market

Developed Plan

- ✦ Assigned dedicated project manager
- ✦ Cross-functional team
- ✦ Prepared a detailed scope of work
- ✦ Developed budget and project timeline



Gather Market Intelligence

- ✦ Spoke with Industry Leaders
- ✦ Utilized the BioOhio network
- ✦ Attended MD&M trade shows + others
- ✦ Gained a deeper understanding of:
 - ✦ Quality Systems
 - ✦ Risk Management
 - ✦ Our best fit within the medical market
- ✦ Benchmarking and industry assessment & feedback
 - ✦ Confirmed that our business/quality/manufacturing systems were more than adequate to meet the medical market requirements



Implemented cGMP & ISO 13485:2003

- ✦ Managed using a combination of internal resources and consultants
- ✦ Integrated medical quality system requirements into one quality system
- ✦ Passed the ISO 13485 audit with no negative observations













Designed as a Plant within a Plant

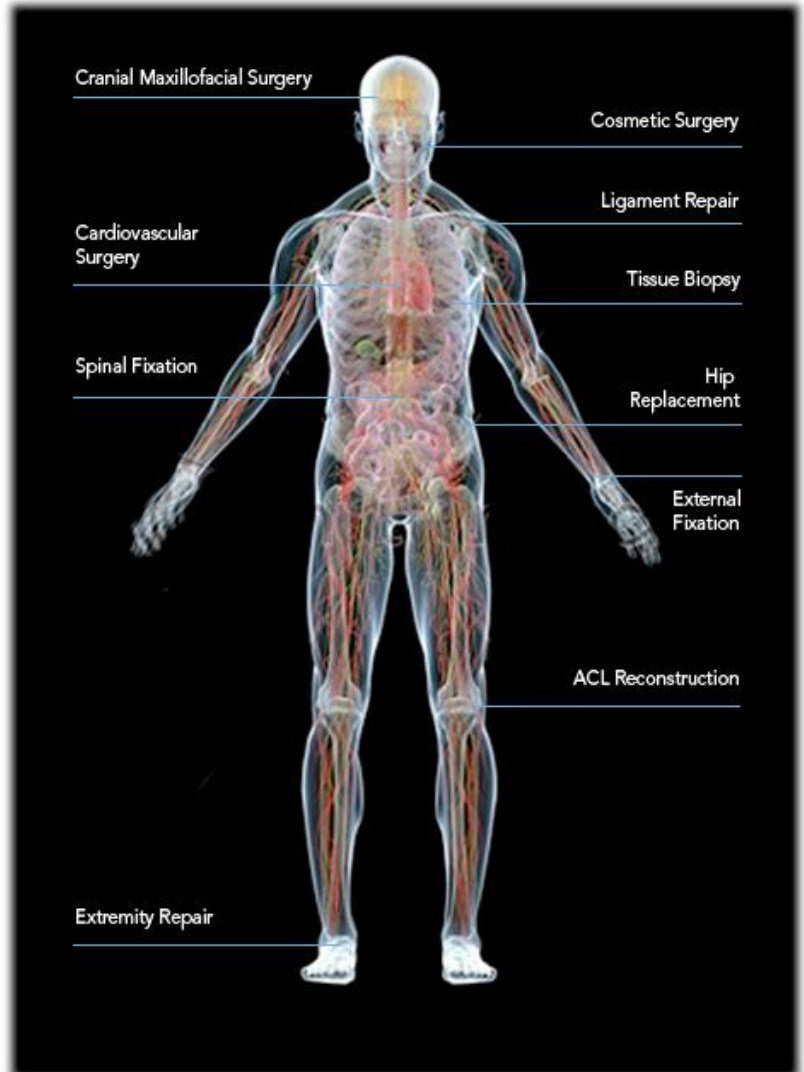
- ✿ Clean Room – best in class
 - ✿ Show knowledge of the manufacturing environment requirements for medical
 - ✿ Isolated from the rest of the plant
 - ✿ Show a stark difference between medical and non-medical operations
- ✿ Offices, quality and tooling located adjacent to Medical Manufacturing



Execute the Plan

- ✿ Work initiated prior to having any customer commitment
- ✿ Drove internal execution of the plan
 - ✿ Executive leadership and ownership involvement, monitoring and support
- ✿ Pursued some customers as facility & systems were developed

-  Orthopedics
-  Sports Medicine
-  Spine
-  Cardiovascular
-  Cosmetic
-  Tissue Biopsy
-  Diagnostics & Microfluidics
-  Drug Delivery
-  Wound Closure
-  Trauma
-  Women's Health
-  Surgical Devices & Instrumentation



Critical to assess core differentiating capabilities

PMC Medical Market Niches

- ❖ High-Temperature, specialty materials
 - Implantable Biomaterials
 - High precision components (+/- 15 microns)
 - Metal to plastic conversions
- ❖ Regional surgical device & instrumentation
 - Ohio is one of the fastest growing regions for medical devices
 - Indiana's dominant orthopedic presence
 - PMC existing internal assembly and secondary capabilities fit requirements for surgical devices and instrumentation



- ✿ (9) medical customers – and even mix between large OEM, Medium OEM, and small OEM or startup companies
 - ✿ 5 of 9 Biomaterials
 - ✿ 7 of 9 Regional
 - ✿ 5 of 9 Complex processing/hyper-precision
 - ✿ 5 of 9 Complex value-add surgical device/instrumentation
- ✿ Added capacity and value-add capabilities
 - ✿ Special vertical press for complex insert molding
 - ✿ Expanded assembly, packaging, and labeling capacity
 - ✿ Added sterilization management
- ✿ Continuously testing the strategy and asking of customers and applications fit with our niches and strengths
- ✿ We are seeing greater success in higher value/mid-volume opportunities
- ✿ Our focus on implantable applications is extending our reach beyond the typical regional barriers for injection molding



- ✿ It starts at the top – The ownership and senior management need to champion the conversion to medical. The commitment of the rest of the organization will be a direct reflection of the commitment of the senior management.
- ✿ Know your niche(s) and stick to them – “Medical” is a big space with many players
- ✿ It takes time – be patient
- ✿ Finding the right customer can be a catalyst
- ✿ You do not need to hire outside resources for all medical development, train good people and they will respond
- ✿ Be prepared for increased activity and man hours to address:
 - ✿ NDA review and approval
 - ✿ Customer surveys
 - ✿ Liability insurance
 - ✿ Customer audit visits
- ✿ Attention to detail – medical customers look for suppliers with a culture of diligence and a respect for the quality system requirements
- ✿ Continuous improvement initiatives are essential. Margins in the medical market are being challenged at every level of the supply chain.
- ✿ Medical OEM companies are looking for suppliers with a strategy of ongoing capital investment to support new technologies. Knowing which of the new technologies is a fit for your business niche is essential.

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