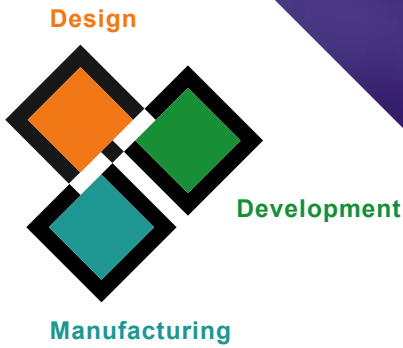


What does it take to get from concept to clinical?

Insight,
Experience,
and Expertise.

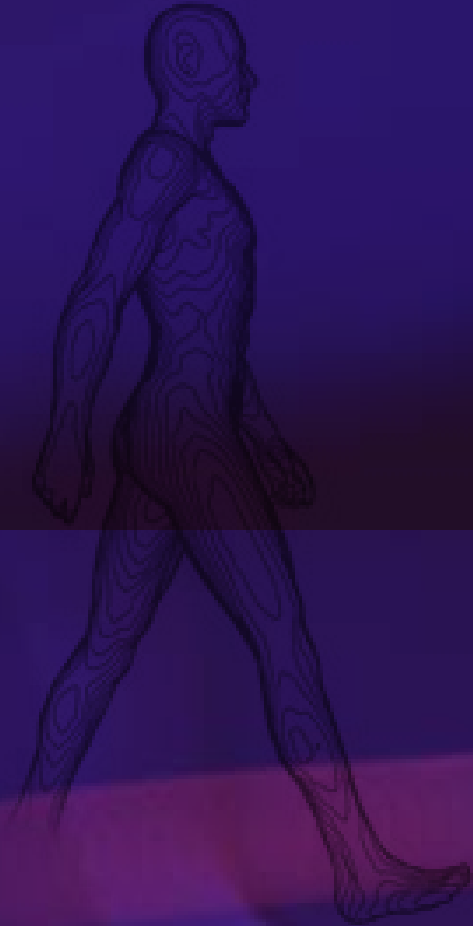


Time and Time Again

TDC Medical provides design, development and manufacturing services for the creation and production of innovative disposable and reusable therapeutic medical devices.

Experience Matters

TDC Medical was founded by a group of veterans in the medical device industry. The Founders, and the many people who have joined the Company, have an enormous breadth of experience in every aspect of medical device product development, quality systems and production.



The Device Company



*concept to clinical*SM



With facilities in both Marlborough, MA and Sunnyvale, CA, TDC provides the entire range of services necessary to take a product from Concept to Clinical including: concept creation, delivery of working prototypes for evaluation, design refinement, generation of necessary quality & regulatory documentation, and assembly, packaging, and sterilization to clinical devices.

These services are offered in a completely modular fashion. TDC is happy to work with you on any or all phases of the process. Whether your needs are small or great, you will receive the same committed service and attention from TDC.

Services Include:

Concept / Brainstorming

- Group selection – TDC staff & outside specialists
- Problem statement – the vision, the challenge, and the rules
- Poster concept sketches – energetic concept sketching and discussions, building upon one another
- Ranking and selecting – variables defined and prioritized
- Documenting and recommending solutions to client

Design

- Concept generation
- Engineering
- Analytical studies
- Prototyping
- IP Review
- Testing design FMEA
- Device cost estimate
- Regulatory strategies
- Design review

Development

- Concept generation to support design or to help strengthen IP portfolio
- Model generation
- Concept evaluation through prototyping & analysis
- Design for manufacturing
- Design verification testing
- Biocompatibility testing
- FMEA
- Packaging development
- Development of product for clinical trials
- Validation & verification protocol development and execution
- Regulatory submission
- Documentation generation ranging from drawings to complete design/device history files
- Final manufacturing strategy

Quality & Regulatory

- Certified ISO 13485:2003
- 2 clean rooms
- Experienced and skilled QC/RA personnel
- Customize quality systems to meet specific company needs & business objectives
- Audit suppliers to ISO 13485:2003 and QSR
- Conduct internal audits
- Develop procedures and processes for project support
- Regulatory submission support, including drafting of submissions
- Oversight and ongoing support of contract sterilization vendors
- Biocompatibility and sterility testing
- Clean room and environmental monitoring
- Document control through the Document Change Order process
- Completed documentation packages:
 - Design History Files
 - Device Master Records

Manufacturing

- Process development
- Design & assembly tools
- Process FMEA's
- Process & product validation
- Design review for manufacturability
- Manufacture of clinical & commercial product

For more information please contact us at:

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