

## Netspective Business Consulting and Regulated IT Services for Medical Device Manufacturers and Biomedical Solutions Firms

Netspective has over 14 years of experience in the biomed industry helping companies focus on delivering the right solution to market in a cost-effective and timely manner and helping facilitate and manage the right strategic partnerships to provide revenue, growth and industry extensibility.

We provide services to all aspects of the biomed industry, working with medical device companies, turnkey manufacturers, regulators, hospital users, and government agencies. Our breadth of experience and expertise is extensive, allowing us to address strategic and tactical issues around innovation, conceptualization, design, development, manufacturing, market preparation, regulatory validation, clinical validation and launch of biomed devices. We have a very deep understanding of regulatory environments in the US and Europe and intimately understand the customer use cases and product utilization nuances that exists within each market segment. Combined with our expertise in healthcare information technology and innovation processes, we help our biomed customers extend the life of existing businesses and product portfolios and/or establish new lines of growth through new businesses and market creation. By helping to bring comprehensive solutions to market whose value proposition goes well beyond a traditional device, we provide revenue and growth extensibility.

Our goal is to help our customers in all facets of their operations to help address issues with existing product portfolios and bringing new products/solutions and related businesses to market. Our model is extremely flexible, allowing the customer to determine the level of involvement they require from Netspective and being able to throttle up or throttle down the expertise and output being requested. Our processes allow us to be interjected at any stage or phase of the life cycle and help bring successful resolution to issues at hand.



Our Services for the biomed industry are extensive and range from complete turnkey engagements where Netspective can provide services from A-Z to very targeted and specific services:

- ▶ Regulated product portfolio analysis and management
- ▶ Business/product creation strategy development
- ▶ Innovation process facilitation, creation, and management
- ▶ New business/solution creation modeling and fiscal projections
- ▶ Integration and data/information/IT strategy and solution creation for both regulated and unregulated components
- ▶ Vendor selection and RFP process management
- ▶ Requirements and specifications creation, risk analysis, and product management
- ▶ Solution architecture and design for safety critical systems
- ▶ Regulated IT security and deployment strategies
- ▶ Hardware engineering expertise for rapid prototyping and product development (electrical and mechanical)
- ▶ Connectivity strategy, architecture, and design (networks topology, cloud based solutions, and RF expertise)
- ▶ Embedded code expertise in design, development, and selection of operating systems.
- ▶ Enterprise server software, database design, development, optimization, testing / QA, and deployment
- ▶ FDA requirements comprehension and communications.
- ▶ Quality system analysis, creation, resolution management
- ▶ Regulatory and security strategy and analysis
- ▶ Market analysis and customer validation services
- ▶ Manufacturing process validation
- ▶ Manufacturing process efficiency and streamlining (Lean Six Sigma)
- ▶ Facilitating production and manufacturing relationships

Netspective understands the needs of the biomed industry and the transformations taking place in the marketplace. Combined with its comprehensive expertise and dynamic engagement model, we provide our customers with the best possible solution to their issues and can rapidly adopt and scale according to their needs. Our goal is to help you build a better business, with the least amount of risk, in the most flexible manner possible.