

Guadalupe Bend Consulting LLC

Providing Expertise to the Medical Device Industry:

- *Operations*
- *Quality*
- *New Product Commercialization*



Jay McElhenney
Owner / Principal Consultant

Background:

- 30+ years in the medical device field primarily in manufacturing operations (internal plant and external contract manufacturing), new product commercialization, quality engineering and quality systems.
- 6+ years with Vidacare, a successful medical device start-up and growth company focusing on intraosseous vascular access and bone biopsy devices. Part of the leadership team implementing significant company growth in the positions of Director, Product Quality and Commercialization Services and Vice President, Manufacturing and Quality.
- 6+ years with KCI as Director, Global Quality Systems and Director, R&D Engineering Services.
- 11+ years with Johnson & Johnson (Ethicon Endo-Surgery and Cordis) in leadership roles guiding new product commercialization, contract manufacturing, internal manufacturing, business development and marketing.
- 4 years with Bard Electro Medical Systems in R&D.
- BS Electrical Engineering and MBA from the University of Colorado.

Expertise and Capabilities:

- Full quality system implementation and management, including design control, complaints, CAPA, supplier quality assurance, risk management and auditing.
- Quality engineering including root cause analysis, product & process qualification and statistical analysis.
- Implementation and management of contract manufacturing and supply chain.
- Domestic and international product distribution and logistics.
- Internal plant manufacturing operations.
- New product commercialization, including project management and new product development process.
- Business development.
- Support to the start-up process and path to commercialization.

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