

MEDICAL DEVICE OUTSOURCING SOLUTIONS

Dishnow & Associates

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Scott Pletzer has over twelve years of accomplished quality and engineering experience with medical device companies including Becton Dickinson, C.R. Bard, Boston Scientific, and West Pharmaceuticals. He is a versatile quality professional adept with broad technical aspects of Quality System Regulations (QSR) and ISO 9001/13485 requirements related to the development, scale-up, commercialization, and maintenance of medical devices. Scott has hands-on experience with quality systems, internal & external audits, CAPA and nonconformance systems, equipment & process validation (IQ, OQ, and PQ), test method development, capability assessment, document control systems, FMEAs, failure investigations, statistical analysis, supplier auditing, and complaint handling.

Four years ago, Scott co-founded CARZER Technologies, LLC. CARZER offers a broad array of medical device outsourcing solutions and is committed to assisting organizations regulated by both ISO standards and FDA regulations.

He holds a bachelor's degree in Mechanical Engineering from West Virginia University, and a master's degree in Bioengineering from Clemson University. Scott is a Certified Quality Engineer (CQE) by the American Society for Quality (ASQ) and also a certified ISO 9001:2000 Lead Auditor.

Services offered include:

- **Quality Systems Implementation & Management**
- **Compliance Assessment & Readiness**
- **Training & Development**
- **Regulatory Support**
- **Contract Engineering & Manufacturing**
- **Supply Base Management**