

## OUR SERVICES

### QUALITY MANAGEMENT SYSTEMS

- New standard implementation
- Configuration management
- Training programs
- Document control
- Start-up systems
- System clean-up

### COMPLIANCE

- Compliance comprehension
- Mock audits (including PAI)
- Audit findings resolution
- Risk management

### REGULATORY

- Regulatory Comprehension
- Submission preparation
- Submission review
- Testing

### CONTRACT ENGINEERING

- Development
- Validation
- Process
- Design

### SUPPLY-BASE MANAGEMENT

- Assessment and qualification
- Contract Preparation
- Audit Management
- Monitoring



...understands the needs of today's changing industry. We provide an array of outsourcing solutions to support organizations regulated by ISO and the FDA. Let us be your solution experts.

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## FAQs

### What are the benefits of outsourcing?

Shorter time-to-market, less expense, more efficiency. Not every organization has the capabilities and resources to effectively commercialize medical devices. Often, the need is short-term and project related, further justifying the need to outsource.

### When do I know my organization requires outsourcing?

Most organizations already have a need for outsourcing as evident by projects that are over-budget, exceed timelines, or fail to meet deliverables. It is important to establish the need for outsourcing prior to embarking on new projects, through an assessment of the current capabilities and resources against project requirements.

### How do I choose an outsourcing organization?

Your organization must be comfortable and able to express your expectations, to ensure project success. CARZER recognizes the criticality of the relationship with the organization and encourages your organization to ensure the proper fit.

### What qualifies CARZER to help me with my outsourcing needs?

CARZER offers a staff experienced in all aspects of medical device manufacturing. Our staff has extensive experience as both device manufacturers and suppliers, so we understand and appreciate the relationship with an outsourcing organization.