

Led by a diverse executive team, RMC Pharmaceutical Solutions offers clients access to over 85 years of combined pharmaceutical/biotech, product development and quality/compliance experience. Services, from consultation through project execution, are available in:

### **PRODUCT & PROCESS DEVELOPMENT**

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- CMC for IND, NDA and BLA
- Timelines, budgets, advanced planning and decision-making
- Product formulation
- Process development for API (including bioprocesses) and final dosage forms
- Drug/device combination products

### **FACILITIES**

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- Design Consultation
- Construction Monitoring
- Commissioning and Validation

### **STRATEGIC PLANNING**

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- Product development
- Quality/Compliance
- Intellectual property
- Business development

### **DUE DILIGENCE EVALUATION**

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- Chemistry, Manufacturing and Controls (CMC)
- Intellectual property
- Quality/Compliance

### **QUALITY SYSTEMS**

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- GxP (i.e. GMP, GLP, GCP and QSR) regulations
- SOPs and change-control
- Master manufacturing & testing documentation
- Quality Control
- Stability and Training programs

### **PROJECT MANAGEMENT**

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- Facility construction and start-up
- Technical transfer
- Contract supplier management
- CMC development
- Clinical trials materials management
- Validation
- Compliance systems development
- Quality systems tracking

### **COMPLIANCE**

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- US and international GxP supplier and service provider compliance audits
- Gap analyses and internal audits
- Mock Inspections
- Comparative system analysis (e.g. ISO 17025 vs. GMP)
- Supplier Quality Agreements
- Compliance Enhancement Plans

### **VALIDATION & CALIBRATION**

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- Product, process, systems, equipment and analytical method validation
- Equipment calibration, including master plans, scheduling/tracking and certification

### **ANALYTICAL SERVICES**

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- Analytical method development or optimization
- Qualification (pre-validation) or parameters, additional sample types, etc.
- Design of method validation protocols
- Comparison of techniques
- Troubleshoot “problem” methods
- Documentation (procedures, technical reports, etc)
- Technology transfer
- Specification development
- Production and processing troubleshooting, and problem solving

**Call 303-554-0308**

**or email**

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\*15-25% discounts in pricing offered to Fitzsimons tenants



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