

# IT REGULATORY COMPLIANCE and QUALITY ASSURANCE

a Life Sciences offering



RCM specializes in providing innovative options to pharmaceutical, medical device and biotechnology companies in need of guidance, support or remediation of quality, compliance and business initiatives.

Our proven team of subject matter experts recognizes that each RCM customer faces unique challenges in a regulated environment. Through the SME leadership, RCM's solutions are consistently flexible, scalable and customizable.

## RCM Technologies

### At a glance

- Publicly traded since 1971 (NASDAQ: RCMT)
- 2013 Revenue \$171 million
- 1,000+ national, regional, and international clients
- 29 offices in US, Canada and Puerto Rico

### Practices and Capabilities

#### IT

- IT Staffing and Solutions
- MS Solutions

#### Life Sciences

- IT Compliance and Quality Assurance
- GMP/GLP/GCP and QMS
- Equipment/Facilities/Utilities
- HA Observations Response Program

### Delivery

- Staff Augmentation and Project work
- Solution provisioning, including Project Management and Engagement Oversight
- Fixed Price or Time/Material
- SOW or VMS

## WHAT WE DO

Cost Effective Life Sciences IT Regulatory Compliance and CSV

### Computer Systems Validation

Risk-Based Framework (GAMP5)  
Initial Systems Deployment  
Change Controls  
Phase-Focused Staffing  
Leadership and Implementation

### GxP and 21 CFR Part 11

Establishing Full Compliance  
Compliance Audits / Assessments  
Methodology Implementation  
Part 11 Technical Controls  
Part 11 Procedural Controls

### Quality Assurance/Control

QMS Audits / Assessments  
ISO 9000- and FDA QSR-based QMS  
Designed for IT Organizations  
Scalable To Fit The Client Need  
Defendable "Real-Life" Compliance

### Infrastructure Qualification

Initial Implementation  
As-Built and To-Be Design  
Maintenance and Guidance  
Full Program Implementation  
ASTM E2500 and GAMP Principles

## HOW WE DO IT

### Solution Provisioning

Deployment of Top Industry Talent  
Full Project or Program Ownership  
Organizational Change Control  
Center of Excellence Principles  
Managerial/SME Engagement Oversight

### Staff Augmentation

Life Sciences & IT Recruitment Expertise  
Talent Selected by Industry SME  
"Immediate Productivity" Programs  
Long-Term Retention and Utilization  
Attrition Minimization Programs