

HEALTH AUTHORITIES

OBSERVATIONS RESPONSE PROGRAM

a Life Sciences offering

Compliance



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

FDA issues

21 FDA-483 and 3 Warning Letters every day

WHAT WE DO

FDA 483

Observation Response

Help Understanding Observations
Observation Root Cause Analysis
Response Based on FDA Guidance
Remediation Planning
Ongoing Correspondence with FDA

Inspection Support

General FDA Inspection Readiness
FDA Inspection Training
Follow-up Inspection Preparedness
Support During Inspections
Transition to Observation Response

Warning Letters

Observation Remediation

Remediation Plan Implementation
Expertise and Staff Augmentation
Assessment of Related Areas
Evidence Collection and Submission
Transition To Preventative Activities

Preventing Future Problems

General FDA Inspection Readiness
FDA Inspection Training
Follow-up Inspection Preparedness
Support During Inspections
Transition to Observation Prevention

Consent Decrees

HOW WE DO IT

Solution Provisioning

Center of Excellence Principles
Full Project or Program Ownership
Organizational Change Control
Ready Access to Top Industry Talent
Managerial/SME Project Oversight

Staff Augmentation

Talent Selected by Industry SME
"Immediate Productivity" Programs
Long-Term Retention and Utilization
Minimal Attrition
Professional Growth and Training