



## Accelerating Part 11 Compliance for IT Systems

EMC Consulting helps life sciences companies realize business value from compliance programs through our unique ability to integrate compliance, business process, and technology. Our experienced and industry-focused consultants work with clients in all business areas to optimize processes and implement technology solutions while ensuring compliance via policies, procedures, and validation systems.

### Challenge

Designed to promote the widest possible use of electronic technology and paperless record keeping systems, Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11) presents increased challenges for IT managers trying to ensure compliance across multiple parts of the organization.

The stakes are high; companies that fail to comply with regulations face fines or even government shut down of the business. Yet the complexity involved in managing information across organizations, across databases, and across platforms makes Part 11 compliance a major IT undertaking. One company struggled on its own for over three years without success. Then they brought in EMC® Consulting.

### Solution

EMC was able to assess the impact of the client's three-year effort and identify gaps and opportunities for remediation. EMC recommended a risk-based approach for achieving compliance with current regulations and industry practices. Trusting in their ability to drive consensus and implement recommendations, the client asked EMC to provide overall program management of Part 11 compliance across divisions and third parties.

### EMC Gap Analysis

- Assessed the existing remediation plans
- Identified potential gaps
- Developed recommendations for ensuring compliance

### EMC Program Management

- Developed a corporate interpretation of Part 11 for the infrastructure, mapping existing IT Standard Operating Procedures (SOPs) to topics required by Part 11
- Summarized the client's approach to Part 11 compliance referencing supporting documentation
- Updated Part 11 policy to be in alignment with recent FDA guidelines

### EMC Remediation

- Retrospectively qualified network devices at prioritized locations
- Coordinated remediation plans across the organization

### Result

Working with EMC, the client was able to get organizational buy-in, implement a program plan, and develop a clear roadmap for ensuring infrastructure compliance going forward. In just a short time after engaging EMC, the client was on the road to success.

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### Take the next step

For more information, contact your local EMC representative, call us at 1-866-464-7381, or visit our website at [www.EMC.com/consulting](http://www.EMC.com/consulting).