Professional Services for Data Integrity

Waters is focused on working directly with your laboratory teams to provide the expertise you need to manage increased regulatory pressures associated with the integrity and security of your valuable data.

Take a proactive approach with your quality system and address potential issues before your next audit.

Expand your capabilities with Waters Professional Services Consultants.

www.waters.com/professionalservices

PREVENTABLE RISK

Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards (21 CFR 211.194(a)).

Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture.

85%

Of warning letters issued by the FDA in 2016 included citations of data integrity concerns.

Many were avoidable.

Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records (21 CFR 211.68(b)).

As a result, FDA has placed your firm on Import Alert.

TRAINING & WORKSHOPS

Best Practices for Laboratory Personnel

Quality Data Review

Empower Overview for QA Reviewers

Using Empower in the Regulated Lab

Basics of Data Integrity

Culture of Compliance, Regulatory Expectations

Computer System Validation

Risk-Based Approaches to Audit Trail Review

ASSESSMENT & CONSULTATION

System Policy/ User Privilege Review

21CFR Part 11/ Annex 11 Checklist

Data Integrity Checklist & Gap Analysis

Findings/Recommendations Report

Computer System Validation Consultation

Custom Field and Report Development

Method Transfer from Third Party CDS to Empower

Laboratory Analytics Implementation

OPTIONS THAT WORK FOR YOU

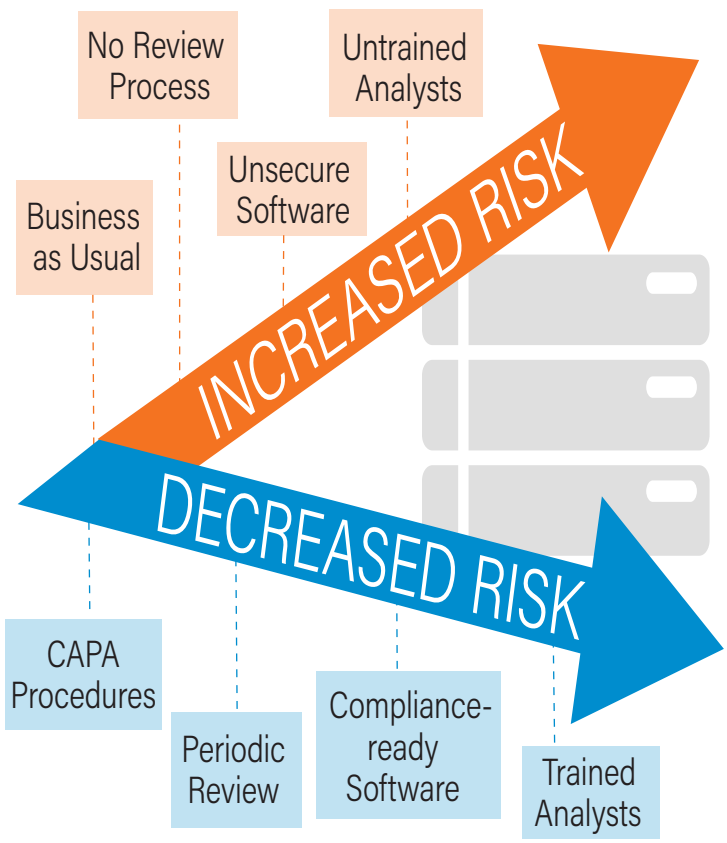
DATA INTEGRITY SERVICE BUNDLES

	TIER 1 BUNDLE	TIER 2 BUNDLE	TIER 3 BUNDLE
Workshop	●		●
Assessment	●	●	
Training	●	●	●

CSV SERVICE BUNDLES

	PREMIUM	ADVANCED	FUNDAMENTAL
Risk Assessment	●		
Validation Plan	●	●	
RQ Specifications Development	●	●	●
System Design Specifications	●	●	
Software OQ	●	●	●
Traceability Matrix Development	●	●	●
Validation Report	●	●	
PQ Development	●	●	
SOP Development	●		
Validation Test Execution	●	●	●

ASSESSING YOUR DATA RISK



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THE SCIENCE OF WHAT'S POSSIBLE.®