



••• Compliance and Validation Services and Support

SumTotal Services

Partnering to Unleash the Power of Your Organization

Supporting validation requirements can be a challenge for many organizations trying to ensure compliance with their learning system while managing updates in the cloud. GP Strategies® knows that validation is complex—this is why we have partnered with SumTotal Systems to provide compliance and validation services and support, helping reduce your risk of noncompliance while increasing your time to value. GP Strategies has implemented hundreds of compliant related solutions and is considered one of the world's leading authority on FDA 21 CFR Part 11 system validation.

••• Validation: How Does It Impact Me? Predicate Rules

A predicate rule is any FDA regulation that requires companies to maintain records and submit information to the agency as part of required compliance. Training records covered by predicate rules must comply with “good practice” quality guidelines and regulations (GxP): Good Manufacturing Practices (GMPs), Good Clinical Practices (GCPs), and Good Laboratory Practices (GLPs). If your learning system maintains records in support of GxPs, parts of FDA 21 CFR Part 11 apply and you could be at risk of noncompliance, remediation, and costly fines.



Experience Supporting Highly Regulated Industries

GP Strategies has more than 20 years of experience supporting learning and technology solutions for highly regulated organizations. With extensive experience coordinating with Quality Assurance and Compliance departments, GP Strategies specializes in supporting organizations with highly complex learning requirements. Utilizing our detailed platform and quality assurance experience,

GP Strategies has provided learning technology services for a myriad of highly regulated organizations, including healthcare organizations, life sciences corporations, and pharmaceutical companies. Below are topics and areas that we can help you with:

System Validation Documentation

- Validation master plan/risk assessment
- User requirements
- Functional requirements
- Traceability matrix
- Installation Qualification (IQ) (Install)
- Operational Qualification (OQ) (Test)
- Performance Qualification (PQ) (Monitor)
- Validation summary reporting
 - Ongoing system health checks
 - Product release review sessions

GP Strategies SumTotal Practice

GP Strategies is a recognized leader in learning management system implementation and support, with nearly two decades of experience working with the SumTotal platform. Our team specializes in SaaS migration projects, bringing a wealth of best practices and lessons learned to every initiative that we lead and support.

- SumTotal Partner since 1999
- Dedicated SumTotal practice team
- Collection of proven best practices for SumTotal migration



Full suite of SumTotal Services including:

Implementation and Migration Services

Help Desk Administration

System Maintenance

Consulting Support

Release Management

For more information on **Compliance and Validation Services and Support**, contact us at HTSales@gpstrategies.com.



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