Consulting services

Reduce validation time, control costs. We've got your back.

Trust your computer system validation to the company that designs and supports your system

Laboratory, manufacturing, and quality workflows that follow industry good practice (GxP) guidance protocols and/or Good Automated Manufacturing Practice (GAMP™) require validation of computer systems. This can include compliance to 21 CFR Part 11, Annex 11, or similar local regulations, standards, or guidance for data integrity of electronic data records. Validating computer systems helps ensure that complete, accurate, reliable, consistent, secure, and reproducible electronic data records are readily available to users.

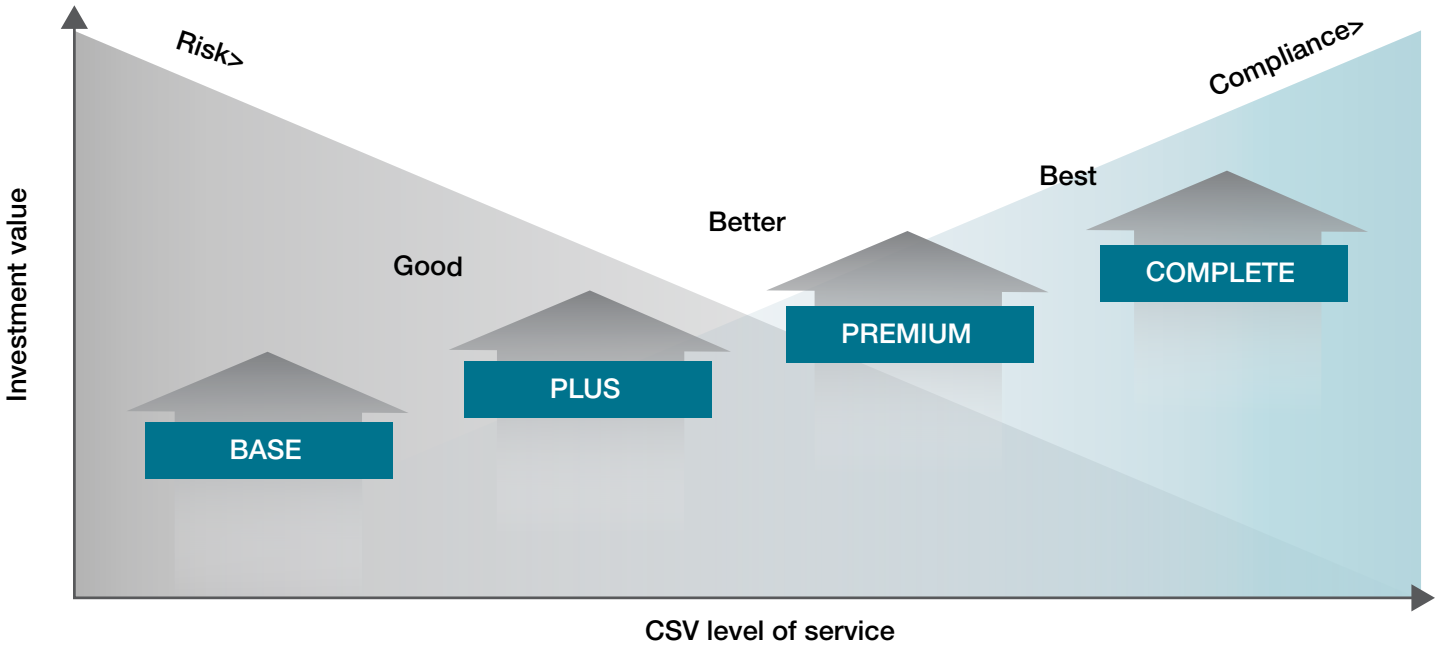
Our computer system validation (CSV) consulting services provide comprehensive and flexible audit-ready–style documentation packages that help you reduce risk and comply with regulations and standards. Our CSV services help save you valuable time and costs because they are managed and delivered by experienced CSV project manager specialists who help ensure your systems comply with regulations, standards, and guidance for maintaining and securing electronic data records.

CSV consulting services include comprehensive documentation to help you meet regulations and standards

- Validation plan
- Validation risk assessment
- User requirements specification
- System configuration specification
- Validation test plan
- Installation qualification (IQ) with objective evidence*
- Operational qualification (OQ) with objective evidence*
- Performance qualification (PQ) with objective evidence*
- Traceability matrix
- 21 CFR Part 11/Annex 11/GAMP5 assessment
- Quality assurance review
- Validation summary report

Select the CSV consulting service that best fits your budget and needs

We've developed 4 tiers of CSV plans** with increasingly comprehensive levels of service and documentation so that you can invest in only the services that fit your specific needs and budget. The more you invest the more comprehensive the documentation you receive, offering you the peace of mind that we've helped you mitigate risk and increase compliance.



* Objective evidence is collected by our CSV specialist with the add-on execution service for PLUS tier or with the COMPLETE tier services.

** Applied only to instrument software.

	BASE	PLUS	PREMIUM	COMPLETE
Documents and services included				
Validation plan			•	•
Validation risk analysis (RA)		•	•	•
User requirements specification (URS)		•	•	•
System configuration specification (SCS)	•	•	•	•
Validation test plan		•	•	•
Software installation qualification (IQ) with objective evidence*	•	•	•	•
Software operational qualification (OQ) with objective evidence*	•	•	•	•
Software performance qualification (PQ) with objective evidence*			•	•
Traceability matrix			•	•
21 CFR Part 11/Annex 11/GAMP5 assessment			•	•
Quality assurance review			•	•
Validation summary report			•	•
Document customization support	Template only	Template only	•	•
Full validation support				•
End-to-end project management and execution support (on-site and remote)				•
Add-on services available with additional charges				
Execution add-on		•		
Document add-on	•	•		
Expedited documentation add-on	•	•	•	•
Custom request (including revalidation)		Request a quote		

CSV services are available for the following instruments**	
Applied Biosystems™ capillary electrophoresis (CE) instruments	
3500 and 3500xL Genetic Analyzers	
SeqStudio systems	
MicroSEQ ID Microbial Identification Software†	
Applied Biosystems™ real-time PCR (qPCR) instruments	
7500 and 7500 Fast systems	QuantStudio 7 Flex system
ViiA 7 system	QuantStudio 12K Flex system
QuantStudio 5 Flex system	QuantStudio 7 Pro systems
QuantStudio 6 Flex system	AccuSEQ Software†
Invitrogen™ iBright imaging systems	
iBright imaging systems	
Invitrogen™ flow cytometry instruments	
Attune NxT Flow Cytometer	

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** If you do not see your Applied Biosystems or Invitrogen instrument here, please contact your service sales specialist for assistance.

† Complete only consulting service.

Ordering information

Product†	Cat. No.
CSV consulting services for qPCR instruments	
BASE service	A43569
PLUS service	A43570
PREMIUM service	A43571
COMPLETE service	A43572
CSV consulting services for CE instruments	
BASE service	A43577
PLUS service	A43578
PREMIUM service	A43579
COMPLETE service	A43580
CSV consulting service for flow cytometry instruments	
COMPLETE service	A47478
CSV consulting services for iBright fluorescent imaging system	
COMPLETE service	A51103
Add-on services for CSV consulting service	
Document add-on service for qPCR instruments*	A43826
Expedited add-on service for qPCR instruments	A43827
Execution add-on service for qPCR instruments**	A44195
Document add-on service for CE instruments*	A43824
Expedited add-on service for CE instruments	A43825
Execution add-on service for CE instruments**	A44196
Secondary analysis software for CE instruments	A47537
Custom/re-validation computer system services	
Custom/re-validation computer system services for qPCR instruments	A44281
Custom/re-validation computer system services for CE instruments	A44282
Custom/re-validation computer system services for iBright fluorescent imaging system	A51105
Custom/re-validation computer system services for flow cytometry instruments	A52143
CSV consulting services for pharmanalytics	
Computer system validation for MicroSEQ ID	A39692
Computer system validation for AccuSEQ	A45528
Computer system validation for custom pharmanalytics	A47610

* Charges apply for each additional document.

** Execution service add-on is available for PLUS service only.

† If you do not see your product here, please contact your service sales specialist for assistance.

Find out more at **thermofisher.com/csv**