When it comes to QA/QC, we offer everything to stay compliant each step of the way, from our analytical instrumentation to our unique OneSource® service and support. When these tools come together, they work as a system to create safe, quality products you can trust and feel confident about.

Current Good Manufacturing Practice (CGMP) not only drives the QA/QC inside your company, but it also guides our development of the technologies, tools, and processes we build to ensure you are meeting your regulatory obligations – all while continuously manufacturing compliant products.

Click Here to Explore Our Solutions

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For the Better

THE PRESCRIPTION FOR PEACE OF MIND

QA/QC headaches? We've got the remedy for that. Our analytical instrumentation, informatics solutions, and service and support, give you – and drug manufacturers – confidence in the quality of analysis and compliance in the process from beginning to end.

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PERKINELMER PORTFOLIO		CONTROL OF IMPURITIES			DRUG SUBSTANCE AND EXCIPIENTS	DRUG PRODUCT	STABILTY TESTING
INSTRUMENT	**21 CFR Part 11 / EU GMP Annex 11**	**Organic**	**Inorganic (Elemental)**	**Residual Solvents**			
▶ Atomic Absorption (AA)	■		■				
▶ Inductively Coupled Plasma (ICP-OES and ICP-AES)	■		■				
▶ ICP Mass Spectrometry (ICP-MS)	■		■	■			
▶ Gas Chromatography (GC)	■	■		■	■	■	■
▶ UV/Vis Spectroscopy	■	■			■	■	■
▶ Infrared Spectroscopy (FT-IR)	■				■	■	
▶ Liquid Chromatography (HPLC and UHPLC)	■	■			■	■	■
▶ Organic Elemental Analysis (CHNS/O)	■				■	■	■
▶ Differential Scanning Calorimetry (DSC)	■			■	■	■	■
▶ Thermogravimetry Analysis (TGA)	■			■	■		■
▶ Dynamic Mechanical Analysis (DMA)	■					■	
▶ Fluorescence Spectroscopy (FL)	■				■	■	■
▶ Multimode Plate Reader	■					■	
▶ Microfluidics	■	■			■	■	■
SERVICE							
▶ Laboratory Data Integrity	■	■	■	■	■	■	■
▶ Computer System Validation	■	■	■	■	■	■	■
▶ Instrument Qualification	■	■	■	■	■	■	■
▶ Temperature Mapping	■	■					■
▶ Dissolution Testing	■	■			■	■	
▶ Remote Monitoring (AA, ICP-OES, ICP-MS, FL, FT-IR)	■						■
CONSUMABLES							
▶ Atomic Spectroscopy Consumables			■		■	■	
▶ Chromatography Consumables		■		■	■	■	■
▶ Molecular Spectroscopy Consumables		■			■	■	
▶ Reference Standards			■				
INFORMATICS							
▶ ChemDraw®		■	■	■	■	■	■
▶ E-Notebook™	■	■	■	■	■	■	■

CONFIDENTLY COMPLIANT FROM START TO FINISH

We take the principles of data integrity very seriously when designing and manufacturing our instruments. That's why we've built the most important features of ALCOA Plus (attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available) right into our platform and software, allowing our products to be installed and validated as compliant, meeting the requirements of 21 CFR Part 11.

PERKINELMER ENHANCED SECURITY SOFTWARE COMPLIANT TO 21 CFR PART 11									
PHARMA QA/QC GMP REQUIREMENTS	AA	ICP-OES	ICP-MS	UV	IR + NIR	FL	Chromatography - TotalChrom®	Thermal Analysis (DMA, TGA, DSC)	Multimode Plate Reader (EnVision®)
GXP Data and Metadata	■	■	■	■	■	■	■	■	■
Audit Trail	■	■	■	■	■	■	■	■	■
Data Archive and Restore	■	■	■	■	■	■	■	■	■
Data Availability (Copies of Eletronic GXP data)	■	■	■	■	■	■		■	■
Data Entry	■	■	■	■	■	■	■	■	■
Data Protection	■	■	■	■	■	■	■	■	■
Data Review	■	■	■	■	■	■	■	■	■
Electronic Signatures	■	■	■	■	■	■	■	■	■
Event Sequencing	■	■	■	■	■	■	■	■	■
Date and Time Settings	■	■	■	■	■	■		■	■
Data Transfer	■	■	■	■	■	■		■	■
User Access	■	■	■	■	■	■	■	■	■

GLOSSARY

GXP Data and Metadata: The instrument software has the capability to supply accurate and complete copies of electronic records (including metadata)

Audit Trail: The instrument software comes equipped with the capability of capturing not just system information and events, but also application information and events such as security, user management, event management, and data lifecycle management. Audit trails can be printed and are human readable. No level of user access has the privilege to disable the audit trail function or delete it

Data Archive and Restore: Data can be archived and restored. All actions are recorded in the audit trails

Data Availability (Copies of Electronic GXP data): Data can be exported as a CSV file and treated as a GMP record.

Data Entry: System checks the correct format of data entry at the time of entry. System captures the data and audit trail immediately after data entry

Data Protection: System protects data and records from modification or deletion

Data Review: All acquired data is maintained and can be queried, sorted and filtered as required

Electronic Signatures: System is capable of enabling electronic signatures that require two factor authentication. The system does not allow electronic signatures to be copied

Event Sequencing: System checks enforce sequencing of GxP steps and events and doesn't allow non-permitted sequencing of events

Date and Time Settings: System configures to display the date and time in accordance to the local time zone. Date and time settings are unalterable by users.

Data Transfer: Data can be transferred to another system keeping the same attributes and information as the original, and retaining the entire content of the original

User Access: Multiple system user types can be configured with permissions and access levels suitable to the responsibility and role of the user.

Data Integrity Is at the Heart of Laboratory Compliance

Data Integrity: What Is It and Why Is It Important?

For more information please click here.

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