

A QC SUITE MADE PHARMA & ALCOA-COMPLIANT DATA INTEGRITY

1 AIR QUALITY | **2** WATER QUALITY | **3** PARTICLE SIZING | **4** CELL & MEDIA HEALTH

ATTRIBUTABLE

Records to include an electronic signature linked to the instrument/person who made the measurement. Compliant systems automatically track who/when records were created, changes made, and the reason.

LEGIBLE

Illegible hand-written records are not acceptable; data should be presented in a clear, standardized format.

CONTEMPORANEOUS

Final electronic record created directly from the instrument in the same timeframe as the test.

ORIGINAL

To ensure credibility, store original records, not photocopies. Original electronic records allow for audit trails to track all subsequent changes. No manual transcriptions.

ACCURATE

Capturing electronic records should avoid manual calculations and data entry. Electronic records enable audit trails to ensure transparency and prevent data from being altered.

Our suite of QC instruments is ALCOA+ ready, each creating electronic records straight from the device for review/approval and compliance audits

QC Step	Instrument	Application	Supports Regulation	A	L	C	O	A
Raw Material	ANATEL PAT700	On-line Water for Injection (WFI), Purified Water (PW) Total Organic Carbon (TOC), Temperature and Conductivity	USP<643> USP<645> EP2.2.44 EP2.2.38	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	QbD1200	Grab-sample point of use testing for Water for Injection (WFI), Purified Water (PW) Total Organic Carbon (TOC),	USP<643> EP2.2.44	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	LS 13 320 XR	Particle size distribution in parenterals	USP<787>, <788>, <1787> and <1788>	Multi-level, individual User Name and Password for all users	Legible, secure PDF export as well as Audit Trail and Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
Production	Vi-CELL BLU	Mammalian cell viability and concentration	USP<1046>	Multi-level, individual User Name and Password for all users	Legible secure PDF export for measurement results	Secure data records stored and tracked at time of measurement	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	Vi-CELL MetaFLEX	Mammalian cell bioreactor media health		Multi-level, individual User Name and Password for all users	Legible reports can be printed or viewed on the instrument	Secure data records stored and tracked at time of measurement	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	MET ONE 3400+	GMP Cleanroom routine environmental monitoring (airborne particulates)	EU GMP Annex 1 CGMP ISO 14644-1 & -2	Multi-level, Microsoft Active Directory Username and Password control creates unique electronic signatures for users	Legible, secure PDF electronic record export for measurement results	Secure PDF electronic records created in the counter - no manual data transcription or scanning of paper reports	Original electronic record created directly inside the counter	Your SOPs and sampling maps uploaded into the counter with version control. Completed records reviewed and approved for accuracy in the counter remotely via web-browser. No manual counter configuration or sample location entry.
	MET ONE Facility Monitoring System	Sterile manufacturing cleanroom continuous air particulate monitoring	EU GMP Annex 1 CGMP ISO 14644-2	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure data records stored in database at time of measurement	Original electronic record created directly from the instrument	Your SOPs pre-programmed into the User Interface and automated. No manual data entry or Pass/Fail calculations
Final Product Testing	HIAC 9703+	Final product sub-visible particulate counting in parenteral drug products	USP<787>, <788>, <1787> and <1788>	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Alarm Trail, Audit Trail, Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated
	Multisizer 4e	Particle size and count in parenterals	USP<787>, <788>, <1787> and <1788>	Multi-level, individual User Name and Password for all Users	Legible secure PDF export for Audit Trail, Measurement Results	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programmed into the instrument and automated

A QC SUITE MADE PHARMA

Our QC instruments were designed for bio/pharmaceutical manufacturing—from cleanroom production through final product testing and ALCOA-compliant data management for streamlined reporting and audits.

Let us help you automate processes and reduce the potential for human errors by eliminating pass/fail calculations, manual data entry and paper records.



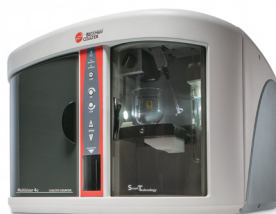
**Cleanroom Air
Particle Counting
MET ONE 3400+**



**HIAC Final Product
Particle Pass/Fail Test
HIAC 9703+**



**Total Organic Carbon
and Conductivity
PAT 700**



**Coulter Principle -
Particle Size and Count
Multisizer 4e**



**Laser Diffraction
Particle Size
Distribution
LS 13 320 XR**



**Cell Viability and
Concentration
Vi-CELL BLU**



**Bioreactor Media Health
Vi-CELL MetaFLEX**

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21.06.1781.PCC