BECKMAN COULTER
Life Sciences

MAINTAINING DATA INTEGRITY

Did you know that lack of data integrity has been a top reason for FDA Drug GMP warning letters?*

ATTRIBUTABLE Records should include an electronic 'signature' to link them to the instrument/person that made the measurement. Compliant systems automatically track who and when a record was created, changes made, and the reason a change was made.

LEGIBLE The record is required to be 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 time-frame as the test.

ORIGINAL To ensure credibility, store original records rather than photocopies. Original electronic records allow audit trails to track any and all subsequent changes. No Manual transcriptions.

ACCURATE The process for capturing electronic records should be robust, i.e., avoid manual calculations and manual data entry. When records are electronic, audit trails can provide transparency to prevent data from being altered.

DESIGNED TO FACILITATE DATA INTEGRITY


Cell Viability/ Counting Analysis


Powder Size Distribution for API and Excipients


Final Product Testing to USP <787> and <788>


Flow Cytometer


PW and WFI testing to USP <643> and <645>


Cleanroom Routine Environmental Monitoring and Classification

YOUR SOP AUTOMATED

COMPLETE All data are available, nothing has been deleted (evidence: audit trail)

CONSISTENT Data are recorded chronologically with data and time (evidence: audit trail)

ENDURING Data are accessible for an extended period of time.

AVAILABLE Data are accessible over the lifetime of the product

ALCOA+ ready electronic record straight from the instrument for review and approval

*Pharmaceutical Online, An Analysis Of FDA FY2018 Drug GMP Warning Letters By Barbara Unger, *Unger Consulting Inc.*, https://www.pharmaceuticalonline.com/doc/an-analysis-of-fda-fy-drug-gmp-warning-letters-0003, published February 1, 2019

Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials By GCP Inspectors Working Group https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-expectations-electronic-source-data-data-transcribed-electronic-data-collection_en.pdf, published June 09, 2010

21 CFR Part 11 QC Instrument Suite

QC Step	Instrument	Application	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-programed 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-programed into the instrument and automated
	LS 13 320 XR	Active Pharmaceutical Ingredient, Excipients	ISO 13320	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-programed into the instrument and automated
Production	Vi-CELL BLU	Mammalian cell viability and concentration	USP <1046>	Multi-level, individual User Name and Password for wall 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-programed 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-programed into the instrument and automated
	MET ONE 3400	Routine environ-mental monitoring (air particulates) in sterile manufacturing cleanrooms	EU GMP Annex 1 CGMP ISO 14644-1 & -2	Multi-level, individual User Name and Password for all users	Legible secure PDF export for Measurement Results including metadata	Secure PDF created on day of sample analysis	Original electronic record created directly from the instrument	SOP parameters pre-programed into the instrument and automated
	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> USP<788> USP<789>	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-programed into the instrument and automated
	Multisizer 4e	Final product visible particulates counting in parenteral drug products		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-programed into the instrument and automated

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PART-5405IFG06.19