



SERVICES OFFERING

MAS-100® & RCS® Air Samplers

Validation | Regulatory References

“Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.” 21CFR 820.3

“The suitability of all testing methods used shall be verified under actual conditions of use”. 21 CFR 211.194 (2)

“Use of a validated procedure with qualified analytical instruments provides confidence that the procedure will generate test data of acceptable quality.”
USP<1058> Analytical Instruments Qualification

“The Validation Master Plan should present an overview of the entire validation operation, its organizational structure, its content and planning.... Responsibilities relating to the plan should be stated. PIC/S Pi006-03, 4.2.1 : Purpose

Training | Regulatory References

“Training curricula should be established for each laboratory staff member specific for their job function. They should not independently conduct a microbial test until they are qualified to run a test.” USP<1117> : Microbiological best laboratory practices, Training of Personnel

“Sterility testing should only be performed by personnel who have been trained, qualified and certified to perform the various tasks and procedures related to sterility testing.”

“Supervisors should ensure that all personnel are monitored and follow Standard Operating Procedures (SOPs). Personnel should undergo periodic recertification. Personnel training should be documented and records maintained.” PIC/S pi012-03, 2017 : Recommendations on Sterility Testing. 7.1 Training

FDA cites training in 30% of Warning Letters. FDA

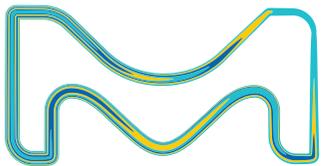
Maintenance | Regulatory References

“Equipment shall be adequately inspected, cleaned, and maintained....” 21 CFR 58.63 (Good Laboratory Practices)

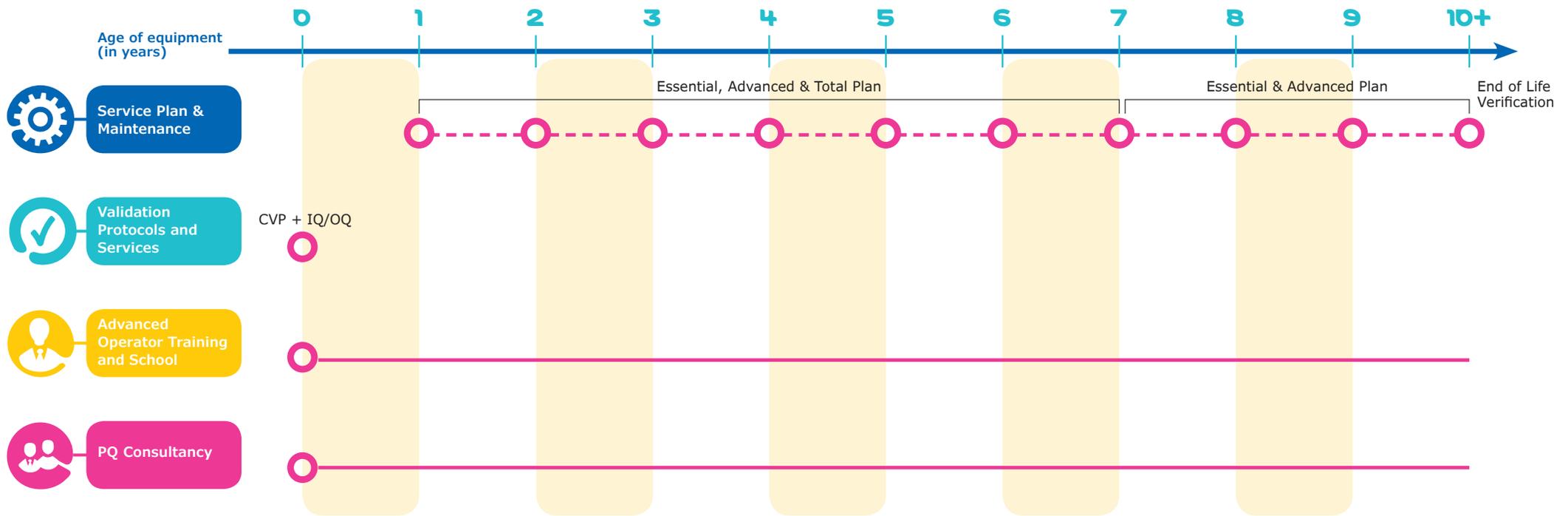
“Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods.” Eu GMP Part I, Chap 3.41

“Periodic preventive maintenance are required for many instruments. This may include calibration. Document the preventive maintenance plans, including procedures and frequency as part of the AIQ package (Analytical Instrument Qualification).” USP<1058>

“Schedules and procedures (including assignment of responsibility) should be established for the preventative maintenance of equipment” ICH Q7, 2000, Chap. 5.2, “Equipment maintenance and cleaning”



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*For MAS-100 NT and RCS HFT only

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