



Audit Checklist – Be Prepared to Avoid any Loss of Reputation

Laboratories are frequently audited to ensure that the facilities and processes comply with the regulations and maintain data integrity. Should a laboratory not have the ability to ensure regulation compliance and data integrity, they may be subject to a form 483 or other such warning letters.

PST offers real-time monitoring solutions (RMS) that are designed to help customers ensure compliance within regulated applications.

In order to ensure that audits run smoothly PST offers a list of important points to be considered helping to get well prepared.



Audit points	Yes/No	Document
Are all critical areas with environmental control monitored with RMS?		
Is the equipment used for maintaining the environmental conditions adequate, well maintained and effective?		
Do records of operation, maintenance, verification, calibration and validation of measurement equipment and devices (including RMS) exist?		
All measurement data and event data is available within the RMS software. This data collected by RMS cannot be manipulated and is always available.	Yes	Please request for the RMS white paper.
Has sufficient staff been trained on RMS and training certificates are available?		
Are SOP's in place for use, maintenance, cleaning, calibration and validation of RMS and the environmental control equipment?		
Are SOP's in place for record-keeping, reporting, storage and retrieval of records and reports within RMS?		
Were measurements, observations and examination in accordance with the relevant SOP's?		
All changes in RMS include who carried out a change, when the change was carried out and why the change was carried out.	Yes	Please see the audit trail within RMS.
All data generated and stored by RMS are protected against unauthorised amendments and loss	Yes	Please see the RMS-WP.
Ensure that RMS is reliable, accurate and has been validated.		
Ensure that any unforeseen events recorded in the audit trail have been investigated and evaluated.		
Ensure that all records and materials are retained for the required or appropriate period of time and are protected from loss or damage by fire, adverse environmental conditions...		