PERIODIC REVIEW CHECKLIST

Note: The below tables do not contain the complete set of items to be evaluated as part of Periodic Review process and serves as a guidance or example on how a Periodic Review Template could be created. Based on the applicable local regulations, processes at your organization, system classification and intended usage tailor the template as needed.

If you have more questions, please write to us at compliancesolutions@zifornd.com

Periodic Review Start Date:

Periodic Review End Date:

S. No.	Question	Results	Recommended Next Steps (if applicable)	Additional comments
1	Is Risk Assessment and System Classification performed up to date?	☐ Yes ☐ No ☐ N/A		
2	Is the supplier Evaluation up to date?			
3	Are the changes performed on the system follows the applicable change process?			
4	Are there any incidents, deviations, Nonconformances happened since the last review?			
5	Are the incidents, deviations, Nonconformances analyzed and closed with proper justification?			
6	Are there any changes to the procedure (business operations as well as system administration) for the review system? Does this impact the current package and periodic review process?			
7	Is the qualification performed on the system follows the applicable change control process and remains in compliance?			
8	Are the Calibration / PM activities performed as per the schedule?			
9	Is there an Instrument Logbook (s) available and meets the requirements set?			
10	Is the audit trail review process performed?			

S. No.	Question	Results	Recommended Next Steps (if applicable)	Additional comments
11	Is the archiving of data happens as described in the procedures?			
12	Has user certification process performed on the frequency defined?			
13	Is the data restricted folders and network drives remain in the restricted state for users?			
14	Are there any procedural controls establish as par to the Remediation or Qualification or previous Review? If yes, are these still valid?			
15	Are there any new upgrades available from the vendor that could be leverage for better compliance?			

Summary of Documents Reviewed

Document Number	Document Title

Overall Conclusion of Review

Periodic Review Report Approvals

Function	Name	Signature	Date
Author			
Business System Owner			
Quality Assurance			