
Standard Operating Procedure

Risk Assessment for Laboratory Systems



This is an example of a Standard Operating Procedure. It is a proposal and starting point only. The type and extent of documentation depends on the process environment. The proposed documentation should be adapted accordingly and should be based on individual risk assessments. There is no guarantee that this document will pass a regulatory inspection.

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Signatures	
Author	<p>I indicate that I have authored or updated this SOP according to applicable business requirements and our company procedure: Preparing and Updating Standard Operating Procedures.</p> <p>Name: _____</p> <p>Signature: _____</p> <p>Date: _____</p>
Approver	<p>I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.</p> <p>Name: _____</p> <p>Signature: _____</p> <p>Date: _____</p>
Reviewer	<p>I indicate that I have reviewed this SOP and find that it meets all applicable quality requirements and company standards. I approve it for use.</p> <p>Name: _____</p> <p>Signature: _____</p> <p>Date: _____</p>

1. PURPOSE

FDA's 21st CGMP initiative suggests risk-based inspections. Companies are expected to document risks that the system has on product quality, product safety and public health. Information is used, for example, to define the extent of validation, to define the scope of 21 CFR Part 11 and to implement functions such as electronic audit trail and archiving of records. Information may also be used as a criterion when deciding which systems will be subject to FDA inspection. This procedure establishes a method for identifying, evaluating and prioritizing the risks associated with the use of laboratory systems in applicable GxP applications, specifically but not only where such systems are subject to regulation under 21 CFR Part 11.

2. SCOPE

The SOP applies to laboratory systems used in GxP regulated environments and to records acquired, evaluated, transmitted, archived and retrieved on computers. The SOP is limited to risks the system has on public health and does not apply to other business risks like business continuity.

3. GLOSSARY/DEFINITIONS

Item	Explanation
Harm	Physical injury and/or damage to health or property.
Hazard	A source of potential harm.
Risk	Probable rate of occurrence or hazard causing harm or significant impact to business, regulatory compliance, customers or users. For the purpose of the risk analysis procedure, the risk is expressed as a quantitative value based on the degree of regulatory risk, business risk and patient/user risk.
Risk Level	A quantitative estimate that describes the level of degree of risk. The value is additive based on quantitative values assigned for public health (severity), regulatory risk and business risk.

Note: For other definitions, see www.labcompliance.com/glossary.

4. REFERENCE DOCUMENTS

N/A

5. RESPONSIBILITIES

5.1. Laboratory Staff

- 5.1.1. Collect information needed for the risk assessment.
- 5.1.2. Continuously monitor the processes for potential new risks.

5.2. Laboratory Supervisor

- 5.2.1. Evaluates and prioritizes risks.

5.3. Quality Assurance Department

- 5.3.1. Advises on regulations and guidelines related to risk assessment.
- 5.3.2. Checks if processes and documentation are in compliance with internal policies and regulations/guidelines.

6. FREQUENCY OF USE

- 6.1. Initially whenever systems are used in GxP and Part 11 environments.
- 6.2. Whenever reviews of risk assessment indicate a change of risk factors or categories.

7. PROCEDURE

7.1. Initial Assessment

- 7.1.1. Laboratory staff collect information on potential risks of all laboratory systems using the form in Attachment 8.1. Information is collected from system documentation (intended use, environment, validation documents), interviews with users of the system and system logs (system failures, downtime).
- 7.1.2. Laboratory supervisor makes a risk assessment using matrix table in Attachment 8.2. Relative risk levels are defined and systems are categorized as high, medium or low risk systems.
- 7.1.3. Staff supervisor creates a list of systems in his/her areas with high/medium/low risk categories using Attachment 8.3.

7.1.4. QA collects lists of systems with high/medium/low risks and generates and maintains a master list.

7.2. Ongoing Reviews and Updates

7.2.1. Laboratory staff continuously monitor the laboratory systems for potential new risks and bring potential risks to the attention of the supervisor using Attachment 8.1.

7.2.2. Laboratory supervisor reviews staff inputs and updates the risk assessment.

7.2.3. Staff supervisor reviews and updates yearly the tables listing systems with high/medium/low risks.

8. ATTACHMENTS

8.1. Attachment - Collecting Information for Risk Assessment

Employee:
Supervisor:
Department:
Date:

System ID:
System Location:

Source	Information	Comment
Example: <i>System Description</i>	Example: <i>Computerized HPLC system to analyze impurities in drugs.</i>	Example: <i>Data generated by the system will be used as a criterion to release a batch or not. Recommend classifying as high-risk system.</i>
Example: <i>Operators</i>	Example: <i>Operators sometimes have to re-adjust operating parameters and re-evaluate data generated by the automated system because of scientific reasons.</i>	Example: <i>Human interactions can influence decisions to release a batch or not. Recommend classifying as high-risk system.</i>
Example: <i>SOP on Record Retention</i>	Example: <i>The SOP requires retaining raw data and the ability to reprocess the data for five years.</i>	Example: <i>As data generated by the system and processability must be preserved for five years, records should be retained in electronic form together with software for reprocessing original or migrated files.</i>

8.2. Attachment - Risk Assessment

Supervisor:
Department:
Date:
System ID:
System Location:

Relative Risk	Description
High	<p>The system has a direct impact on product quality. Failure of the system may result in an inappropriate decision or action relative to product quality that may cause harm to a patient. This also means that there is no other system to check or verify the product quality.</p> <p>Or</p> <p>Missing, incomplete or changed data generated by the system may make it impossible to reproduce the decision process that led to the decision or action relative to product quality such as a release or shipment decision that may cause harm to a patient.</p> <p>Example: Systems that generate or record data to be used for a release or shipment decision.</p>
Medium	<p>The system can have an impact on product quality, but it is not direct. Failure of the system may result in an inappropriate decision or action relative to supporting processes or systems that have direct impact on product quality.</p> <p>Example: Environmental monitoring system for an area where a system classified as “high-risk” is located and inadequate environmental conditions can impact the result generated by the high risk system.</p>
Low	<p>The system does not have an impact on product quality. Failure of the system may result in an inappropriate decision or action relative to supporting processes or systems that have no direct impact on product quality or failure of the system may be delayed.</p>

