



### Auditing of a Technology Vendor Checklist

This checklist is intended to be a guide to planning your next audit. The items here should be evaluated for completeness. It is crucial for both Quality and the responsible area to acknowledge if the risks are acceptable.

# Standard Operating Procedures

Topic	Response
Standard Operating Procedures (SOPs): Is there an SOP on SOP development and lifecycle? This should include review periods and how the SOPs are managed.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Regulatory Compliance: Is there an SOP that describes applicable Regulations/Standards; including an identification of what standards they comply/adhere to?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Software Development Life Cycle (SDLCI): Is there an SOP describing an established SDLC (e.g., Agile)? This should clearly outline the process and phases for the development of the company's software.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Change Management: Is there an SOP on Change Management? <ul style="list-style-type: none"><li>• How does the company handle changes to its product and/or infrastructure?</li></ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Code Promotion: Is there an SOP on Code Promotion? <ul style="list-style-type: none"><li>• How is code promoted through environments?</li><li>• How does the company ensure the right code is used?</li></ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:

<p>Customer Support: Is there an SOP on Customer Support?</p> <ul style="list-style-type: none"> <li>• How will the technology vendor support you?</li> <li>• What is their availability?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Software Testing: Is there an SOP on software testing?</p> <ul style="list-style-type: none"> <li>• What types of testing does the vendor perform?</li> <li>• Are they performing Unit, Regression, Positive, and Negative testing?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Archival/Retirement: Is there an SOP on Archival/Retirement?</p> <ul style="list-style-type: none"> <li>• What is the retention period for the vendor?</li> <li>• How do they archive your information?</li> <li>• What is the availability of your information once it is archived?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Incident/Complaint: Is there an SOP that describes Incident/Complaint handling, including timelines and notification?</p> <ul style="list-style-type: none"> <li>• How are reported issues handled?</li> <li>• Is there an investigation into the issue which establishes root cause?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>CAPA Management: Is there a CAPA (Corrective Action/Preventive Action) program in place? How is it managed?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Quality Assurance Roles: Is there an SOP that describes the role of Quality within the organization?</p> <ul style="list-style-type: none"> <li>• Are they active members of the team?</li> <li>• Do they have the ability to stop work?</li> <li>• Are they checking for adherence to processes?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Validation Checks: Is there a SOP in place that defines what types of validation checks are performed?</p> <ul style="list-style-type: none"> <li>• How does the vendor assure the software is fit for use?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Internal Auditing: Is there an SOP that describes the process for internal auditing?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:

<ul style="list-style-type: none"> <li>• Is there an internal audit schedule?</li> <li>• How are internal audits conducted?</li> <li>• How often?</li> <li>• What is the scope of internal audits?</li> <li>• Are they proactive to ensure quality or only reactive when there is an issue?</li> </ul>	
<p>Data Modifications: Is there an SOP in place for making data modifications?</p> <ul style="list-style-type: none"> <li>• Who has the ability to change data?</li> <li>• How is this documented?</li> <li>• How is the integrity of the data preserved?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Data Privacy and Security: Is there an SOP that describes what steps are in place to safeguard your data?</p> <ul style="list-style-type: none"> <li>• What are the physical and logical security standards in place?</li> <li>• What type of monitoring is in place?</li> <li>• What type of data is the vendor storing?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Vendor Evaluation/Usage: Is there an SOP on Vendor Management?</p> <ul style="list-style-type: none"> <li>• Who is responsible for evaluating third parties your vendor is using?</li> <li>• How often are they requalified?</li> <li>• What roles are vendors/subcontractors playing in the development of your technology?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Training: Is there a formalized training program for new and existing employees?</p> <ul style="list-style-type: none"> <li>• How is training determined?</li> <li>• How often are employees trained?</li> <li>• How is training tracked and documented?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
<p>Document Management: Is there an SOP that defines document version control, electronic signatures, and ink signatures?</p> <ul style="list-style-type: none"> <li>• How are documents managed?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:

<ul style="list-style-type: none"> <li>• What information is captured?</li> <li>• How are paper documents stored?</li> <li>• Where are electronic copies of documentation stored?</li> </ul>	
<p>Requirements Management: Is there an SOP that describes the development of user requirements?</p> <ul style="list-style-type: none"> <li>• How are these requirements managed?</li> <li>• How are they approved?</li> <li>• Are all versions of the requirements document available for the software?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are these risks acceptable - Quality <input type="checkbox"/> Yes <input type="checkbox"/> No	
Are these risks acceptable - Operations <input type="checkbox"/> Yes <input type="checkbox"/> No	
Notes:	
<h1>Security</h1>	
Topic:	Response:
Are password settings configurable?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Is user access controlled in the system? <ul style="list-style-type: none"> <li>• How is user access controlled?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

<ul style="list-style-type: none"> <li>Who manages this?</li> </ul>	Comments:
Are there controls which enforce a specific flow of actions? Have these controls been tested?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are there checks in place to see if roles are authorized to perform specific actions? Have they been tested?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are Electronic Signatures in use and compliant with applicable electronic signature standards (e.g., 21 CFR part 11/Annex 11)? <ul style="list-style-type: none"> <li>Has acknowledgement been obtained from the staff on the e-signature being the equivalent of a hand written signature?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are these risks acceptable - Quality <input type="checkbox"/> Yes <input type="checkbox"/> No Are these risks acceptable - Operations <input type="checkbox"/> Yes <input type="checkbox"/> No	
Notes:	

# Quality Assurance

Topic:	Response:
Does QA provide oversight for software validation activities? <ul style="list-style-type: none"> <li>• Are they members of the software team?</li> <li>• Are they doing additional testing?</li> <li>• Are they ensuring SOPs were followed?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Does QA have the authority to stop work when issues or errors arise?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Does QA perform routine internal audits? <ul style="list-style-type: none"> <li>• What is the scope/frequency of the internal audits being performed?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Does QA demonstrate familiarity with applicable Regulatory Standards?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Does QA provide support to the customer during regulatory inspections? <ul style="list-style-type: none"> <li>• How does QA satisfy regulatory requests from a customer?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
How many inspections does the vendor support?	Per Month? Per Year?
Has the vendor themselves been through a regulatory inspection (FDA/MHRA)? What were the results of these inspections?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:

Are these risks acceptable - Quality  Yes  No  
 Are these risks acceptable - Operations  Yes  No

Notes:

# Deliverables

Topic	Response:
Are the following deliverables present? <ul style="list-style-type: none"> <li>• User Requirements Specifications</li> <li>• Data Loading Procedures</li> <li>• Testing Reports</li> <li>• Trace Matrix</li> <li>• Build Reports</li> <li>• Validation Report</li> <li>• Compliance Assessments</li> <li>• Quality Review</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
For IRT vendors, are there also the following deliverables present? <ul style="list-style-type: none"> <li>• Code Promotion Documentation</li> <li>• Project Scope and Management Documentation</li> <li>• Unblinded Addendums for requirements and randomizations, Installation Qualifications through each environment</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are there an inventory of tools in use for the SDLC? <ul style="list-style-type: none"> <li>• Are they customized or off the shelf?</li> <li>• Are they validated?</li> <li>• What role do the vendor's tools play in storing information?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Is unit testing performed prior to functional testing?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:

Is there a process in place for when regression testing is performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Is objective evidence captured and stored for the duration of the trial?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are there different personnel writing requirements, developing the system, and then performing the functional testing?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are there reviews of the test cases to ensure they are covering the applicable areas?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Does the SDLC clearly outline who is performing each task and what the staff is doing?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are these risks acceptable - Quality <input type="checkbox"/> Yes <input type="checkbox"/> No	
Are these risks acceptable - Operations <input type="checkbox"/> Yes <input type="checkbox"/> No	
Notes:	

# Hosting

Topic:	Is this applicable? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is a third party data center in use?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are there Service Level Agreements in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Has the Data Center been audited? Does the vendor only review the certificates? Are you able to review it?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
How will your information be stored? Will it be in a public or private cloud? How does the vendor ensure compliance with data privacy regulations?	Response:  <input type="checkbox"/> N/A
Does the vendor ensure protection of data? • What type of security is in place to protect your data?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
How often are the servers backed up?	Response:  <input type="checkbox"/> N/A
Does the vendor check their backups beyond making sure the tape can be read? Do they restore the data and access it?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
What type of backups are performed? Are they full or incremental backups?	Response:

	<input type="checkbox"/> N/A
What is the frequency of the backups being performed?	Response:  <input type="checkbox"/> N/A
How long are backups kept for? What is the retention schedule for the backups?	Response:  <input type="checkbox"/> N/A
Who owns and maintains the servers and equipment in the data center where your data will be stored?	Response:  <input type="checkbox"/> N/A

Are these risks acceptable - Quality <input type="checkbox"/> Yes <input type="checkbox"/> No
Are these risks acceptable - Operations <input type="checkbox"/> Yes <input type="checkbox"/> No

Notes:

# Outsourcing

Topic:	Is this applicable? <input type="checkbox"/> Yes <input type="checkbox"/> No
What work is outsourced for your project?	Response:

	<input type="checkbox"/> N/A
Where are the development teams based?	Response:  <input type="checkbox"/> N/A
What type of background/qualification checks are performed?	Response:  <input type="checkbox"/> N/A
Are Technical Support staff outsourced?	Response:  <input type="checkbox"/> N/A
Are the personnel working on your studies full time employees or consultants/contractors?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Is there a process around supporting your project once it is live?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Comments:
Are these risks acceptable - Quality <input type="checkbox"/> Yes <input type="checkbox"/> No Are these risks acceptable - Operations <input type="checkbox"/> Yes <input type="checkbox"/> No	

Notes:

# Disaster Recovery

Topic:	Is this applicable? <input type="checkbox"/> Yes <input type="checkbox"/> No
How long will it take the vendor to access your data?	Response: <input type="checkbox"/> N/A
How old will that data be once accessed?	Response: <input type="checkbox"/> N/A
What types of redundancies are in place?	Response: <input type="checkbox"/> N/A
How are redundancies maintained? How are they assessed?	Response: <input type="checkbox"/> N/A

<p>Is disaster recovery Testing Performed?</p> <ul style="list-style-type: none"><li>• How is disaster recovery tested?</li><li>• Is this a table top exercise or is there an actual shutdown/failover?</li><li>• What is the frequency of the disaster recovery testing?</li></ul>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>Comments:</p>
<p>What is the vendor's notification process in the event of an outage?</p>	<p>Response:</p> <p><input type="checkbox"/> N/A</p>
<p>Are these risks acceptable - Quality <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are these risks acceptable - Operations <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Notes:</p>	