

# Required items and its schedule for Part 11 compliance (new system introduction)

## Step 1

### Part 11 unified understandings and corporate consensus

- Goal agreement document for Part 11 compliance
- Internal notification
- Agreement on practical understanding on Part 11
- Internal education program and record management system



## Total support from Shimadzu

		[1] Unified understanding of Part 11, corporate consensus	Output required at minimum	Available Support from Shimadzu
Before introduction	1	<ul style="list-style-type: none"> <li>● Documented consensus on goals for Part 11 compliance                             <ol style="list-style-type: none"> <li>① Objective of Part 11 compliance</li> <li>② Scope and time limit (deadline to achieve 100% compliance)</li> <li>③ Gather Project Team (Objective: to establish process for Part 11 compliance)</li> <li>④ Preparation of progress report system and templates</li> <li>⑤ Preparation of corporate internal training materials</li> <li>⑥ Submission of Corporate Certification to FDA (when Electronic Signature is employed)</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>• Agreement on goals (document)</li> <li>• Progress report</li> <li>• Training materials</li> <li>• Corporate Certification</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for preparation</li> <li>• Training Materials</li> <li>• Review of documents</li> <li>• Support for work</li> </ul>
	2	<ul style="list-style-type: none"> <li>● Proper communication of goals for Part 11 compliance                             <ul style="list-style-type: none"> <li>• notification of the related departments in the company</li> </ul> </li> </ul>	Corporate internal notice	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Support for documentation</li> </ul>
	3	<ul style="list-style-type: none"> <li>● Agreement on understandings on Part 11 clauses                             <ul style="list-style-type: none"> <li>• Practical understandings on each clause of Part 11, and application to analytical systems</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Understanding documents for Part 11 compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Support for documentation</li> <li>• Referential information</li> </ul>
	4	<ul style="list-style-type: none"> <li>● Preparation of the internal training program and record control systems for project team and users</li> </ul>	<ul style="list-style-type: none"> <li>• Education program</li> <li>• Education record</li> <li>• Education material lists</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• List for education materials</li> </ul>
	5	<ul style="list-style-type: none"> <li>● Revision of User SOP                             <ul style="list-style-type: none"> <li>• Addition of new documents to the document management system</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Review of the document management system</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> </ul>

## Step 2

### Practical works for Part 11 compliance

- System requirement specification and collection of vendor information
- Execution of D Q /IQ/OQ/PQ
- System introduction, trial use, and internal audit



		[2] Part 11 compliance by employing a new system (before introduction)	Output required at minimum	Available Support from Shimadzu
Before introduction	1	<ul style="list-style-type: none"> <li>● Personnel training and training records</li> </ul>	<ul style="list-style-type: none"> <li>• Preparation of training records</li> <li>• Review of training materials</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Referential information</li> </ul>
	2	<ul style="list-style-type: none"> <li>● Preparation of system requirement specifications</li> </ul>	<ul style="list-style-type: none"> <li>• System requirement specification</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Referential information</li> <li>• Support for reinforcement works</li> </ul>
	3	<ul style="list-style-type: none"> <li>● Collecting information and proposal documents from vendors related to the requirement specifications</li> </ul>	<ul style="list-style-type: none"> <li>• Proposal documents from vendors</li> </ul>	<ul style="list-style-type: none"> <li>• Proposal documents</li> </ul>
	4	<ul style="list-style-type: none"> <li>● Evaluation of vendor's proposal documents</li> </ul>	<ul style="list-style-type: none"> <li>• Gap analysis record</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Referential information</li> </ul>
	5	<ul style="list-style-type: none"> <li>● Vendor inspection                             <ol style="list-style-type: none"> <li>① Making vendor inspection program, and execution</li> <li>② Making vendor inspection report</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>• Vendor inspection program document</li> <li>• Vendor inspection report</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Referential information</li> <li>• Support for reinforcement works</li> </ul>
	6	<ul style="list-style-type: none"> <li>● Preparation of the Design Qualification (DQ) and validation records</li> </ul>	<ul style="list-style-type: none"> <li>• DQ documents</li> </ul>	
	7	<ul style="list-style-type: none"> <li>● Review of the validation program including Part 11 compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Review of validation SOP</li> </ul>	
	8	<ul style="list-style-type: none"> <li>● Making validation documents additionally required for Part 11                             <ol style="list-style-type: none"> <li>① Validation master plan</li> <li>② IQ program document / IQ report</li> <li>③ OQ program document / OQ report</li> <li>④ PQ program document / PQ report</li> <li>⑤ System operation management procedure document (for administrator)</li> <li>⑥ System operation procedure document (for operator)</li> <li>⑦ PM program document / PM report</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>• Validation master plan</li> <li>• IQ program document</li> <li>• OQ program document</li> <li>• PQ program document</li> <li>• System operation management procedure document (for administrator)</li> <li>• System operation procedure document (for operator)</li> <li>• PM program document (including back-up program)</li> </ul>	
	9	<ul style="list-style-type: none"> <li>● Discussion with vendors for system introduction</li> </ul>	<ul style="list-style-type: none"> <li>• Confirmation of document and record content</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> </ul>
	10	<ul style="list-style-type: none"> <li>● Making system introduction program document                             <ul style="list-style-type: none"> <li>• including trial period, review of procedure documents</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• System introduction program document</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for procedure</li> <li>• Referential information</li> <li>• Support for reinforcement works</li> </ul>
Installation	11	<ul style="list-style-type: none"> <li>● System installation                             <ol style="list-style-type: none"> <li>① Execution of IQ/OQ/PQ</li> <li>② Execution of training and making education record</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>• IQ report (record)</li> <li>• OQ report (record)</li> <li>• PQ report (record)</li> <li>• Education record</li> </ul>	<ul style="list-style-type: none"> <li>• Support for IQ/OQ/PQ execution</li> <li>• Suggestion for practical procedures</li> </ul>
	12	<ul style="list-style-type: none"> <li>● Participation to training course offered by vendor for Part 11 compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Education record</li> </ul>	<ul style="list-style-type: none"> <li>• On-site training</li> <li>• Off-site training</li> </ul>
	13	<ul style="list-style-type: none"> <li>● Making internal audit program and confirmation of Procedural control</li> </ul>	<ul style="list-style-type: none"> <li>• Internal audit program document</li> </ul>	<ul style="list-style-type: none"> <li>• Support for contents reinforcement</li> </ul>
	14	<ul style="list-style-type: none"> <li>● Internal audit                             <ul style="list-style-type: none"> <li>• to be done at the end of trial period</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Internal audit execution record</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for countermeasures for points raised up by the audit</li> </ul>

## Step 3

### Part 11 compliant system operation

- Change control
- Internal education
- Execution of PM
- Periodic internal audit

		[3] Part 11 compliance after new system has been employed (after introduction)	Output required at minimum	Available Support from Shimadzu
After starting operation	1	<ul style="list-style-type: none"> <li>● System change management                             <ul style="list-style-type: none"> <li>• Client/User Addition/deletion etc.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Change control record</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for practical procedure</li> <li>• Change control document support</li> </ul>
	2	<ul style="list-style-type: none"> <li>● Periodic education, new user education</li> </ul>	<ul style="list-style-type: none"> <li>• Education record</li> </ul>	<ul style="list-style-type: none"> <li>• On-site training</li> <li>• Off-site training</li> </ul>
	3	<ul style="list-style-type: none"> <li>● Execution of PM (including back-up record)</li> </ul>	<ul style="list-style-type: none"> <li>• PM report (record) (including back-up record)</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for practical procedure</li> <li>• Support for documentation</li> </ul>
	4	<ul style="list-style-type: none"> <li>● Periodic internal audit</li> </ul>	<ul style="list-style-type: none"> <li>• Internal audit execution record (Correction record/Re-education record)</li> </ul>	<ul style="list-style-type: none"> <li>• Suggestion for countermeasure for points raised up by the audit</li> </ul>