

<b>Company Name</b>	Procedure Number:	Page 12 of 35
Title: <b>PAI Protocol for API</b>	Implementation Date:	Version Number 1.0

<b>PAI Protocol for API</b>	Name of document to be prepared / Document No.	Planned completion target Date	Status of documen t 6 months before filing	Status of documen t 3 months before filing	Status of document before filing	Status of document 1 week before inspection	Responsible Expert for document preparation	Responsible Expert for presentation during inspection	Location of storage / archive
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Availability of logbooks according to PAI Protocol API Attachment 7									
Completeness of equipment operating SOPs according to PAI Protocol API Attachment 7									
Completeness of equipment cleaning SOPs according to PAI Protocol API Attachment 7									
Completeness of qualification plans according to PAI Protocol API Attachment 7									
Completeness of qualification reports according to PAI Protocol API Attachment 7									
Completeness of cleaning validation plans according to PAI Protocol API Attachment 7									