



Simplify assessments.

Supplier Assessment Questionnaire Manufacturer User Guide

5 Steps for Using the SAQ

1.The manufacturer directs the supplier to the SAQ online at Rx-360.org/SAQ.

2.Indicate the modules you request and/or require to be completed.

- Refer to SAQ Module Descriptions and specify which modules you need completed by the supplier:
 - Module 1 Company Information
 - ·Module 2 Site-Specific Information
 - Module 3 Product Information
 - Module 4 Service Supplier
 - Module 5 Pre-Audit Questionnaire
 - ·Module 6 Single Use Bioprocessing Products

3. Receive completed SAQs.

 Expect the supplier to send you their completed SAQ in a PDF (for human review) and a JSON (for computer use).

4.Incorporate the completed SAQ into your supplier qualification process.

 Note anything from the completed SAQ that require further review and/or documentation and proceed according to your organization's process (e.g., requesting additional documents).

5.Use completed SAQ files to compare responses across time and/or across suppliers, according to the needs of your organization.

The SAQ is a product of the Rx-360 Supplier Quality Working Group. For more information about the group or support using the SAQ, email info@rx-360.org.

The SAQ Feedback Loop

Manufacturer Initiates Request

- Specifies required SAQ modules (e.g., Company Info, Product Info)
- Directs supplier to complete the SAQ online

Supplier Completes SAQ

- Fills out relevant modules with accurate, current data
- Electronically signs and reviews the submission

Supplier Sends SAQ Files

 Shares PDF (human-readable) and JSON (machine-readable) files with manufacturer

Manufacturer Reviews Submission

- Evaluates responses for completeness and accuracy
- Identifies areas needing clarification or additional documentation

Manufacturer Provides Feedback

- Requests updates or supporting documents as needed
- May compare responses across time or across suppliers

Supplier Updates SAQ

- Revises and resubmits SAQ based on feedback
- Maintains current information proactively

Loop Continues

 Ensures ongoing alignment, compliance, and qualification readiness