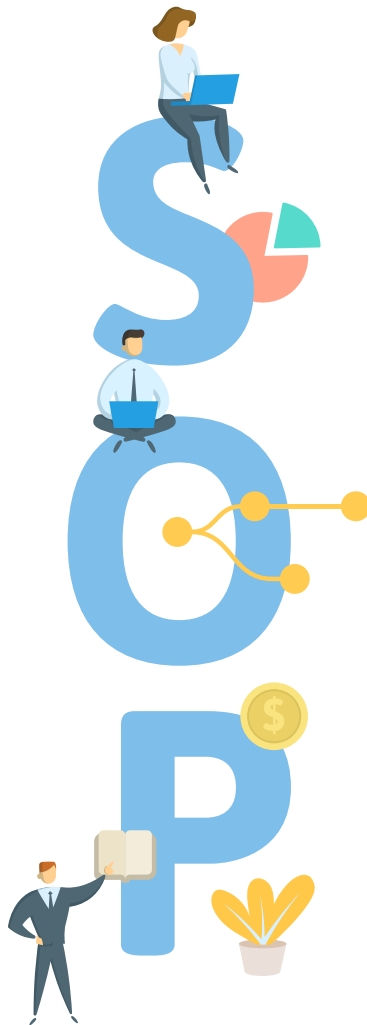




Your RFP Template for Selecting an **SOP** Application





A written Standard Operating Procedure (SOP) creates an exact procedure for completing a task, and when trained staff adhere to the SOP, they are repeating an explicitly defined process. And that means that the same process is repeated again and again, and the organization will climb the learning curve and get better and better at it. More efficient. With higher quality.

The result can be transformative because repeatable, high-quality, and cost-efficient execution is the fuel for rapid growth.

But here's the kicker - storing those SOPs in a file share or a Dropbox and managing how your employees view and are trained on them in a spreadsheet, is the opposite of transformative; it's excessively complex and hard to control. And let's not even get started on how you create and update new SOPs.

An application that helps you store, collaborate, and manage SOP is necessary for success if you manage many SOP documents. An SOP application that also enables you to control how your employees are trained is better.

But not all SOP applications are alike. So, when you decide it's time to invest in one, you need to know precisely what you are looking for and why.

We developed this RFP guide to help you do just that. Use this template as a guide - add things we may have missed and take out what doesn't apply to your situation.

And if you have any questions, please feel free to reach out. We're here to help.

[Company Name]

Request for Proposal for a System for
Managing **Standard Operating Procedures**
and related Training Records

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1. Introduction

<Company> is a **[describe company]**.

<Company> is seeking to implement a system for managing Standard Operating Procedures in order to **[describe high level goal]**.

The purpose of the Request for Proposal is to gather alternative solutions from multiple vendors in order to compare and contrast the capabilities of the systems, the qualifications of the vendors and the cost of the solution.

2. Scope

The scope of this RFP includes a system for managing SOPs as well as the services to implement the system, train users, ensure validation and begin production use. It also includes on-going support services for the duration of the use of the system.

There will be approximately **[number of users]** of the system. This includes administrators, individuals responsible for creating and reviewing SOPs, and general users of the system who will access and read SOPs and for whom the system will maintain training records.

The system will be used by users in the following locations:

- [Location 1]
- [Location 2]

The relevant schedule for the activities described in this proposal are for the work to start on or around **[date]** and for the system to be in production use by **[date]**.

3. Submission of Responses and Evaluation

Responses to the RFP are due no later than close of business on **[Date]**. They should be delivered as PDF documents in a format of the responders choosing, but including all information requested in this RFP.

Submissions will be evaluated according to the following criteria:

- Experience and qualifications of the vendor
- The functional match with the requirements documented in the RFP
- The cost of the solution over a three-year period
- The schedule for the implementation of the system
- The strength of the references provided by the vendor

4. Vendor Description

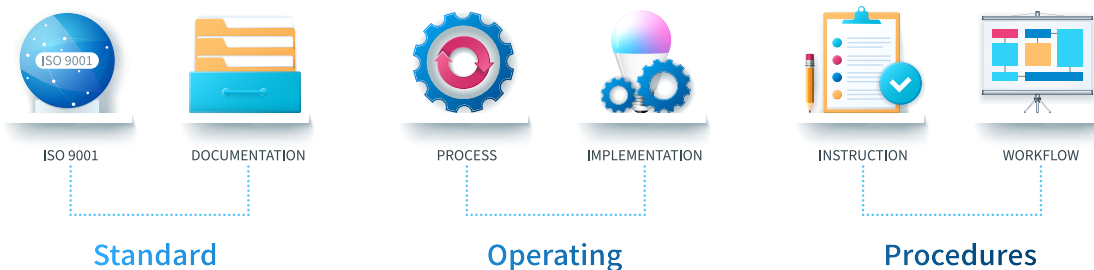
In your proposal, please provide a description of your company, including

- Location
- Years in Business
- Size of business in employees (full time and contractor, as two numbers)
- Where development is done
- Years in business
- Years the proposed solution has been available
- Approximate number of customers of the proposed system

5. Software Solution Description

In your proposal, please provide a description of your proposed software solution, including

- The basic functionality and capabilities of the system
- How the system addresses relevant regulatory requirements
- How the system is different than alternative solutions
- The required hardware and software environment
- Whether it is cloud-based or on premise
- Of cloud-based, whether it is multi-tenant
- If cloud, where and by whom it is hosted
- Who manages the execution environment
- Where the software is developed
- Where the support organization is located



6. Vendor Description

In your proposal, please provide a description of your proposed approach to implementing the proposed solution and providing associated services, including

- Location
- The planned schedule for the implementation project
- The steps or phases of the implementation plan
- The date the system will be available for production use
- The resources (people) who will be assigned to the implementation
- The time and resources that will be required by our team members
- How you will communicate progress to us on the project
- How the system will be validated
- How you will train users
- How you will support us after the system is in production use

7. System Costs

In your proposal, please provide a listing of all the associated costs of the system, including

- Initial cost for the software
- Recurring annual cost of the software
- The costs for the proposed services
- How your services will be billed: fixed price, hourly or other



APPENDIX A

Please provide an analysis of your systems capabilities based on the attached requirements matrix on the following pages

Appendix A: Analysis of Application Requirements

Please provide an analysis of your proposed solutions capabilities based on the requirements matrix below.

Use the following system to rate each requirement in comparison with your proposed solution:

1. Completely addressed
2. Partially Addresses
3. Addressed Differently
4. Not Addressed

System Requirements

System Requirements	Rating	How is the requirement addressed in your solution?
The solution is provided as a cloud-based service		
The system is a Multi-Tenant application, that is, the same core code is used by multiple customers		
The system is offered on an annual subscription basis, with payments due annually		
The system can be accessed by any user via a browser		
Provide different standard roles for individuals and groups		
Include disaster recovery, ensure business access within standard timeframes and include regular backups and administration		
The service includes disaster recovery, ensures business continuity within standard timeframes and includes regular backups and system administration		

Document-Related Requirements

	Rating	How is the requirement addressed in your solution?
Store and manage templates for standard document types such as SOPs and Work Instructions		
Create standard documents such as SOPs and Work Instructions and the ability to require (or not) creation from a template		
Allow the creation of new quality document and item types, with defined metadata, and the ability to require (or not) creation from a template		
Allow creation and editing of documents without the need for external software application such as MS Word		
Allow related documents to be linked or related		
Store any type of file		
Automatically number and name new documents		
Allow external users to upload documents to the system		
Be easily searchable and sorted and "folderized" by their attributes		
Control access to documents by role		
Maintain archive for all retired documents and enforce archive rules such as allowing no changes		
Add custom fields (metadata) to further categorize and classify documents		
Create custom categories to view, manage and track documents		
Allow multiple users to comment and edit on a document while tracking comments and edits		

Document-Related Requirements (cont'd)

	Rating	How is the requirement addressed in your solution?
Allow preview of a document without the need for an external product (such as MS Word)		
Include the ability to search items by metadata or full text content		
Track and retain versions of all items		
Control check in and checkout processes		
Option to automatically name and number documents based on a standard pattern that utilizes metadata as component parts		

Workflow Requirements

	Rating	How is the requirement addressed in your solution?
Manage documents through life cycles from draft to final		
Create customizable workflow review/approvals based on document category		
Allow definition of specific workflows based on the type of document		
Upload and route a draft of a document to users for review and approval		
Provide notifications by eMail of tasks that are assigned to users		
Assign tasks to users		

Workflow Requirements (cont'd)

Workflow Requirements (cont'd)	Rating	How is the requirement addressed in your solution?
Create customizable workflow review/approvals based on document category		
Use custom fields to further categorize and classify documents		
Export any document to to a PDF		
Export table data to .csv		
Allow multiple users to comment and edit on a document while tracking comments and edits		
Allow preview of a document without the need for an external product (such as MS Word)		
Upload and route a draft of a document to users for review and approval		
The system should have a possibility to link documents e.g. SOP and associated form		
Status and version of the document should be visible on printed document		
Apply watermarks to documents based on the stage of the document		
Choose any two drafts while in draft review and see differences between two documents		
Allow external users to upload documents to the system		
Allow definition of specific workflows based on the type of document		
Provide notifications by eMail of tasks that are assigned to users		
Control access to printing		

Training Record Requirements

	Rating	How is the requirement addressed in your solution?
Store training content		
Create training records related to specific documents and groups of users		
Support training content delivery & training record management		
Allows the assignment of training requirements by user and by role		
Track the completion of training requirements per user as official training records		
Notify users when training is due /overdue		
Provide reporting on training history by individual, groups, direct reports, and the entire company		
Notify relevant user (manager) of user training failure		
Generate a report showing users who are delayed with their training		
Generate a training matrix with required training for user, job role or department		
Create training events for groups or individuals		
The system should offer automated testing functionalities (e.g. quizzes)		

Document Change Control

	Rating	How is the requirement addressed in your solution?
Create and manage change controls related to any SOP or item		
The system should have an option to allow Quality only to close or cancel a change control		

Import, Export, Archive, Printing

	Rating	How is the requirement addressed in your solution?
Import groups of documents in to the application while retaining metadata		
Export an entire study to a ZIP file while retaining folder structures		
Export any document to to a PDF		
Export table data to .csv		
Control access to printing		
Status and version of the document should be visible on printed document		
Apply watermarks to documents based on the stage of the document		
Choose any two drafts while in draft review and see differences between two documents		
The system will have the ability to assign tasks to users		
The system will allow users to set due-dates for assigned tasks		

Compliance Requirements

	Rating	How is the requirement addressed in your solution?
Capture and track creation dates and dates of any action on any item		
Provide special limited access to an auditor		
Provide an audit trail showing every change to every item in the system		
Support Electronic Signatures		
Track and retain all versions of every item in the system		

List any additional capabilities not listed above:

	Rating	How is the requirement addressed in your solution?

About Agatha SOP

Agatha SOP is a cloud-based application that enables you to track employee SOP compliance and training activities. It comes with a standard set of templates and processes which you can configure to support your requirements.

The SOP application provides audit records, documented changes, and electronic signatures to ensure every activity is fully documented and ready for inspection.

[Learn more](#) about our application or Request a [demo](#) or [free trial](#)



About Agatha

Agatha, Inc. is a strategic software solutions provider to the healthcare and life sciences industry, providing SaaS-based business applications for managing SOP, regulatory documents, and clinical trial master file records.

With offices in the US, Europe, and Japan, Agatha is dedicated to helping the world's Hospitals, biotechnology, pharmaceutical, contract research organizations, and medical device firms optimize the management of their Quality, Regulatory and Clinical documentation and processes.

With lower costs and faster onboarding, Agatha delivers the best ROI on business applications for life sciences that are ready to use, fast to deploy, and easy to adopt.

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