**Use this worksheet to plan your SOP development Project.**

*The first step when embarking on an SOP development “project” is to gather your thoughts and set up a planning meeting. You should come to the planning meeting with as much of the following information as possible – the rest can be determined during the meeting.*

* 1. **What is the name of this SOP development project?**

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* 1. **What are the objectives of the SOP development project?**

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| * + 1. **Is there an “inspiration piece”?**

*Sometimes we start with one particular goal:** *There is a new or updated regulation that you need to meet.*
* *A new policy has been issued and you need procedures to comply with it.*
* *You’re starting a new project and the contract mandates SOPs.*
* *You have a form, and now you need a procedure to go with it.*
* *You have a process that you’ve been doing for years, but you need to make it more efficient.*
* *You have good, efficient processes, but the size of your group is growing, so you need written procedures to ensure consistency between established and new staff.*
* *You have a set of existing procedures that need to be updated, harmonized, or globalized.*
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| **What is your *inspiration*?** |
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| * + 1. **What standards apply?**

Include:* Regulations and guidelines
* Contractual requirements
* Company policies
* Industry standards
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* 1. **What is the scope of the project?**

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| * + 1. **What is the scope of the SOP development process?**

Will the project include?* A single SOP
* An entire series of SOPs
* SOPs and supporting documents
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| * + 1. **What is the scope from a *Process* perspective?**
* What processes and tasks will be covered?
* How should they be organized and grouped?
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| * + 1. **What is the scope from a *People* perspective?**

To whom will the procedures apply? * Are the procedures “general” (applying to everyone within a group)?
* Will the procedures only apply to one particular functional area?
* Are the procedures for a specific project or client?
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* 1. **Who will be involved in the project?**

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| 1. **Who are the folks who will be involved in SOP *development*?**
* Who are the technical experts?
* Who will be writing the procedures?
* Who should be invited to meetings?
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| 1. **Who are the folks who will be involved in SOP *review*?**

Who are the key stakeholders? * Does the process or procedure intersect or connect with other processes within or outside of your functional area?
* Will this process or procedure utilize the resources of another functional area?
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| 1. **Who are the folks who will be involved in SOP *approval*?**

Who will be the signatories for the procedures?* Who are the process owners?
* Who are the functional area heads?
* If the procedures are project-specific, who is the project director or project manager (PM)?
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* 1. **What is the plan for SOP implementation?**

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| * + 1. **Is there a specific date targeted for implementation of the procedures?**

Consider the following, as applicable:* Effective date of new or revised regulation
* Compliance date for new or revised policy
* Start date for newly awarded project or new task
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| * + 1. **What is the strategy for awareness and training on the new procedures?**
* Who will need to have documented training on the procedures?
* How much time will need to be allowed for training between the issue date and the effective date?
* What type of training will be utilized?
	+ Read-and-sign
	+ Live training
	+ Objective assessment
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* 1. **Access to and Control of Documents**

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| * + 1. **Who will need access to the documents once they become effective?**
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| * + 1. **Is there any expectation for external distribution?**
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