**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.* |
| **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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