

[Back to Articles](#)

Current Quality Newsletter

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IN THIS ISSUE

[Feature Article](#)

[Sandra Recommends](#)

[Have A Topic Idea?](#)

I'd love to hear it! Just let me know what Quality Assurance topics you'd like to know more about.

[Have A Question?](#)

Please don't hesitate to hit the reply button if you have any questions.

SIDE BLOG

[Resistance to Change: We've Always Done it This Way...Why Change Now?](#)

[If Your Corrective Action Isn't Effective, Then You've Missed the Point!](#)

NEW PODCAST

[Reclaim 2-4 Hours of Your Work Day by Following These Strategies....](#)

PODCAST ARCHIVE

Hello

It looks like summer has somewhat arrived in New England. Although the rain has let up, the temps overall have been unusually cool for this time of year....maybe we'll have a late summer this year?



I hope you've had the chance to listen to the most recent podcast, '[Reclaim 2-4 Hours of Your Work Day by Following These Strategies](#)', with Bill Jensen. Bill's a very dynamic individual with years of experience helping people cope with their daily workload (e.g. Too many useless meetings, too many emails to read or respond to, etc.)....he truly understands the importance of work-life balance and shares several strategies and tips in the podcast on how you too can enjoy a better work-life balance. He also has a fun presentation style and personality....his bio made me laugh....his 'personal fantasy is to bicycle around the globe via breweries'.

Let me know if you'd like to hear more podcasts that focus on time-saving tips and strategies....just hit the reply button right now!

If you're struggling with trying to implement a Risk Management program, but don't have many resources to dedicate towards the implementation or if you're just not sure where to start, then take a few minutes and read the feature article, '[9 Steps to Implementing Risk Management: A Fast & Easy Approach](#)'.

Take care,
Sandra

9 Steps to Implementing Risk Management: A Fast & Easy Approach

by Sandra Gauvin

If you're looking for a straightforward approach to implementing a Risk Management Program that complies with the [FDA Guidance for Industry Q9 Quality Risk Management](#), or [ICH Q9 Risk Management](#) (the requirements are the same), then keep reading! This approach can also be applied to medical device and non-biotech industries.

Follow these 9 steps to implement a Risk Management Program:

1. **Take the process approach.** Whether your implementing risk management into your Quality System, project, or product life-cycle, you should start out by identifying the core processes within the scope that you've defined.

TIP - Involve process owners so they're accountable for assessing and managing the risks related to their process, plus it's a great way to incorporate risk management into your organizational culture.

2. **Know your potential risks.** For each process, identify potential risks that may exist if a process step is either done incorrectly or not at all. You'll need to define

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the types of risk that you're assessing for...common risk types include: patient safety, compliance risk, and business risk.

TIP 1 - The easiest way to identify your potential risks, is to complete a mid-to-high level process map for each process within your scope. By doing so, the process steps will be evident and you can then assess what would happen if a step was done either incorrectly or not at all.

TIP 2 - If you don't have flowcharting software, consider using [Google Docs](#)....it's easy to use and it's free!

- 3. Consider your current controls.** For each risk, identify what controls you currently have in place that would either reduce or eliminate your exposure to risk.

TIP - Make sure that you consider only the controls that you currently have in place and not the controls that you plan on implementing. Any in-process or future controls should be documented in your action plan.

- 4. Assess your risk exposure.** Quantify your risk exposure by determining the likelihood of the risk occurring multiplied by the severity of the risk....make sure that you consider the controls you currently have in place when performing the calculation.

Risk Calculation: Likelihood of Occurrence x Severity

TIP 1 - Regardless of the risk tool that you use to determine your risk exposure (e.g. Risk Matrix, FMEA, HACCP), make sure that you define a rating system before you begin assessing your risk. Otherwise, your results will be left to interpretation.

TIP 2 - Never complete a risk assessment independent of process stakeholders, otherwise you may not identify all risks. Also, you'll need their involvement when it's time to implement controls....unless of course, you want to do all of the work yourself....I didn't think so!

- 5. Mitigate your risks.** Depending on the assessment of your risk exposure, you can mitigate your risks by either: Accepting the risks (i.e. doing nothing), put controls in place to lower your risk, or transfer your risk (i.e. purchase insurance).

TIP - Identify action thresholds within your rating system so it's clear when you should take action (i.e. mitigate risks) and when it's optional. For example, all high risks should be addressed immediately, while low risks may be optional.

- 6. Verify effectiveness of your controls.** Take the time to verify that your controls are effective, otherwise your Risk Management Program is just a documenting exercise that any auditor will see through.

TIP - One way you can verify effectiveness, is to take a look at your nonconformance's to see if your controls are robust enough to minimize your risk exposure. If you continue to have nonconformance's associated with a process, then your controls are not effective.

- 7. Create an action plan** - Document which risks will be addressed, along with a high-level implementation plan that outlines what actions will be taken within a certain time-frame.

TIP - It's a good idea to use your Corrective Action (CA) process to document the action plan for each risk that needs to be addressed. This will provide management visibility regarding the progress of each action, plus you'll have documented evidence of the actions. You can reference the CA number in your risk assessment.

- 8. Communicate your results** - It's important that Senior Quality Management and

the process owner are aware of the risks associated with a process and what actions need to be taken. You may also want to include process stakeholders in the communication process.

TIP - Document your risk assessment....make sure that Senior Quality Management and the process owner signs the risk assessment (for a total of 2 signatures), verifying that they're aware of the risks, controls, and action plan. Process stakeholders don't need to sign, but should be informed.

- 9. **Re-Assess risk.** If changes are made to a process, no matter how insignificant, make sure that you go back and re-assess your new risk exposure, if any. Your re-assessment shouldn't take you as long as the original risk assessment, unless you're making major changes to the process.

TIP - Use revision controls to document your re-assessment....and don't forget that Senior Quality Management and the process owner needs to sign the new revision.

Sandra Recommends....

[Google Docs](#) is a free tool that allows you to create flowcharts, diagrams, spreadsheets, presentations, surveys, forms, plus share these documents with several people at the same time so you can get feedback real-time. This tool is great if you're working on a project and need the teams feedback without scheduling a meeting.

If you already have a gmail account then you're all set....just sign-in. Otherwise you'll have to set up an account.

This is how easy it is to use Google Docs....Here's how you would create a flowchart/process map:

1. Select New Document
2. Insert Drawing
3. Drag & drop your shapes
4. Save & close

It's really that easy!