

13485Academy vs. do it all on your own

Utilize our convenient 13485Academy vs. do everything by yourself comparison matrix for a speedy analysis of the advantages and disadvantages of self-implementation of ISO 13485:2016, i.e., without any expert assistance. You can also analyze the advantages of using our experts’ knowledge at 13485Academy to help you in your completion of ISO 13845 project.

Our comparison matrix will help you to rapidly conclude which alternative is optimal for your company, considering overall money and effort, difficulty, and comprehensiveness of the documentation.

So, what will it be? Complete your ISO 13485 project all by yourself, or with the group of professionals at 13485Academy?

| Implement all on your own | 13485Academy |
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| <p>“Our employees can design and develop the documents, and that won’t cost us a penny.”</p> | <p>Our study demonstrates that doing it on your own can cost 500% more than purchasing our toolkit – your employees would consume several hundred man hours developing documents from scratch, which could be productively used in other areas for the growth of the company.</p> |
| <p>“Our employees are well organized and have sufficient experience in similar projects. They can make all these documents rapidly.”</p> | <p>It requires about half the time to complete ISO 13485 projects with our templates. If your employees have never applied this specific standard, it will probably take them numerous attempts to make it right.</p> |
| <p>“Our employees understand standards. They’ll search through the standards and make sure that nothing gets overlooked.”</p> | <p>Those implementing the standard for the first time are 5 times more likely to fail the ISO 13485 certification audit. You can’t understand the criteria for the certification audit by merely reading the standard.</p> <p>13485Academy gives you the guidelines on how to implement the standard through document templates, video tutorials, document reviews, and one-on-one meetings.</p> |

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| <p>Those free documents you got online are typically missing one-third of the documented information the standard requires.</p> | <p>Our toolkit encompasses all mandatory documents required by ISO 13485, and also some non-mandatory documents that are commonly used.</p> |
| <p>Those free toolkits have templates collected from multiple sources and authors. This means documents are based on different structures, and may not even observe the same rules.</p> | <p>One team of experts developed all of our documents, keeping them coherent and related. And, to assist you in understanding interactions between documents, every document is cross-linked with its accompanying documents.</p> |
| <p>Free toolkits usually have an inadequate structure.</p> | <p>Our toolkit is well aligned with the needs of smaller and medium-sized companies. Templates are placed in folders, in the exact sequence in which they need to be implemented.</p> |
| <p>“Our employees know their respective processes, so they can make the documents that are customized for their needs.”</p> | <p>You can adapt our templates to your specific needs – in reality, you can amend as much as you want to use them in your daily work.</p> |
| <p>Starting the work from scratch means that you have quite a lot of work to do.</p> | <p>Our documents are 80 to 90% completed, and they have guidance on what needs to be filled in.</p> |
| <p>Self-implementation leaves you on your own, even when you get stuck.</p> | <p>The 13485Academy delivers the following support as part of the toolkit: a one-on-one consultation with an expert, review of your documentation, and templates that clearly show what needs to be filled in and what can be left out.</p> |

Click here to [download a free demo of the ISO 13485 Documentation Toolkit](#) that will help you implement the standard with 13485Academy expert support.