Common Sense Systems

Case Study: IEC 60601-1 3rd Edition Compliance Management

One of the biggest challenges facing our clients today is compliance with the *third edition* of IEC 60601-1 because it represents such a radical change from its predecessor. Unlike the *second* edition which addresses risk management in a relatively limited fashion, the third edition requires documentation of risk management and essential performance *throughout the product lifecycle*. Certification to 60601-1 also requires compliance to ISO 14971, *Application of Risk Management to Medical Devices*, an elaborate set of risk management requirements for medical devices.

The updated requirements have resulted in time-consuming testing and documentation, which requires more company resources than their predecessor, *second edition*. This, in turn, can jeopardize product shipping schedules because, failing compliance, regulatory bodies and agencies will not permit companies to ship their devices within the regions of their governance.

Following is a case study of a project that Commons Sense helped facilitate through 60601-1 3rd edition compliance and the ensuing results. We hope you can benefit from our experiences for your own 3rd edition efforts.

Situation:

Our client had initiated the process to get multiple products in the market tested and approved for IEC 60601-1 3rd Ed compliance. To certify compliance, the client retained the services of a recognized third party testing laboratory. Submission of the products to the lab, however, required extensive product documentation, completed checklists (mandated by the test lab), test results from the client's own lab, risk management illustrations, essential performance illustrations and other documents. Additionally, constant communication was required between the client and the test lab regarding structure and contents of these documents, resulting in extensive modifications and resubmission. All work had to be completed according to a project schedule which was designed to get the products shipped and achieve dominant market share and optimized profit.

How Common Sense Helped

To facilitate quality, compliance and efficiency, we took over preparation of all documents and checklists in advance of submission, made the modifications required by the test lab and resubmitted documentation as necessary. This required expertise in risk management, understanding the workflow, interaction with multiple client teams, coordinating outputs from different teams, version control and attention to detail, all the while adhering to the client production schedule.

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The Results

Since Common Sense handled all documentation, checklists and illustrations, the client's Compliance team was able to dedicate all its resources to ensuring compliance of multiple products and meeting multiple project schedules. As a result, submission to the testing lab and the ensuing 60601-1 3rd Ed certification were completed on time and the client was able to bring its products to all its major markets on schedule.. It also gave them an edge over their competition because they were one of the first in the industry to be IEC 60601-1 3rd Ed compliant. Which mean, they were able to:

1. Seize the dominant, first-mover position in their marketplace and

2. Optimize their return on R&D and manufacturing investments.

To conclude, this is the type of project which Commons Sense Systems is uniquely suited to handle. While it is not always glamorous, participating in the successful introduction of new medical devices to a world that can benefit from them . . . well, that's why our regulatory affairs and compliance engineering professionals come to work every day.

Solution: Common Sense Systems can help!

We are experienced in developing software tool validation plans and protocols. We can help develop a customized solution for your tool chain.

About Commons Sense Systems:

Common Sense Systems was founded in 1996 by computer design engineer John Sambrook to help regulatory affairs and compliance engineering professionals at medical device manufacturing companies.

He believed (and still does) that a fresh, common-sense approach would radically improve existing methodologies and dramatically decrease the time required to bring new products into the competitive medical device marketplace.

Today Common Sense can boast of many successes in significantly and rapidly improved productivity and operational results for medical device manufacturers.

How do we do it?

Common Sense brings an expert team of software engineers and regulatory affairs experts to its clients. But just as importantly, we provide our clients with the management tools to report on the status of all regulatory affairs and compliance engineering processes and projects to all audiences within client organizations – from design to compliance engineering to engineering and executive management. This vital communication ensures that all product decisions are fully informed and aligned with overarching company goals.

Is it magic? In a word, no. In fact, the praise we are most proud of is when we are told by clients that, in the final analysis, our solutions are just common sense. To us, that means that our services seem natural, are non-disruptive to implement and deliver very obvious procedural and financial rewards.

We are located in the Greater Seattle technology hub, in Woodinville, Washington, USA. If you'd like to chat about how we can be of service, please contact us today.