3rd Annual Lifecycle Management for Combination Products

SPEAKER INTERVIEW

November 16-18, 2020 | 100% Online
9.00am - 5.00pm EDT | 6.00am - 2.00pm PDT

Industry Speaker

Alan Golden
Principal
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Ahead of the **3rd Lifecycle Management for Combination Product Summit,** we caught up with Alan Golden, Principal at Design Quality Consultants, LLC. Alan has over 30 years of experience in the medical device industry. He spent 31 years at Abbott Laboratories, spanning across diagnostics R&D and quality assurance, where he was responsible new product development, on-market product support and operations.

Alan is a seasoned expert in design control, change control, risk management, process and test method validation – and has been training drug and device developers worldwide over the last 10 years.

Alan will be leading a panel discussion on September 9, 2020, on **Design Control - Fundamentals, Requirements & Practice.**

Alan, thanks for taking the time to speak to us. Coming from a device manufacturer background, how has design control evolved over the last 10 years?

The basic concepts of design control have remained consistent over the past 10 years. What has evolved is the implementation. More and more companies are working to introduce or refine their design control procedures to meet the needs of modern medical device development and manufacturing as well as continual updates to comply with worldwide regulations. More and more countries are now requiring full and traceable design control prior to approval of products. With the introduction of the EU MDR and IVDR, a lot of legacy products will need to be remediated to current design control standards to remain on the market.

As we see the shift of definition of an injectable device to become a combination product, and the increased emphasis of usability demanded by the FDA, design control and risk management have never been more important. However, we see drug developers struggle to execute these activities well.

This is very true. An injectable device has always been a "medical device" product. Where it gets complicated is when you are selling the device pre-filled with a pharmaceutical. Since you don't conceptually design a pharmaceutical drug the same way you design a piece of equipment (a device), pharma companies have to shift their thinking to designing something that is going to be used, not just ingested by the end user or patient. This adds the additional burden of designing for human factors (usability), as well as adding risk profiles for human factors and potential misuse. This could also include risks from electrical, software, and human interface issues depending on the device. There is also the extra complexity of increased labelling requirements from the regulatory agency. Now not only does the drug developer need to consider and demonstrate the dosing and potential side effects, but also clearly tested and defined instructions for the use of the device.

Most device engineers are challenged by post-approval changes. Recently we see a lot more discussion around the best practice of design history files and process validation. Do you have any tips for our audience?

Post approval changes are challenging for any organization. Typically, the design team will have moved on to other projects already, while your manufacturing line will be busy with routine production.

> "Not only does drug developer need to consider and demonstrate dosing and safety to the regulatory agency, but also clearly tested and defined user instructions for the use of the device – and pharma companies must shift their mindset to this"

Take a look at the full program

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> Design control and maintaining a good design history file are extremely important – but can also be a challenge for mid-sized biotech. Depending on business and goals, it might make sense to farm out design control to external partners. However, if they intend to tap into medical device activities, my advice would be to build in-house capabilities.

To be successful with post market changes, a dedicated team needs to be in place to manage through the change, where R&D and manufacturing personnel will play a supporting role. The biggest gap which I often see is limited, or a lack of, appropriate impact assessment before implementing a change. Without a complete, well thought out and well documented impact assessment, it is easy to break something while trying to fix the problem. Drug and device developers need to recognize the importance of a thorough verification and validation, and correctly categorizing the risks and impact level of the change, as opposed to avoiding shortcut. My best advice and rule of thumb is having a well thought through, well documented SOP outlining changes' impact level and risk assessment, enabling clear understanding and protocols to manage this change and ensuring quality assurance.

Secondly, the value (and regulatory requirement) of a good design history file cannot be overstated. It is the basis of the device design and is a living document from product inception through the life of the product. During a post approval change, the design history file is the first place to look to determine the logic behind the device design and what was done to verify/validate the product. It is where the basic design inputs for the product are stored, such as user needs and product requirements. During the change impact assessment, it is essential to ensure that after the change, the product is still meeting approved user needs and product requirements. In the case of a new or altered use for the product, user needs and/or product requirements should be updated and the new or updated requirements need to be verified/validated per design control requirements.

Finally, process validation is essential in both pharma and medical device manufacturing, and there is no practical difference in this between industries. Any process that is not 100% verified must be validated to ensure confidence that you are making a product of sufficient quality. This also gives you the benchmark and reference point to post approval changes. Any process involved in manufacturing the product being updated or changed must be evaluated to ensure it is still meeting the needs of a quality product. The changes may require addition validations or extensions to existing validations. This is all part of the complete impact assessment that must be conducted for any post market product change.

Design control, change control and design validation play an integral role in injectable device's lifecycle and speed-to-market. It is however challenging for smaller biotech where they might not have the resource support to execute this well. What's your view?

This is a challenge to many smaller firms. The implementation of design control, maintenance of a design history file and having adequate change control are not easy or simple tasks, and require dedicated personnel. In this case, the firm has to make a decision, whether to put that expertise in place "in-house" or contract out. That decision is really based on economics. If the firm plans to get into the medical device business, it makes sense to work to build the expertise in-house. Maybe starting with consultants to build the infrastructure and documentation needed. On the other hand, depending on the goals, size and direction of the firm, it may make more sense to farm out the design control work like many companies use contract manufactures.

Ahead of the 10th Injectables Summit, could you give us a preview of what to expect in your panel discussion?

Recognizing the challenge and importance of design control, I will be leading a panel discussion on this subject. I hope to hear my fellow panellists' experience in this space, and compare different approaches.

I hope we can all get inspirations and takeaways of design control and how it applies to the design, development and post market maintenance of medical devices and combination products.