Defensible Compliance

Background

Compliance to regulatory requirements is evaluated based on providing evidence that established regulation requirements have been satisfied. This translates into having documentation to support that certain activities have been performed, procedures established, and/or performance requirements satisfied.

Because regulatory requirements tend to be general it is often hard to define what specific evidence (documentation) is sufficient to convince an FDA reviewer or investigator that the company has adequately addressed the requirements. We are all aware of many stories about companies that have provided a tremendous amount of documentation and still had questions with regard to submissions or problems during inspections. There are also many stories about very detailed questions being raised and very prescriptive observations being noted during inspections. As a result, there is a tendency to err on the side of caution and to continually add more documentation, or evidence, than may be necessary. This can pose a problem in terms of how much evidence is enough?

If there is no strategy to defend the adequacy of existing documentation, there is a tendency to continually add additional documents to address any potential questions that might be raised by a reviewer or investigator. The question becomes how can you be confident in your ability to defend the adequacy of compliance without going overboard on documentation? The answer: Defensible Compliance.

What is Defensible Compliance?

Defensible Compliance means that there is a documented rationale (objective evidence) that shows how your quality system provides coverage of specific regulatory requirements. If implemented properly, a defensibly compliant approach to your quality system can prevent the all too common incremental creep of added complexity into your quality system over time.

The Benefits of Defensible Compliance:

A Defensible Compliance strategy can prevent your quality system from becoming overly complicated due to “creeping complexity”. Creeping complexity may be due to detailed audit observations (internal or external), overzealous CAPA activities that end up making processes more cumbersome and difficult to follow, or fears that documentation needs to continually increase to meet escalating regulatory demands.

A quality system aligned with a Defensible Compliance strategy has also been shown to reduce compliance risk in that procedures are easier to follow and more simple to audit resulting in less non-conformance observations.

How do I implement an approach to ensure "Defensible Compliance" for my quality system?

There are several key elements to the implementation of a defensibly compliant approach to your quality system.

1. Know the applicable regulations and standards for the regulatory requirement to be addressed.
2. Translate the applicable requirements into a checklist that can be used to trace specific requirements to applicable practices in your quality system.
3. Ensure the relevant requirements are adequately documented in your quality system being careful to define practices in a manner that is aligned with quality benefits for your products and processes and not overly complex or burdensome.
4. Provide a rational for the regulatory requirements that are not applicable to your quality system or for which you have tailored the requirements to fit your specific products or practices. (If you have documented a reasonable rationale it is very likely to be accepted by any FDA investigator or ISO auditor.)

What are some signs of quality systems that have become overly complicated?

1. Excessive numbers of review and approval signatures on procedures or forms, resulting in increased time for finalizing documents without added benefits from these delays
2. Excessive documentation and test requirements for even the most trivial product changes
3. Reluctance to use automated tools because of validation of "Part 11" fears (21 CFR Part 11 is the FDA's Electronic Record and Electronic Signature Regulation)
4. Selection of suppliers with inferior quality products or services because of supplier qualification complexity

CAUTION: Defensible Compliance is not an excuse to avoid value added processes

Do not allow Defensible Compliance to be used as an excuse to avoid practices that are appropriate and relevant to ensure quality products and processes.

Summary

Defensible Compliance emphasizes quality over quantity. Defensible Compliance is a strategy for defending your quality system from challenges to add more detail when you do not believe that more complex procedures will provide added benefits. There are occasions where additional or more detailed procedures may be essential to improving your quality system; however, you should make sure you are not adding process complexity and compliance risk without commensurate benefits.

To learn more about industry best practices for quality system implementation contact Dan Olivier at dolivier@certifiedcompliance.com.