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Why you need an ISO certified design house and Contract Manufacturer

Working with a development firm with a certified quality system saves time and reduces cost.

A company's quality system defines the development, manufacturing, and product lifecycle management procedures that are critical to establishing effective internal processes. ISO-13485 is the primary quality system used in the medical industry, while AS9100 is the top level system used in aerospace. ISO 9001 is used in many industries and is the quality system from which both ISO 13485 and AS9100 are derived.

Many design firms claim that by not becoming ISO certified they will save you money. Their usual rationale is that they are compliant on their own so you will get the benefits without the cost. In reality, the cost of certification is a very small part of a typical firm's overhead, and the resulting improvements to the development process serve to reduce development cost and reduce program risk. The only way for a quality system to be compliant is through verification with regular audits.

Certification is available for both design and manufacturing activities. The purpose of a quality system during product development is to ensure that products are designed using procedures and processes that enforce thorough and effective planning and risk mitigation methodologies. This serves two important purposes: it ensures that all necessary features are designed into the product from the beginning, and it prevents the inclusion of deficiencies. A potential flaw or weakness that never makes it into a product because it gets caught by a solid quality-driven development process saves considerable time and effort. Compare this to a deficiency discovered during a later testing phase, or worse yet, when a high volume product has been released into the field. These problems, when found late in the process, can be very expensive to correct. Likewise, an important product feature or requirement that is omitted from a design during development is much more costly, if not impossible, to implement later in the program.

During manufacturing and throughout the product lifecycle, a properly executed quality system ensures that every product built will meet customer and regulatory requirements. When problems are discovered in a finished product, the quality system provides a process for identifying the defect, determining its root cause, and implementing the corrective action to be taken so that the problem does not recur. In an ISO-13485 environment, the goal of the system is to achieve continual improvement in effectiveness, quality, reliability, and yield.

When companies are registered to ISO 13485 or any other quality standard, they are audited regularly by internal auditors and by external registrar auditors. This ensures that they are following their quality system faithfully, that their quality system conforms to the current standard, and that they are always improving their systems. Our registrar, NAB, schedules audits on a one or two year cycle, depending on the length of time a company has been registered. Our practice is to hire an independent auditor to verify our compliance at about the midpoint between our registrar's surveillance or recertification audits, ensuring that we remain compliant and up to date. A company that claims to be compliant without submitting to the certification process and regular audits is, by definition, non-compliant.

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Maintaining our quality systems in full compliance is a cornerstone of ensuring that we develop safe and efficacious products for our clients and that the products we manufacture are reliable and meet customer and regulatory requirements, whether for medical, aerospace, or other markets.

HDA is registered to ISO 13485 for the design and manufacture of medical devices, and to AS9100 and AS9001 for the design and manufacture of aircraft systems. We are also registered with the FDA and California FDB to manufacture medical devices.