

Developing a Strategy for Global Development Teams

A versatile regulatory compliance strategy is crucial to tapping into the expertise of global product development teams. This article outlines four steps to achieving a successful solution.

The FDA has recently changed its position on electronic records and signatures, promising more rigorous compliance audits to monitor their use.

AT A GLANCE

- • Process defined
- • Benefits to team members
- • Problems to avoid
- • Project documentation

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Maintaining regulatory compliance in an ever-evolving medical industry can challenge even the most experienced of medical manufacturers. Within the last decade, advances in travel and technology have provided greater access to global markets and international engineering talents, encouraging many medical manufacturers to assemble global product development teams. These teams can provide added engineering expertise and proximity to international markets at a lower overall cost.

With these advantages, come potential risks. Many international engineering resources are inexperienced with the mandates of FDA and ISO. Furthermore, cultural, geographic, and linguistic barriers can hamper communication among team members stationed in different countries. These risks, if not closely monitored, can derail a development project and cost a medical company time, money, and reputation.

Step #1: Design Process

The solution? When seeking the versatility of a global product development team, a medical manufacturer must support it with an equally versatile regulatory compliance strategy.

The first step in creating a successful regulatory strategy is to establish a detailed design process. A detailed design process will ensure that all team members have clear expectations as to what the project entails from documentation to deliverables. The design process should first identify the end market where the product will be sold. It should then identify the regulatory requirements for that market, make provisions for each requirement, and then clearly define all deliverables needed to satisfy those requirements.

Step #2: Training

Even after establishing and clearly defining a design process and its requirements, it is not uncommon to find that different team members located in different countries will interpret the process differently. Therefore, the second step is to ensure that all team members share a thorough and uniform understanding of the design process. This goal can be achieved through team training, where a single, authoritative source—preferably a corporate trainer—can present the rules and expectations of the design process clearly and thoroughly to the entire group.

Step #3: Risk Analysis

After all team members have been trained, the third step in a successful regulatory strategy is to identify the risks and hazards associated with the new product. Early in the development phase, team members should identify product risks and share them in a common forum with the entire team. This action will allow team members to work in unison to mitigate potential problems and improve product safety, avoiding costly product redesign. Although miscommunication can thrive in a global development team where members communicate across geographic, cultural, and linguistic barriers, a concerted effort to communicate and reduce risks will result in a better product.

Team members should continue identifying risks as the development process continues, reviewing and updating risk-analysis documentation during each phase of the design process. Frequent review will help prevent residual risk from surfacing during the latter stages of product development, such as in the verification or validation phase, or even worse, in the manufacturing phase, where it becomes more costly for the company and more dangerous for the customer.

Step #4: Electronic Files

The fourth and final step in a successful global compliance strategy is to establish an electronic design-history-files repository for all project documentation such as design deliverables, project schedules, design review minutes, engineering changes, and supplier approvals. Storing these documents electronically makes

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them immediately accessible to team members around the globe, who can access current documents through e-mail, the Internet, or network access and update them real-time. When documents are completed or updated, they can be quickly routed around the world for approval and made immediately accessible to all team members. The database acts like an electronic progress chart for the design project, displaying project status as documents are updated and deliverables completed. Like any other process or system used in the development of medical devices, electronic document approval and storage systems require proper validation to ensure they perform as intended. The FDA has recently changed its position on electronic records and signatures, promising more rigorous compliance audits to monitor their use. The extra validation processes and closer attention by the FDA may seem daunting, but these electronic databases¹⁵when used with frequent video teleconferences and comprehensive design reviews¹⁵can virtually eliminate geographic barriers between team members and convert a global development team into a close-knit, effective design group.

A versatile regulatory compliance strategy is the key for medical manufacturers to effectively tap into the expertise of global product development teams. By investing in the proper tools, training, documentation, and communication systems, medical manufacturers can enjoy the benefits and limit the risks of committing to a truly global product development program.

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