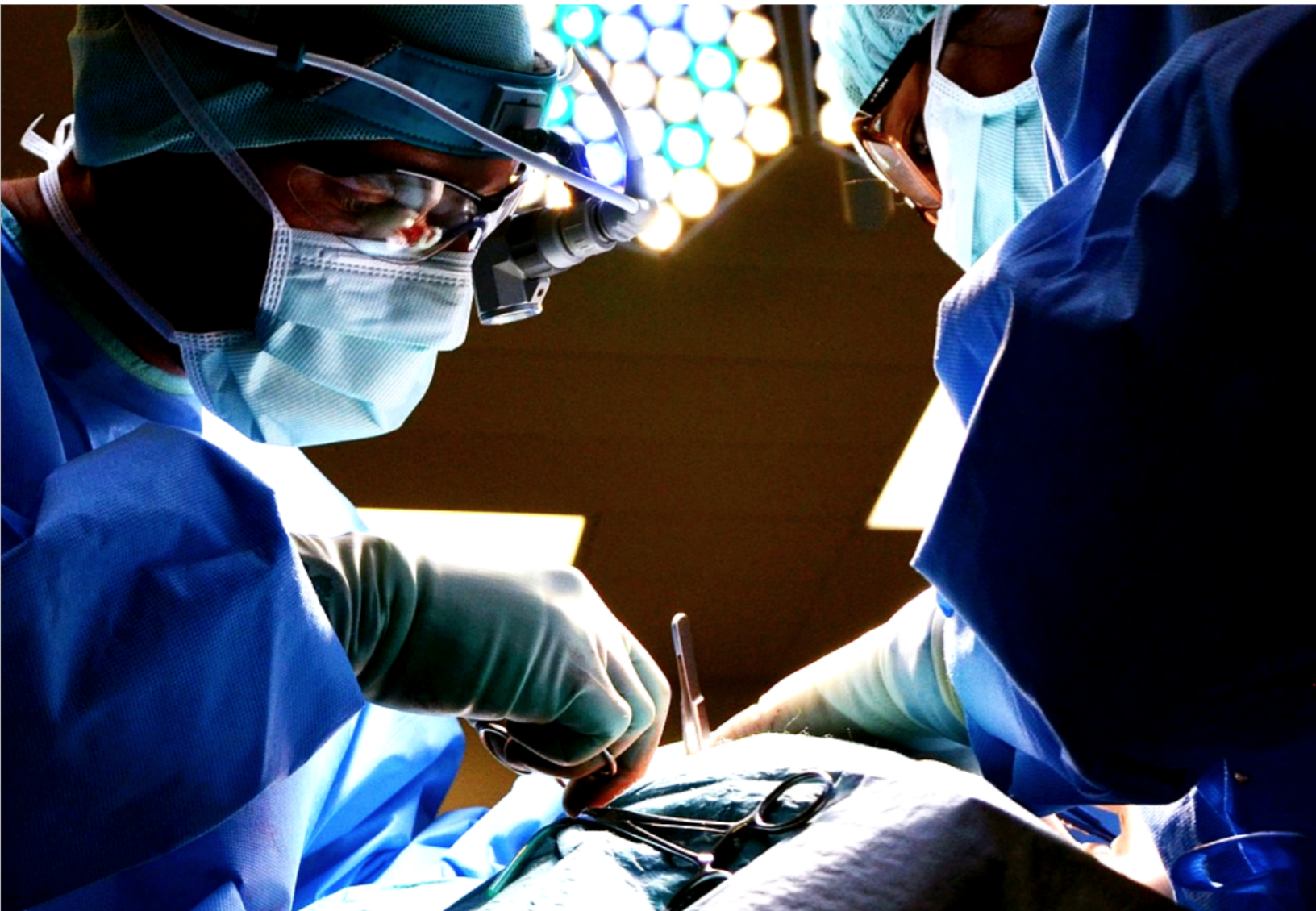
THE ROLE OF QUALITY MANAGEMENT IN DESIGN CONTROL FOR MEDICAL DEVICE MANUFACTURERS

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Temp
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93,21 °f
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Artificial heart
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THE ROLE OF QUALITY MANAGEMENT IN DESIGN CONTROL FOR MEDICAL DEVICE MANUFACTURERS

Medical device manufacturers around the globe are required to comply with regulations regarding Design Control to ensure that specific requirements for a device are met. Device manufacturers are also required to maintain a Quality Management System to ensure safety and efficacy. Here we'll look at the role of Quality Management in Design Control and how both disciplines improve not only the safety and efficacy of the device, but the performance of the business.

I asked Pam Weagraff, MBA and Director of IQVIA MedTech Regulatory, to **discuss the importance of having a quality management system (QMS) and the right resources to support product development and post-market maintenance.**

THE IMPORTANCE OF HAVING A QUALITY MANAGEMENT SYSTEM (QMS)

Weagraff stated, "For any company planning to participate in the MedTech sector, understanding and advocating for a robust and finely tuned quality management system can be a competitive advantage rather than just a cost of doing business, and is imperative." She went on to add that a robust finely tuned Quality Management System (QMS) aids in the delivery of high-quality MedTech products to the market faster, and it keeps these same quality products on the market at a lower cost. Companies that do not invest in or support their QMS are well-known to experience unnecessary project delays and slower time-to-market, as well as experience the high cost of product complaints and recalls. "Quite simply, support for a robust and fine-tuned QMS is good business practice!". Design Control is one of those QMS processes.

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Industry analysts agree. LNS Research studies on Quality Maturity demonstrate that organizations with global, closed-loop, enterprise QMS technology can expect to see improvements in overall organizational metrics. For example:

- ✔ Product Compliance can be improved by up to 4%
- ✔ On-Time Deliveries can be improved by up to 2%
- ✔ First Pass Yield can be improved by up to 2%
- ✔ Supplier Defect Rate can be reduced by up to 45%
- ✔ Successful New Product Introductions can increase up to 21%

Weagraff added, "As for having the right resources on hand, the FDA's Quality System Regulation (QSR) requires management with executive responsibility to assure that adequate resources, i.e., personnel with appropriate education, background and training, are available to assure that all activities that could affect product or process quality are sufficiently supported. Apart from the need to comply with regulatory requirements, it is simply good business practice to have the right resources available to manage and execute design and development activities to bring high-quality products to market as quickly as possible. Once the new product is on the market, the ability to rapidly respond to and address product quality issues

can improve market acceptance and uptake as well as mitigate the need for costly recalls."

Quality Management Systems begin with written policies, procedures and work instructions to achieve consistent application of the methods used to not only control quality, but to aid in regulatory compliance. Whether an organization is adhering to the FDA's QSR, EU MDR, or other regulatory authorities and standards for Design Control, it is important to manage this iterative process and provide documented evidence that a well-defined, controlled process is in place and has been properly executed. Whether the Design Control process is being executed for the development of a new product (pre-launch) or to update an existing product (post-launch), this record of development is important for compliance, but even more importantly, it is essential for managing the product's lifecycle. Whether a product is in conceptualization, or being updated based on post-market surveillance data from other areas of the QMS, a robust Design Control process is key to the success of the product.

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Which leads us to the next question for IQVIA's Pam Weagraff: What are **some key strategies to enable FDA design control requirements?**

Weagraff responded from a business point of view, not a compliance point of view. She said organizations need to "take the long view from a business perspective – one of the most valuable assets of any company, large or small, is intellectual property. Securing patents to protect this valuable asset depends in large part on the company's ability to demonstrate the date of discovery and the detailed technical information supporting the discovery. For this very reason, it is imperative that research (discovery and feasibility phases) is conducted in a disciplined manner and well documented in lab notebooks before a company embarks on formal product development. Establishing Design Controls requirements specifically for use in the research environment, post-discovery but pre-feasibility, introduces the level of rigor needed as a launch pad to the formal product development environment."

Weagraff continued with the following insights:

- Before entering the feasibility phase of research phase, the company could establish basic Design Control requirements in the form of procedures, specific to the design and development of research prototypes for use in a first in human or early feasibility clinical study.[1]

- When the research feasibility phase has been completed, the Research DHF becomes the Design Input to formal product development, assuming the company's management elects to support the project with resources and funding.

- At this point, the application of Design Control to the project should be expanded in scope to support formal product development through to commercialization.

- By establishing a Design Control program early, before entry into formal product development, the company has a strong foundation in place and can leverage some of the research feasibility effort and lessons learned.

Table 1 below shows the difference in scope for Design Controls during research versus during formal product development

Table 1: Application of Design Controls – Research and Formal Product Development

Design Control Requirement	**Required Scope**	
	Research (Feasibility)	**Formal Product Development (Requirements through to Commercialization**
Design and Development Plan	Limited to activities needed to develop the research prototype, may be optional	Content must address design and development activities through to commercialization, e.g., design prototypes, production prototypes, production units for customer shipments
Design Input	Summary requirements for research prototype, includes safety requirements and basic performance requirements, usability to allow safe use	Design History File from Research Feasibility, plus any additional user requirements, performance and safety requirements

[1] Evidence of compliance with 21 CFR Part 820.30 Design Controls is required under Good Clinical Practices and is a companion regulation to 21 CFR Part 812 Investigational Device Exemption.

Design Output	Limited to research prototype specifications, test requirements	Builds over phases of development culminating in finished Design Output, which serves as the basis for the Device Master Record, device, labeling and packaging for commercial distribution
Initial Risk Analysis	Review and evaluation of potential hazards and hazardous situations posed by the research prototype that could result in harm to the patient or user	Development of a Risk Management Plan, Risk Management activities, Risk Management Report, and Establishment of a Risk Management File
Design Verification and Validation	Testing limited to essential requirements, i.e., research prototype functions required for safe use as applicable, e.g., electrical safety, electromagnetic interference, biocompatibility, sterilization and software verification and validation	Testing must demonstrate that the Design Output meets the Design Input requirements, and that the device conforms to defined user needs and the intended use of the device as applicable, e.g., complete suite of bench testing, electrical safety and electromagnetic compatibility, biocompatibility, sterilization, software verification and validation, usability (formative and summative), and clinical studies, (formal feasibility and pivotal)
Design Review	Informal readiness review of research prototype before use in a first in human or early feasibility study	Formal review at pre-defined intervals during device development, e.g., Design Input and Design Output, Risk Management Activities, Design Verification and Validation Plans and Reports of Results, Design Transfer
Design History File	Limited to archival of feasibility phase documentation for research prototype	Archival of all Design and Development documentation associated with formal product development activities, e.g., design prototypes, production prototypes, production units for customer shipments; includes content from feasibility phase DHF.

Design Changes	Change control with limited sign-offs	Formal Change Control applies to any changes to the device, its labeling or packaging or prototype production processes once the Design Input has been approved.
Design Transfer	Not required	Planning of activities to support manufacturability of the product; adequate translation into manufacturing specifications, processes and procedures in the form of the Device Master Record; process validations, etc.

We also asked Weagraff to explain **design control requirements and agile development principles for a least burdensome approach.**

"Design control requirements and Agile development principles can easily go hand in hand," Weagraff said, "to facilitate and streamline design and development activities." Agile development principles are understood to allow for iterative development, where requirements and solutions evolve through the collaboration of cross-functional teams and users. Figure 1 below illustrates how Agile Development Principles can be supported by Design Control requirements without disrupting the flow of design and development activities, and in fact, result in an overall streamlined design and development process.

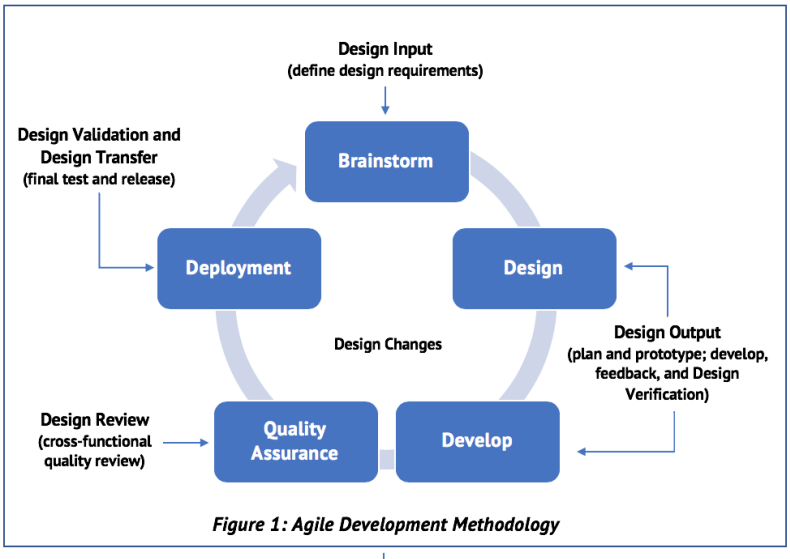

Figure 1: Agile Development Methodology

Whether an organization is using Agile or traditional development methodologies, the collaboration between development, product management, manufacturing, regulatory, risk, and quality (to name just a few of the constituents in this process), is key if medical device products are going to improve clinical outcomes, ensure the safety and efficacy of the device, achieve customer expectations through conformance to their requirements, and improve the lives of the patients using the devices. Quality plays a key role in this collaboration by monitoring and managing an organization's Design Control Process, ensuring it is effectively implemented and integrated with other key systems within the organization.

So why do companies choose to work with IQVIA? What makes IQVIA unique?

IQVIA provides its customers with end-to-end solutions, services and consulting to support the management of those organizations' product lifecycles, from Concept to Market.

IQVIA's integrated SmartSolve EQMS, which includes Design Control, enables quality to become a centralized hub for continuous improvement throughout your business. Build, scale, and evolve your quality system as the demand on it grows, significantly enhancing the quality of your operations, products, and services.

Our life sciences domain expertise and our understanding of business make us more than just a technology supplier – we can put our technology solutions in the context of advancing your quality maturity and solving your business needs, complemented by professional consulting services.

To learn more about our Quality Compliance products and services, and all that IQVIA can offer, contact us at **regulatory_quality_compliance@iqvia.com**.

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