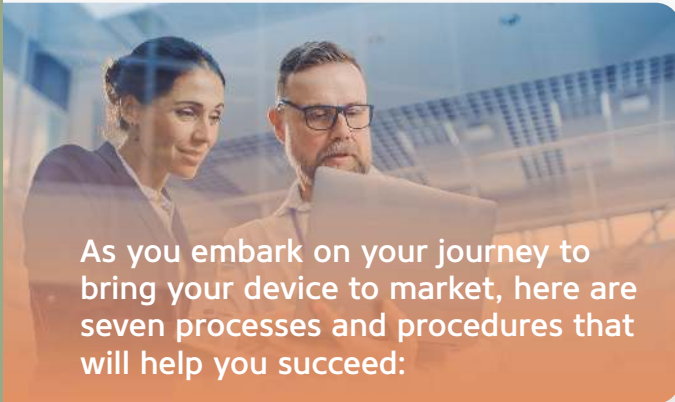# 7 Quality System Must-Haves

As you embark on your journey to bring your device to market, here are seven processes and procedures that will help you succeed:

1. Design Controls

The FDA stipulates that Class II and III medical devices, and a small number of low-risk Class I devices, follow the design control requirements in 21 CFR §820.30.

A simple and pragmatic design control process helps protect patients by identifying possible issues with product development. It may prevent a product redesign or a potential recall downstream.

2. Design and Development Planning

Without a design and development plan that takes into consideration the quality and regulatory requirements of the device you're bringing to market, you're sure to encounter delays and undue expenses.

A design plan that details your goals, objectives, interfaces, responsibilities, and schedules is necessary to bring your product to market most efficiently.

3. Documentation and Record Controls

In such a highly regulated industry, documentation is necessary to meet quality and regulatory requirements. Everything from your design controls to customer complaints must be documented.

Without an efficient document control system implemented effectively across your organization, a minor documentation error can lead to a delay or recall.

4. Purchasing Controls

To satisfy 21 CFR Part 820, manufacturers must document and follow procedures to ensure all products, services, and materials that are purchased adhere to a specific set of standards, including quality requirements.

Manufacturers must define, document, and maintain requirements and purchasing data. The selection of all suppliers, contractors, and consultants must meet these requirements.

5. Supplier Qualification

As a startup, you are likely outsourcing the production of your device, including the assembly and packaging.

Partnering with reliable ISO 13485 and ISO 9001 certified contract manufacturers is critical to your success. Do your due diligence to ensure the suppliers you contract with can meet or exceed your quality and regulatory objectives.

6. Risk Management

All medical devices have some level of associated risk. To mitigate possible issues, start by identifying potential hazards and prioritize the associated risks.

After you've identified potential risks, develop an ISO 14971 compliant benefit-risk profile that considers your risk tolerance.

7. Design Transfer and Process Validation

As your product moves from development into production, the output of your product must be consistent. You must prove that all processes efficiently produce results that are reliably achieved.

Validation protocols, testing requirements, and robust reporting are necessary to meet your timeline for product development.

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