Mastering the Design Transfer Process

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Rook Quality Systems

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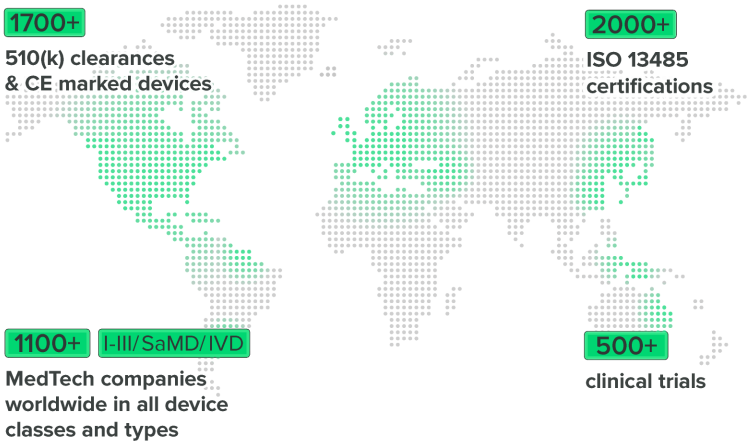

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"User-friendly EDC and esponsive support team"

"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."

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Rook Quality Systems

Rook Quality Systems is a consulting firm dedicated to helping startup to Fortune 500 medical device companies develop and maintain effective and efficient quality systems.

We provide specialized and custom consulting services for all classes of medical devices, including medical software and combination devices.

Experience

Over a decade working with class I-III devices, SaMD, and IVDs. Supporting companies in the very early stages of QMS and device creation, from design through commercialization and post-market monitoring.

Expertise

Rook's team of thirty five quality engineers and certified auditors are experts in FDA regulations, MDSAP audits, ISO 13485:2016 compliance, and MDR conformity and provide support during an external or regulatory audit.

Efficiency

We leverage experience and best practices to help build the QMS so that clients can get their devices to market faster than standard methods, and use these systems to continue producing effective, quality devices.

Rook Quality Systems

We provide specialized and custom consulting services for all classes of medical devices, including medical software and combination devices.

Quality System Design

DHF/TF Creation

Audit Support

Software Validation

Design Control

Risk Management

Regulatory Submission Support (Int'l)

Quality System Training

Webinar Outline

1. Defining design transfer
2. How to prepare for design transfer
3. Steps to take during product development
4. Documentation responsibilities during design transfer
5. Importance of design transfer
6. Best practices for managing suppliers
7. Supplier audits and design transfer
8. Design Transfer Plan
9. Time to transfer
10. Design transfer for SaMD and SiMD
11. Risk during Design Transfer
12. Equipment validation and qualification requirements
13. Internal manufacturing tips for new companies
14. First Article Inspection
15. Audit review
16. Completing design transfer process

What is Design Transfer?

Design Transfer is the process of moving from a prototype or early development phase of your device to a production phase.

This can include some of the following scenarios:

- Developed a device in house but need to move to a contract manufacturer for higher volumes
- Moving from R&D to formal production of a new device within the company
- Changing sites or locations of a manufacturing process
- Outsourcing manufacturing to other parts of the world
- Transferring from a manual to an automated manufacturing process

How to Prepare for Design Transfer?

Provide as much information as you can. The more information you can provide, the more time and money you will save.

Examples of important information to provide:

- DHF information
- Supplier information
- Material specs
- Internal work instructions for manufacturing

Steps to Take During Product Development

Once a product is developed, and a pilot or prototype batch is made. This can be used for some testing or trials.

Ensure the design has been evaluated and is ready to move forward to manufacturing.

Steps to complete in design control prior to design transfer:

- Initial design outputs should be documented
- Design review should be completed
- Design Verification should be completed
- Identify to where the design is going to be transferred

Documentation Requirements During Design Transfer

Design Transfer in 21 CFR 820

Aspects of Design Transfer are captured under the Design Control Section of 21 CFR 820.30 Design Controls.

Section (h) Design transfer. Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

Within the scope of the entire section this is a small aspect but covers a lot of documentation and potential changes.

The following section discusses the design change process which should be incorporated in your design transfer if changes are made:

Section (i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

Documentation Requirements During Design Transfer

Design Transfer in ISO 13485:2016 (QMSR)

Aspects of Design Transfer are captured under Section 7.3.8

7.3.8 Design and Development Transfer

The organization **shall document procedures** for transfer of design and development outputs to manufacturing. These procedures **shall ensure that design and development outputs are verified** as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer **shall be recorded.**

Documentation Requirements During Design Transfer

Design Transfer in MDSAP

Aspects of Design Transfer are captured under Chapter 5 Task 16.

The MDSAP Companion Audit document also provides additional content on how the design transfer process should be audited in relation to ISO/FDA (as well as other MDSAP regulations).

- The audit team should review how the design for the selected project was transferred into production specifications. Based on the medical device organization's identification of **essential outputs and risk management activities, review significant elements of the manufacturing processes, including products from suppliers and the established tolerances for processes, and compare them with the approved design outputs contained within the design records**. These activities can confirm whether or not the design was correctly transferred.

Documentation Requirements During Design Transfer

Design Transfer in MDSAP

Aspects of Design Transfer are captured under Chapter 5 Task 16.

Design transfer is a process that may be initiated not only at the end of the design and development process but may also be initiated immediately before validation stages and may continue as design and development evolves. This early initiation of design transfer is helpful in order to have production processes and device validations conducted properly and allow for corrections during the process. **At the end, design and development process is "finalized" by a "final design transfer."**

- MDSAP also links the design transfer process back to Production and Purchasing to ensure risk, validations, incoming inspection, and other areas are captured in the DT process.

Importance of Design Transfer

- As the standards highlight and the MDSAP document details the Design Transfer process is critical for any company that wants Quality devices.
- The process of ensuring your device meets the initial safety and performance requirements that you established throughout manufacturing is the backbone of medical device quality and quality systems.
- Design transfer is the critical step between your prototype/development device and the device you plan to sell to patients and users.

Best Practices for Managing Suppliers

If you are using a supplier for contract manufacturing or assembly of the device, they will be critical in the design transfer process.

- It is critical to ensure your supplier has worked with medical devices previously and has completed design transfer in the past.
- The responsibilities for each party leading to design transfer and during the transfer process should be agreed upon and defined in formal agreements/records.
- Just because your contract manufacturer or design firm has ISO 13485 or 9001 does not automatically mean they are great at manufacturing your device.
- The design transfer with the supplier will require detailed communication and multiple visits from the medical device owner to ensure the process is completed with minimal failures or defects.
- Meetings should be scheduled on a weekly or more frequent basis to ensure all deliverables meet the timeline.

APAC Suppliers:

- The required technical documents vary depending on which APAC country you are working in.
- We recommend that manufacturers find a cooperating local representative, as the registration documents usually need to be translated into the official local language.

Supplier Audits and Design Transfer

It is best to conduct a supplier audit when the product is being developed.

- Conduct a high level review of the prototype
- Make sure the supplier is manufacturing the product to your specifications
- Conduct the final audit once they are manufacturing your product, audits before then can have mixed results
- Maintain communication with the supplier during design transfer

Design Transfer Plan

A Design Transfer Plan (DTP) is recommended to ensure all parties are aware of the roles, responsibilities, and timeline for the design transfer.

- The DTP should identify the scope of the plan as well as the product undergoing design transfer.
    - If the plan is limited to one supplier or multiple that should be documented in the DTP.
- The plan should identify reference documents, forms, work instructions, DHF, and risk files, BoM, supplier agreements related to the Design Transfer.
- **The DCO/CO process for updated and approving design changes should be defined.**
- Key personnel should be identified by role in the DTP.

Design Transfer Plan

- Gantt charts, project timelines, or task tracking tools can be referenced or embedded in the DTP.
- Include a list of key items and who is responsible for each during the Design Transfer process.
- These can be shared but a description of which party owns what documents and when each is due should be documented. This can be done for internal stakeholders or with your suppliers.
- Outline who is responsible for which records and who needs to sign off

Design Transfer Plan

Identify the DTP or related documents who is responsible for each process/record.

- Bill of Materials
- Purchase Order Process
- FMEA Records (Design and Process)
- Incoming Inspection Requirements
- Sampling Plans
- Work Instructions
- Custom Test Equipment
- Test Equipment Validation
- Process Validation
- V&V Requirements
- QC Requirements
- Labeling Specs
- Packaging Specs

Design Transfer Plan

Approval Matrix

Determine who is responsible for approving each document/record type in the DTP.

Document/Record Approval Type	Project Manager	Product Operations	Quality Manager
Work Instructions	X	X	X
Job Traveler/DHR			X
pFMEA	X	X	X
Deviations/Rework		X	X
New Supplier	X	X	
Engineering Change Order	X	X	
Document Change Order		X	X
Qualification/Validation	X	X	X
Batch Record	X (PM or PO)	X (PM or PO)	X

Time to Transfer

- Once the plan is set the real fun begins and the process for capturing the design transfer begins.
- The DTP should outline who is responsible for initiating Change Orders, the collaboration process, and which eQMS the records are stored.
- The key aspect of the Design Transfer process as defined in FDA and ISO is that the changes be evaluated, and any V&V is completed as needed.
- Small changes to suppliers, molding process, components, or other items related to the design may seem trivial but can have drastic consequences if they are not properly tested.
- Even worse, if these changes are not properly documented then these unverified changes can create a massive CAPA or recall down the road.

Time to Transfer – Internal Preparation

- During development companies learn a lot about their device and this information should be passed to the design firm to ensure they don't make the same mistakes.
- These records and instructions should have been documented as part of your DHF/DMR during development but in some cases, there are gaps with internal documentation especially for startup companies.
- Work instructions should be provided to pass knowledge to the new manufacturing facility.
- Material specifications should also be defined and shared in the event of new sourcing for materials.
- Testing practices and any custom test equipment should be reviewed to see if this needs to be transferred to the new manufacturing facility.

Time to Transfer – Transfer Index/Plan

- **The Design Transfer process does not happen overnight, so the respective teams need to work efficiently to ensure the documentation is tracked and maintained with the project.**
- **We incorporate the ongoing use of the DTP to capture updates to documents or you can create a Design Transfer Index or plan with the new versions of:**
  - Work Instructions
  - Drawings
  - Risk Analysis Records
  - Validations and Qualifications
  - Calibration
  - Training
  - Other DT Documents

Time to Transfer – Testing

- As the design transfer process starts to deliver new product the verification testing plan should be created and implemented.
- Depending on the changes this can include internal or external testing.
- Testing should be evaluated as part of the design change process to determine if the testing changes and of the key device attributes including these identified in ISO 13485:
    - Function
    - Performance
    - Usability
    - Safety
    - Applicable Regulatory Requirements

Time to Transfer – Custom Testing Equipment

- It is very common for companies to have custom test equipment they have created or modified for the testing of their product
- If you are using any custom test equipment or software and plan to transfer this to the new manufacturer it should be documented.
- The equipment itself will need to be moved
- New installation qualification will need to be conducted when the equipment is installed
- Training and maintenance schedules will be required to ensure the test equipment functions properly going forward
- Validation of the custom test equipment will be required to ensure the equipment can properly identify good vs bad product

Design Transfer for SaMD and SiMD

Hardware Development

Before transferring your design to manufacturing you must complete the following steps for the design transfer process:

1. Develop prototypes (Design Verification and Validation Units)
2. Complete testing

Software Development

Develop and release software (Release Candidates) for testing on a non production instance (QA or DEV instance). **The design transfer occurs when the software is deployed to production. Testing of the product occurs while in the production phase.**

The extra step before the SiMD design transfer occurs because you need to do the following things:

1. Test the firmware on the software development environment
2. Test the firmware on the actual system that will be used to deploy the firmware to as the final product

Risk During Design Transfer

- **Risks should be documented in the Design Transfer plan at a high level to identify key risks in the overall process**
- **The internal risk documentation should also be documented before and updated after the DT is complete.**

Design Risk (FMEA or Other Method)

- Should define the risks of critical components
- Should link to your incoming inspection/AQL levels or components

Process Risk (HA or FMEA)

- Should define the risks of each step in manufacturing
- WIP controls and final testing should be linked to Process risk

Equipment Validation and Qualification Requirements

- Incorporate requirements from ISO and FDA standards
- Discuss how custom equipment needs to be validated
- If you are making your own test equipment, make sure to provide this to the supplier

Internal Manufacturing Tips for New Companies

Make sure that the internal manufacturing team is provided with the following:

- Specific, easy-to-use work instructions
- Validation and calibration of the equipment
- Training of operators
- Separated areas for control of materials for both incoming inspection, ready to use, and quarantine
- Ensure the team is trained on the documentation requirements for manufacurting

First Article Inspection

- FAI is the process of receiving the first articles from the new manufacturing process and testing these internally
- Testing should follow the established QC process for testing and potentially repeat a subset of DVT testing
- The risk of the product and changes in the manufacturing/DT process should be evaluated in the FAI testing approach.
- Any issues that are identified during FAI should be captured in the DT documentation and updates made to fix these issues
- FAI is critical for the success of the DT process!

Audit Review

- The records completed for the Design Transfer should be readily available in the event of an audit
- As the legal manufacturer you should maintain a copy of the design transfer records even if the majority was handled by a supplier
- Auditors are going into much more detail on the design transfer process and the amount of documentation required can be overwhelming
- Be sure to track the DT process as you go
- If your audit occurs during the DT process your auditor can review your plans and work to date to show you are meeting the regulations

Completing Design Transfer Process

1. The records completed for the Design Transfer should be readily available in the event of an audit
2. As the legal manufacturer you should maintain a copy of the design transfer records even if the majority was handled by a supplier
3. Ensure all documentation, drawings, risks, and other records from the DT process are finalized and signed off
4. Audit findings are very common for miscommunication between the device owner and contract manufacturer due to differences in versions, documents not being signed, and other DT related items.
5. Confirm with the new manufacturing process who is responsible for batch release after DT is complete
6. Identify if any regulatory updates are needed post DT

Questions?

www.RookQS.com

Make sure to visit our website to learn more about our services and consulting team.

Contact info@rookqs.com for more questions, comments, or to set up a meeting. One of our consultants will be sure to reach out to assist!