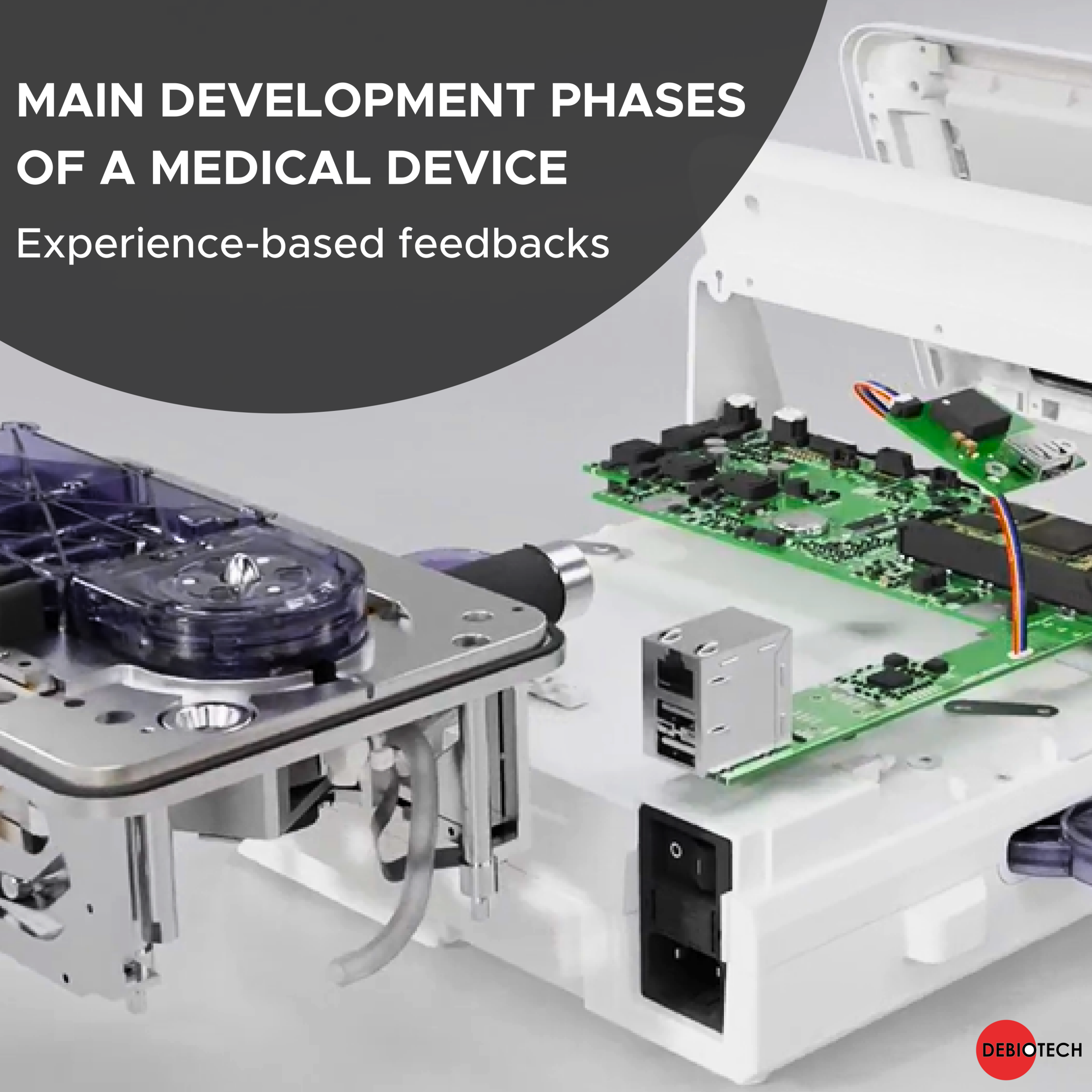
MAIN DEVELOPMENT PHASES OF A MEDICAL DEVICE

Experience-based feedbacks



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When developing a medical device, it's crucial to adhere to regulatory standards, ensure safety, and meet user requirements. How to do so can be a bit overwhelming for the newcomer to our industry.

We tried with this article to give you our take on the device development process along with our advice.

To design a medical device means that you will need to follow the rules given by the quite important number of regulatory constraints. Most of the time, these are translated in your company through your quality management system.

The development lifecycle consists of a succession of phases:

Planning & definition
Development or Design process
Design transfer
Design verification
Design validation
Regulatory approval & commercialization

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This development methodology comes from the waterfall process (fig.1) or the V model.

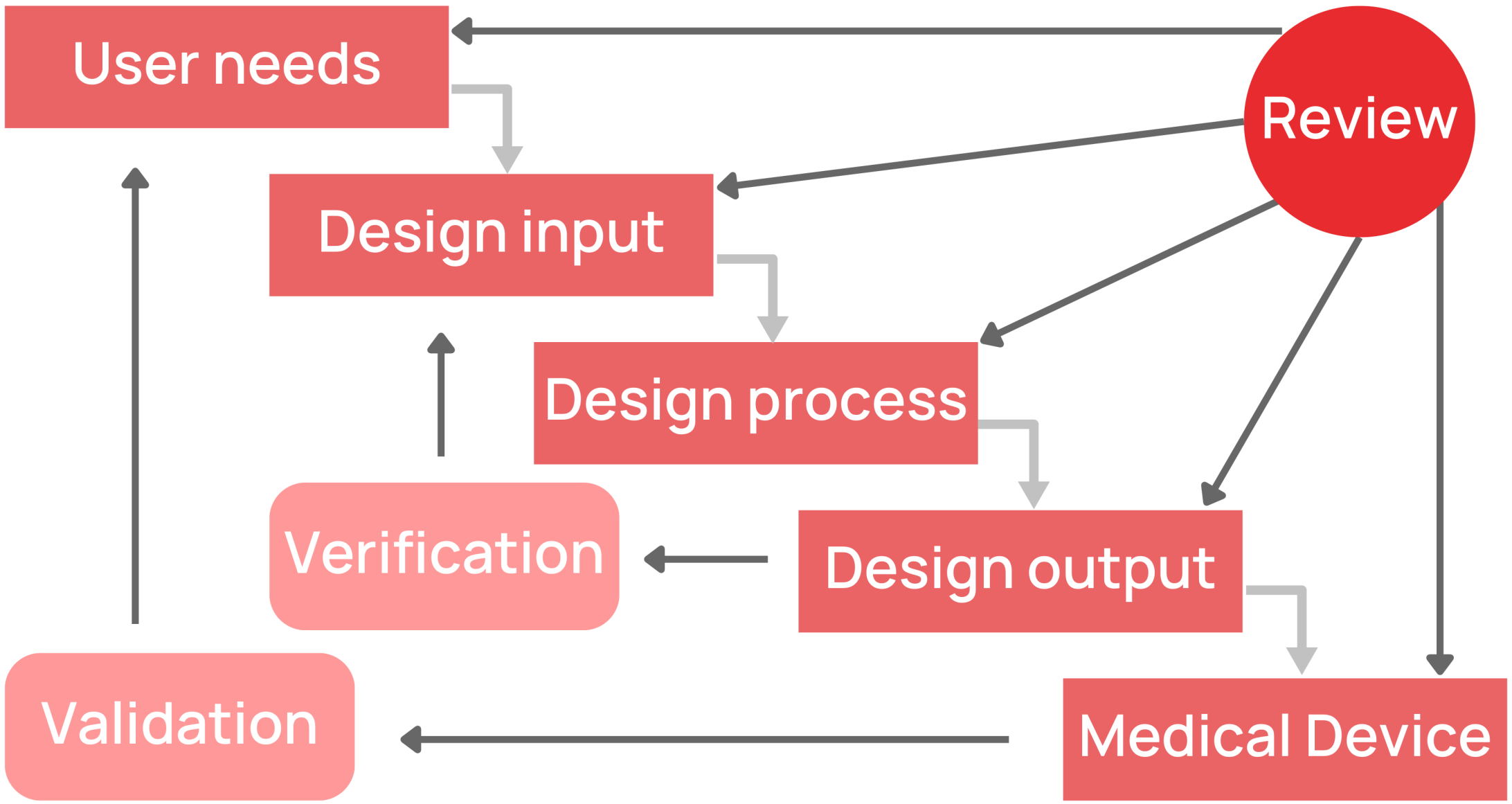

fig. 1: Waterfall process - Design Control

 At Debiotech, for greater efficiency, we always start by resolving all questions relating to project scope, ambiguous requirements, technical challenges and any other project risks before starting the formal process.

All the activities in each phase have to be documented, reviewed, approved, and maintained in the Design History File (DHF).

You don't need to do these steps really in series, you can start earlier, and we advise you to write early drafts of input documentation as soon as possible, but the formal phase execution must respect the imposed inputs and outputs of each phase.

In parallel to this development process, you implement the very important Risk Management process, the Usability process and if there is a connected software in your device, the Security process.

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Planning & definition

At the beginning of this phase, you write the plannings for all processes, to detail all deliverables, and to identify the people who take responsibility for said processes. Make sure their competences are aligned with their roles, as you want to demonstrate to the approval authorities that your colleagues who wrote, reviewed, or approved the Risk Analysis (for instance) understand the impact a wrong assessment can have on patients and know how to avoid it.

Then you will have to formalize the product definition in user requirements (sometimes called User needs) and engineering requirements (also called Design Input).

The first requirements will be validated mainly by users; while the second ones will be verified in a lab by test engineers.

Part of the product definitions are its intended use (acc. to FDA) or intended purpose (acc. to MDR)and its product classification, which depend directly on local regulation of the targeted market(s).

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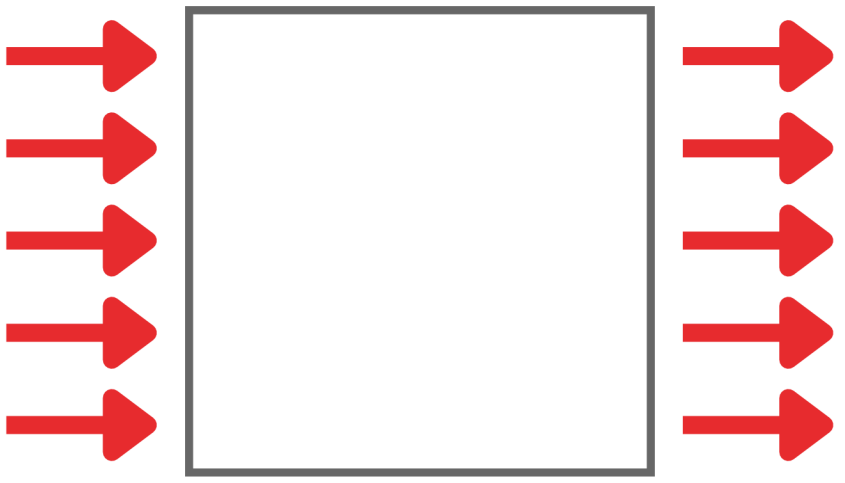
Development or Design process

Document your design (called Design Output).



We highly recommend to involve as soon as possible all manufacturers to start design for manufacturing from the beginning and run engineering tests as much as you can to avoid bad surprises later.
Each change will cost more and more time and money when you move forward in the process.

Involve the test houses and approval authorities as well (e.g. notified body, FDA) as applicable to clarify with them all points that could be subject to any doubt.

We are convinced that a strong system engineering team is extremely beneficial to transfer information to and from the various specialized engineers and act as an efficient interface with external technical entities.

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Design transfer

Your manufacturer has also its own processes. He will use your Design Output to set up his corresponding manufacturing processes. That ends up with the Device Master Record (DMR).
He will provide you with the samples required for verification and validation. These samples must be sufficiently representative of the production according to local regulation, in particular for validation.

Make sure the manufacturers provide complete traceability and certify conformance to your design as it will be needed during your testing.

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Design verification

The Verification is the demonstration that you designed the device right.

It consists of verifying, using objective evidence, that the Design Output meets the Design Input requirements (including the risk control measures from the Risk Management). It can be done by testing but also by theoretical analysis or by inspection (e.g. the labelling). These activities must be planned carefully as they can be time consuming.

You can earn the trust of the regulators by sticking to the rules:
Run your tests on pre-approved protocols only, which include the corresponding acceptance criteria.

Our advice here would be to write the Design Input Requirements directly with that purpose in mind. Write them without ambiguity, with quantified testing criteria, so that you can simply copy paste them as is in the protocols.

You will have to provide a statistical rationale for the sampling size used based on the risk level of each requirement. Having maintained a good traceability matrix between risks and design input requirements will pay for itself at that point.

Design verification

Document the records demonstrating that the samples used are approved, that the instruments used in the test set-ups are calibrated and that the operators doing the tests are trained.

Often, a part of the verification is externalized such as biological safety, sterilization, electrical safety or transport tests, as applicable.
The communication we talked about earlier makes those external tests much simpler.

Finally, you will have to write your Verification Reports and Verification Summary Report.

Writing them in a consistent and clear way will help the authorities review your tests and approve your device. Make sure that all the obtained results stand out and clearly show that the requirements are met.

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Design validation

The **Validation** is the demonstration that you designed the right device.

It consists of validating, using objective evidence, that the product meets the User Needs and corresponds to the intended use/purpose.

If verification is mainly laboratory tests, the validation is oriented towards users and their use environment.

In this phase, the product classification according to local regulation has the most impact as it imposes the testing required.

These testing include the Summative test of the Usability process and may include a clinical evaluation and/or simulated treatments and/or a clinical investigation with patients (that represents of course the most time and effort).
The same documentation rules apply (planning, protocol, sample size, material approval, training of the users, reporting) as in the verification phase. The Risk Management Report and the post market surveillance process are usually the last development activities.

At this point, your DHF is complete. That is, until your first Design Change of course.

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Regulatory approval & commercialization

Hopefully everything went smoothly thanks to your very good preparation.

You are ready to submit your device to the approval authorities or to approve yourself if you are certified to.

Now, commercialization of your Medical Device can begin.

We have written this article to provide you with a valuable and proven overview of aspects to consider when developing your medical device.
We hope you have enjoyed reading it and found it useful.

If you'd like to explore certain topics in greater depth or benefit from our support, our team of expert engineers will guide you and take care of your medical device development.

Don't hesitate to contact us contact@debiotech.com

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