New Product Development Process

How we work

The development of all assays at Future Diagnostics is performed according to our New Product Development Process (NPDP). The NPDP describes the assay development, including all the phases and phase reviews, at Future Diagnostics. The NPDP consists of 4 phases. These phases (1 – 3) are closed with a formal review and the outcome of the phase review will be documented and signed off in a Formal Review Report. During the entire project, technical meetings will be held on a regular basis with the customer.

Phase 0
Contract

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Phase 1
Definition

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Phase 2
Design & Verification

↓

Phase 3
Production & Validation

future diagnostics

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How we work

Phase 0 – Contract

We set up a contract for phase 1, based on the needs and wishes from the customer and technical input from our experts.
An indicative time schedule to develop the test will be given with a detailed overview of costs for phase 1.

Phase 1 – Definition

The purpose of the definition phase is to define the project, to perform antibody/antigen selection, antibody/antigen screening and conduct pre-feasibility studies to explore the quality of the raw materials and assay feasibility.
Within pre-feasibility studies, a first indication of key raw materials or assay/technology performance is given. We identify (technical) risks, and include a reasonable accurate budget estimation for further development.

Phase 2 – Design & Verification

Phase 2 of the project consists of two main work packages; design and verification.

Design

In the design work package, feasibility of the assays will be shown and the assays will be optimized to meet the design requirements described in a product development plan.
Our R&D will produce a bench lot to confirm critical assay parameters before design freeze.

Verification

The goal during verification is to verify the assay designs and complete design freeze (the assay can now be sold for Research Use Only).
During the verification work package, verification lots will be produced at R&D using R&D documentation and benchmarked against the design requirements. Accelerated stability studies will also be initiated for indicative shelf life data.

Phase 3 – Production & Validation

Phase 3 also consists of two main work packages: Production and Validation.

Production

In the production work package, the assay is transferred from Future Diagnostics' R&D to either Future Diagnostics' manufacturing or another manufacturing location.
Time needed for transfer is depending on the location and type of manufacturer to be transferred to.

Validation

In the validation work package, technical validation and (accelerated) stability studies of the assay are performed.
Lots are produced at the manufacturing location and QC released. These lots shall be labelled for **Investigational Use Only** (IUO) and can be used for technical and clinical validation. Technical validation will be performed during the validation work package according to the CLSI guidelines at Future Diagnostics and documented in appropriate reports complying to the ISO13485 standards.

Phase 4 - Closure

Closure consist of transferring all signed technical documentation of the Design History File to the customer.
For **IVD registration** of a product a technical file needs to be set up in compliance with the Medical Device regulation from a specific country. Future Diagnostics will write a part of the technical file that is needed for the legal registration.
This is included in the total development costs.
The customer will be the legal owner and legal manufacturer of the product. The product will only show the name of customer.

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