Verification & Validation Services

Want to get your product CE marked or FDA approved?

Verification and Validation (V&V) are critical components in the assay design to prove that your product meets its requirements and specifications and that it fulfills its intended purpose. Both V&V are critical phases of your Design History File. This Design History File is part of the technical file of your product and above all essential to be FDA registered or CE marked. We can avoid delay in your product launches, because of our ample knowledge on and expertise in the entire process of product registration.

Verification

The nature of verification activities varies according to the type of design output (quantitative, qualitative, multiplex, etc.). We will design the required procedures for your product. Typical verification procedures involve tests devised specifically to ensure that your product meets the initial design requirements, specifications, and regulations. The results of these tests are used to evaluate whether your product is in accordance with these criteria.

Technical Validation

The final manufacturing site produces the required validation lots according to the regulatory- and safety requirements. Our dedicated team verifies that the validation lots comply with the design requirements mentioned in the product specification form. The outcome of the validation studies can/will be used to support the label claims.

Stability Studies

We set-up the stability studies for your product with multiple validation lots as described in a Stability Plan. The designed stability studies will meet the stability requirements stated in the design input and are compliant with NEN-EN-ISO 23640.

future diagnostics

IVD Assay Development & Contract Manufacturing Services

future diagnostics

The Extension of Your Internal R&D

Future Diagnostics Solutions BV offers services for the development and manufacturing of IVD (immuno) assays to IVD multinationals, mid-sized biotech and small start-up companies within the global medical diagnostics and device industry. Since 1997, more than 150 products are developed in accordance with IVD requirements and regulations (ISO13485/ FDA/cGMP). The profound experience makes Future Diagnostics a trusted partner for assay development of any type of assay, with any type of technology on any type of analyzer.

Point of Care

With many years of experience in quantitative POC test developments on whole blood, using dry chemistry and short assay times, we are the obvious choice to bring the lab to the patient.

Immunoassays

Future Diagnostics develops high quality IVD immunoassays on demand and offers flexible support plus advice in feasibility, optimization, verification and validation projects, including technical transfer to manufacturing for third parties.

Pre-Feasibility

Pre-feasibility studies are of great value if the development of a specific assay is under consideration. Preliminary experiments are run with available raw materials to determine whether it is worthwhile to proceed to the feasibility phase.

Validation

We provide documented evidence to show that predetermined assay requirements are consistently met. By performing validation studies according to the CLSI guidelines these specified requirements are confirmed.

(Free) Vitamin D

With a patent on the measurements of FREE 25-OH Vitamin D in blood, Future Diagnostics is leading the market with this new Vitamin D application. Furthermore we have a vast experience in Vitamin-D assay developments, either on automated platforms or manual formats.

future diagnostics

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