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MED TECH OUTLOOK

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IN VITRO DIAGNOSTIC EDITION

FUTURE DIAGNOSTICS SOLUTIONS

CERTIFIED IVD ASSAY DEVELOPMENT

Mike Klinkenberg,
Managing Director

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The In-Vitro Diagnostics (IVD) market is highly competitive and fragmented with several large and small players vying for supremacy. In this marketplace, the success of developing, validating and marketing diagnostics depends considerably on the ability of manufacturers to navigate the specific, complex, and interrelated development requirements. However, IVD companies are struggling to navigate through an increasingly complex development process fraught with uncertainty. Supply chain globalisation, increasing pressure on costs, time to market intervals, and ever-higher quality expectations by customers are some of the critical challenges faced by IVD companies. To stay ahead in this IVD medical device market, one might need a specialised partner that challenges the status quo of the industry.

The Netherlands based Future Diagnostics, since 1997, has been working with start-up companies, mid-sized biotech, and IVD multinationals within the global IVD medical device market, standing tall as an extension of a client's R&D. Future Diagnostics collaborates with innovative companies that require assay development support and manufacturing services to bring new IVD products to the market. With more than 22 years of experience and over 70 skilful employees, the company is dedicated to make successful developments and accelerate product launches for clients. This profound expertise makes Future Diagnostics a trusted partner for the

development of many different types of immunoassays, with different technologies, either manually or automated.

Future Diagnostics develops full high-quality IVD immunoassays on demand, also offering support in (pre-) feasibility, design optimisation, verification and validation (analytical performance) projects. The firm assists companies in materialising their concept assay to an IVD product that is ready for the European (CE-IVD) or US (21CFR809) market. “We believe in taking up challenges based on our experience; We have the guts to make deals for certain projects where clients do not need to pay if we fail to deliver,” asserts Mike Klinkenberg, Managing Director of Future Diagnostics.

When developing an immunoassay, Future Diagnostics utilises its proven four-phase New Product Development Process (NPDP), compliant with ISO13485. Based on clients’ requirements and technical input from its experts, Future Diagnostics draws up a contract and starts with the selection and screening of critical raw materials (e.g., antibodies), followed by pre-feasibility studies to explore the quality of selected materials. After demonstrating the feasibility of the assay(s) and optimising the design to meet the pre-defined product requirements, thorough assay verification is executed. Future Diagnostics then transfers the assay from R&D to either its registered manufacturing facility or another manufacturing location of the clients’ choice. Subsequently, analytical performance studies are executed, according to CLSI guidelines, which will be documented in appropriate reports complying with NEN-EN13612. The clients can monitor the progress of their project in real-time in the SharePoint environment. To close the project, Future Diagnostics transfers all mutually approved technical documentation to its clients as part of the Design History File. During the entire development, the progress of the project is constantly monitored using key parameters such as deliverables, quality, budget, and timelines to adjust projects quickly if necessary. “We are not afraid to try something new, and we like to innovate and discover things that lead to progress,” concludes Klinkenberg.

Apart from developing complete IVD immunoassays, Future Diagnostics also offers analytical performance services, pre-feasibility studies, antibody/antigen conjugation, and micro-array spotting. The analytical performance studies are part of the clinical evidence requirements to ensure a smooth transition from the IVDD (In-Vitro Diagnostics Directive) to the new IVDR (In-Vitro Diagnostics Regulation), as the products currently classified as IVDD will require IVDR compliance. The company reviews current technical documentation and determines studies that have already been reported, all the while assessing their quality. Based on this, the company provides tailored advice and decides on the additional studies that are critical to demonstrate compliance.

> “We have the guts to make deals for certain projects where clients do not need to pay if we fail to deliver

Leading biotech and IVD companies collaborate with Future Diagnostics owing to its proven, transparent approach to assay development. The organisation has developed more than 150 products as per IVD requirements and regulations. Moreover, Future Diagnostics has already planned its implementation strategies according to the European Commission’s new IVDR 2017/746 and is focused on providing clients with a complete package from product development to writing part of the technical file you need for IVD registration of the assay, in compliance with Medical Device regulations in the country of interest.

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Future Diagnostics

recognized by MEDTECH OUTLOOK magazine as

TOP 10 IN VITRO DIAGNOSTIC SOLUTION PROVIDERS IN EUROPE - 2020

The annual listing of 10 companies that are at the forefront of providing In Vitro Diagnostic solutions and impacting the industry

COMPANY:
Future Diagnostics

WEBSITE:
future-diagnostics.com

KEY PERSON:
Mike Klinkenberg,
Managing Director

DESCRIPTION:
Future Diagnostics offers services for the development of IVD (Immuno) assays to IVD multinationals, mid-sized biotech, and small start-up companies within the global medical diagnostics and device industry

TOP 10 IN VITRO DIAGNOSTIC SOLUTION PROVIDERS IN EUROPE - 2020

The global in-vitro diagnostics market is likely to increase at a high rate due to the increasing prevalence of chronic disease around the world. Rising fatal diseases such as CVD, CHD, Stroke, Cancer, and other heart diseases are driving the In-vitro diagnostics market. In recent years, there have been vigorous government contributions as well as company approaches that have supported the growth of the in-vitro diagnostics market. Many companies are putting in more effort to develop newer concepts and theories for diagnosing chronic ailments and other diseases using in-vitro diagnostics. Moreover, a growing emphasis on developing new tests for portable diagnostic devices is likely to supplement the growth of the in-vitro diagnostics market.

Recent developments made in in-vitro diagnostic solutions have been prolific for end-users as well as companies and manufacturers. Due to the portability factor, numerous geriatric prefers in-vitro diagnostics method over other methods. In addition to geriatrics, in-vitro diagnostics help in the treatment of those with severe chronic ailments and bowel disorders or muscle and joint injuries, wherein physical movements are limited. Backed by increasing demand, many companies are setting up in-vitro diagnostic centres with the aim of maximizing their profit.

The in-vitro diagnostics (IVD) laboratory stands at the centre of clinical decision-making because of its role in data generation. A recent study on the awareness of AI in the clinical laboratory showed that most laboratory professionals have already seen some advances driven by AI in their laboratory. As a result, they expect dramatic changes within the next two to five years in both the laboratory landscape and their routine workflow. To help healthcare organizations select the best IVD vendors, a distinguished panel comprising CEOs, CIOs, VCs, industry analysts, and MedTech Outlook’s editorial board has narrowed down a list of IVDs solution providers who are on the forefront of innovative technologies and strategies.

We present to you the “ Top 10 In Vitro Diagnostic Solution Providers in Europe - 2020.”