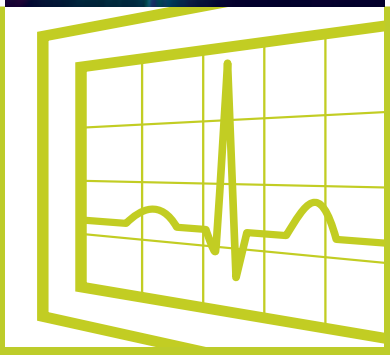
One partner, all the brains you need

Medical Devices & In-Vitro Diagnostics



Medicines and Medical Devices: an important role in human healthcare

Medicines and Medical Devices are used for diagnosis, treatment or prevention of a disease. In the past century healthcare experienced major changes. The technology boost helped inventing new treatments and applications; quality of life improved and life span increased. Safety and protective regulations were designed around Medical Devices.

It's great to have an innovation and to plan an efficient development that leads to successful applications. Doing so, you will help improving human healthcare even more. A plan for an innovation is usually a low cost investment, to plan a controlled development and a successful registration process is the next step to success.

Kinesis
Consultants in drug development

To transfer your innovation into a successful Medical Device requires careful steps that lead to safe and useful medical applications. The innovation has to be developed into a prototype that is tested non-clinically, clinically and at the end is registered as an approved and safe Medical Device. An exciting journey requiring carefully designed small steps to move forward. The more efficiently done, the more optimal return on investment is achieved, so innovations develop into better Medical Devices. Kinesis can help you to be more successful and to be faster. Because Kinesis has extended experience with drug development, there is a match with Medical Devices for companion diagnostics, combination products, pharmacogenetics, personalised medicine and In-Vitro Diagnostics. Join us in the exciting journey and use our brains for your innovations.

What Kinesis offers

- **Feasibility studies**

Kinesis works with you to transfer your innovation into a sellable product. We perform a feasibility study with the next steps necessary to finalize the Medical Device. You use the study results to discuss the advantages of your future Medical Device with potential investors, the manufacturer, Medical Device users and/or patients. You can continue improving the innovation and with the feasibility study you know exactly what the next steps are to reach the end goal of success.

- **Prototype building**

Kinesis advises you what partner you should choose for transferring your innovation into a first prototype. Proper design of the prototype is crucial. If you have the prototype available you are ready for testing, preparation for production and registration of the Medical Device. If you choose the optimal prototype the risk of redesign and additional costs is under control.

- **Non-Clinical testing**

With the prototype in your hands you are probably excited to see it in action for the first time. Proof of concept is what it's all about. Kinesis helps you setting up your non-clinical test program. We can also bring you in contact with suitable test labs and provide you with the plan, controls and feedback. We help you making the best steps to move forward towards clinical testing.

- **Clinical testing**

Kinesis helps you setting up your clinical test program. This stage should link seamlessly with the non-clinical test phase. We write the study protocol and arrange suitable clinical test facilities and manage the clinical testing. Data collection and risk management is needed to prepare for registration of the Medical Device. We guide you through this complex and critical step. Being successful in this phase keeps investors, manufacturers, Medical Device users and patients interested to get their hands on your future Medical Device.

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- **Medical Device registration**

Writing manuals, labels and inserts, having the correct test results on paper makes you ready for registration of the Medical Device. Building the technical files and maintaining the design history is crucial for the success in this phase. Kinesis helps you in an early stage to set the correct route for a successful registration. From the feasibility study, where we selected the device risk class, through prototype design, non-clinical and clinical testing and registration we help and advise on regulatory affairs.

- **Quality system**

Design, testing, production and post marketing, it all needs to happen in a controlled environment. If all earlier steps have been completed successfully and if there is a good controlled environment around your Medical Device, the good work will be rewarded and the risk of not being able to register the product is very low.

In the post marketing phase you will have a system in place for patient and end-user feedback. Incidents or near incidents are reported using a solid and controlled procedure. Kinesis helps with the construction of a certified quality system.

- **Post marketing services**

You're selling now and you have processes in place to deliver high quality and safe Medical Devices. If issues occur you can act as expected and Kinesis offers help when issues arise. You keep your business running and you're not losing track. If the situation changes you stay in control. You're now making money out of your investments and your Medical Device is helping to make human healthcare even better.
If a new innovation arises you're ready to start all over again. If you liked the journey with us, feel free to use our brains again.

Why Kinesis?

- Feasibility studies
- Prototype building
- Non-Clinical testing
- Clinical testing
- Medical Device registration
- Quality system
- Post marketing services
- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

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'Engineering an innovation fast into a Medical Device is our ambition to improve human healthcare'

About Kinesis

Kinesis is an independent drug development organization with headquarters in Breda, the Netherlands. Kinesis aims to facilitate an efficient and high quality development and registration process for medicinal, Medical Device products and nutraceuticals through consultancy and contract research services. Kinesis' service offering includes CMC, non-clinical, clinical, regulatory, quality and project management activities for pharmaceutical, nutraceutical, biotech and Medical Device companies.

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