PRESS RELEASE
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Biotech - Medtech - Chemtech - Quality by Design - CDMO - Nanotechnologies for health

CYBERNANO and STANIPHARM join forces to develop tomorrow's health products

CYBERNANO and STANIPHARM announce a new partnership to enable start-ups to take their products from idea to clinical trial faster and more safely.

Many biotech and medtech start-ups are active in developing high-potential health products and are currently the main players in innovation in these sectors. The process of bringing such a product from discovery through clinical trials is often described as "crossing the valley of death". The path to demonstrating the efficacy and safety of a new product involves a demanding sequence of technical stages. Whether it is setting up a laboratory to complete a proof of concept, obtaining regulatory approvals, statistically validating studies, producing clinical trial batches, controlling quality or preparing for manufacturing scale-up, each step in the process requires experienced and highly skilled personnel and expensive infrastructure. These start-ups therefore need to rely on external service providers for the expertise and infrastructure required at each stage of their product's development.

STANIPHARM is a CDMO which has already successfully developed and manufactured many cutting-edge health products for its customers, including nanoformulations, active ingredients, and injectable polymers. It supports these customers throughout the process, from carrying out experimental studies on a laboratory scale to production and qualification of batches for clinical trials.

CYBERNANO is a biostatistics contract research firm specializing in Quality by Design (QbD). This new approach, which is strongly recommended by all international drug agencies, aims to improve quality control of future products starting from the earliest stages of design, and thus to minimize uncontrolled delays in development.

Both companies are also involved in high-profile European projects with nanotechnologies for health applications.

To stay ahead of development deadlines, optimize quality, identify risk factors early in the process, and develop innovative health products, STANIPHARM and CYBERNANO are creating a new partnership. The complementary nature of their expertise and technologies - CYBERNANO's Quality by Design digital service platform, and STANIPHARM's Good Manufacturing Practices (GMP) development and production platform - will provide complete support for start-ups and SMEs from development through clinical trials.

Frantz Deschamps, President of STANIPHARM, says: "Using CYBERNANO's easyQBD® solution has already helped us to successfully develop nanoformulations for our customers. These start-ups were then able to keep to their often very ambitious development plans and to carry out clinical trials with a de-risked product." »

Thierry Bastogne, co-founder of CYBERNANO, adds, "Ensuring safe development from the very first phases of the project by involving a parter who is aware of the production and validation constraints of these products is a key success factor. This allows us to plan the right experiments to be carried out and obtain reliable data that will be used to better assess risks and more quickly optimize the quality of batches intended for preclinical and clinical trials.

About StaniPharm

Since 2010, StaniPharm has developed technological solutions to meet the challenges of the life sciences industry, particularly in the area of extraction and purification of active ingredients and the development of nanodrugs. At StaniPharm's site in Champigneulles, France, the team operates equipment for formulation, extraction and purification, and runs an analytical development and quality control laboratory and clean rooms for GMP batch production.

About Cybernano

Since 2013, Cybernano has been developing a unique international digital platform to facilitate the implementation of good practice guidelines for pharmaceutical development, known popularly as Quality by Design. This platform is currently being used in two European projects: TBMED, to help develop medical devices that incorporate nanomaterials, and EXPERT, focused on the development of lipid nanovehicles encapsulating messenger RNA to help immune system cells more effectively fight certain cancers.

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