Hitachi High-Tech

News Release

FOR IMMEDIATE RELEASE

Strengthening Our Portfolio of Transmission Electron Microscopes for the Pharmaceutical Industry Through Investment to Vironova AB

Hitachi High-Technologies Corporation (TSE:8036/Hitachi High-Tech) have undertaken a third-party allotment of shares (this capital alliance) with Vironova AB (Main office: Stockholm, Sweden /CEO: Mohammed Homman/Vironova), who develop and sell analysis software for transmission electron microscopes (TEM) along with carrying out contract analysis for pharmaceutical companies. Through this capital alliance, we aim to jointly develop TEM specialized for the pharmaceutical industry and strengthen our sales relationship, as well as open up new markets for quality control of biopharmaceuticals.

In Vironova's core business of contract analysis, there is a growing demand for analysis of viral vectors for gene therapy. Viral vectors are an important tool for gene therapy and are used to introduce the gene used for treatment into the place where it is needed in the patient. This method is considered to have few side effects and is expected to be highly effective, so there has been growing interest in viral vectors as biopharmaceutical products. However, wider use of viral vectors for gene therapy remains a challenge, due to the need to comply with regulations and to establish the technologies required for mass production in various countries. In particular, strict quality control measures surrounding contamination and imperfections during manufacturing are required, leading to increased applications for TEM, which can reveal great detail in small-quantities of specimen.

Vironova develops and sells automated measurement and analysis software for TEM using Al image recognition, together with providing contract analysis business for biopharmaceuticals in its GLP-compliant*¹ facilities. In their contract analysis, they are actively working on the viral vector analysis business using TEM, providing reliable analytical data with their own software that is compliant with the FDA's "21 CFR Part 11*2".

Hitachi High-Tech has been developing and providing TEM that meets the changing needs of customers across a wide range of fields, including semiconductors, materials, medicine and biology. Through this capital alliance, we aim to provide cutting-edge solutions by combining Vironova's regulatory-compliance and automated measurement and analysis software, developed based on their experience gained from their existing business, with Hitachi High-Tech's high-quality, user-friendly TEM.

This capital alliance is part of Hitachi High-Tech's growth strategy aimed at strengthening its automation technology and creating a new biotechnology field. Strengthening their cooperative relationship as strategic partners will help both companies to provide seamless development, manufacturing, sales and after-sales services going forward and contribute to the expansion of the pharmaceutical market.

^{*2} FDA 21 CFR Part 11: A regulation in the United States for preventing tampering with electronic records. Development and manufacturing records submitted by pharmaceutical companies when applying for permission to sell new pharmaceutical products must also comply with this regulation.



^{*1} GLP (Good Laboratory Practice): A standard that stipulates the facilities, equipment, systems and testing procedures, etc. that a testing facility should provide in order to ensure the reliability of examinations and tests that evaluate the safety of pharmaceuticals and foods.

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[About Vironova]

(1)Name	Vironova AB
(2)Location	Gävlegatan 22, 113 30 Stockholm, Sweden
(3)Representative	Mohammed Homman
(4)Main Businesses	· Viral clearance testing
	· Contract analysis for the pharmaceutical market
	· Development of automated measurement and analysis software
	for transmission electron microscopes
(5)Estblishment	2005

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