### Healthcare & Analytical Systems

**Connective Industries** 

#Healthcare, QoL #Co-creation and Open Innovation #Productivity Improvement #Generative AI #IoT/Data Utilization #Digital Solutions #Measurement & Analytical Systems

#### 1. Development of Particle Therapy System Enhancement Business

Hitachi High-Tech Corporation's Healthcare Business Group inherited Hitachi Ltd.'s particle therapy cancer treatment equipment business in April 2024. Since then, the company has been developing its business with the aim of realizing a world without the fear of cancer, based on its vision of "a society full of smiles, where all can enjoy a secure, safe, healthy way of life."

Enhancement projects aimed at improving and maintaining the functionality of existing facilities in the field of particle therapy have been rapidly growing in recent years, in addition to system installation and maintenance projects. As particle therapy continues to spread, this growth is being driven by an increasing customer demand for improvements in system performance and maintenance of facilities that have been in operation for 10 to 20 years. Building long-term trust with customers is an essential component of the enhancement business, and Hitachi High-Tech Corporation is growing the business through meticulous and steady improvement proposals tailored to each customer's specific circumstances.

The University of Tsukuba, which began operation of its proton therapy system in 2001, is constructing a new facility to address increasing treatment needs, and is planning to switch to this new facility in 2025. In addition, Hitachi High-Tech Corporation has received enhancement projects from domestic local governments and academic institutions such as those in Hyogo

[01] Artist's Rendering of Completed New Proton Therapy Facility at University of Tsukuba (left) and Existing Proton Therapy Facility (right)



Prefecture, Fukui Prefecture, Gunma University, Nagoya City University, and Hokkaido University, as well as from international clients.

(Hitachi High-Tech Corporation)

## 2. Supporting Work Style Reform in Clinical Laboratories with the LABOSPECT 006 $\alpha$ Automated Analyzer

Starting in April 2024, Hitachi High-Tech Corporation has been promoting task shifting and sharing within medical institutions through its "Work Style Reform for Physicians." Clinical laboratory technicians are also expected to expand their roles beyond traditional responsibilities. Given this background, automated biochemical analyzers are increasingly required to minimize sample volumes, accelerate testing, and improve operational efficiency to reduce workload.

To this end, LABOSPECT 006  $\alpha$  contributes to a reduction in testing time through the following three key features:

(1) Reduced morning preparation time

The system automatically performs blank calibration during startup, which previously had to be conducted manually every day.

(2) Reduced time spent on consumable management

The system has expanded space for the alkaline detergent used in cleaning, thereby enabling automatic switching to a new detergent bottle when the current one runs out, which reduces downtime due to detergent shortages.

(3) Reduced maintenance time

The automatic sample probe cleaning function has been improved through the use of heated detergent, reducing the need for daily manual wiping to once per week.

Moving forward, Hitachi High-Tech will continue to develop new functions based on feedback from laboratories, applying ideas and technology in order to support new ways of working in clinical testing.

[02] LABOSPECT 006 α Automated Analyzer



#### 3. Analysis of Human Genome Structural Variants Using Genome Mapping

The rapid evolution of deoxyribonucleic acid (DNA) sequencers in recent years has led to significant improvements in the ability to analyze human genes and genomes. And yet, when it comes to conditions such as mental disorders or cancer, it remains difficult to find a clear correlation between DNA sequence information and the diseases. The reason for this is that DNA sequences must be shortened for the DNA sequencers to be able to read them.

Next-generation sequencing (NGS) can read DNA sequences of up to several hundred base pairs, while long-read DNA sequencers can read up to about 20,000 base pairs. However, recent findings have revealed that large structural variations (SVs), such as deletions, insertions, translocations, and inversions ranging from 50 base pairs to over a million base pairs, occur in human chromosomes. Some of these variations have been discovered to be causes of diseases. However, due to the significant difference in size between SVs and the length of DNA that DNA sequencers can read, it is difficult to detect the presence of SVs. This has been a major reason why the correlation between diseases and DNA sequences remains elusive.

To resolve this, Hitachi High-Tech's genome mapping and analysis technology uses a method that records the positions of specific patterns that appear in DNA fragments ranging from 50,000 to 5,000,000 bases in length by encoding each DNA fragment with a barcode-like system. By reading long DNA fragments, this makes it possible to detect SVs over 100,000 base pairs that were difficult to detect with existing technologies. This new technique is expected to greatly contribute to the identification of diseases and the establishment of treatment methods.

(Hitachi High-Tech Corporation)

[03] Human Chromosome Structural Variation Analysis Solution Using the Nabsys OhmX Platform and Hitachi High-Tech's HCE-based Genome Mapping Technology



HCE: human chromosome explorer

#### 4. "ASDAMS" Support Software for FDA 21 CFR Part 11

FDA 21CFR Part 11 (hereinafter referred to as "Part 11") is a regulation established by the Food and Drug Administration (FDA) concerning electronic records and electronic signatures for pharmaceuticals, medical devices, food, and other related industries. Part 11 is one of the components of data integrity for which guidelines have been issued by regulatory authorities such as those in the United States and Europe, and compliance with Part 11 is becoming essential in the pharmaceutical and food industries.

Hitachi High-Tech Analysis Corporation's Analytical Solution Data Management System (ASDAMS) is a data management platform designed to support Part 11 compliance for analytical instrument software. ASDAMS has features necessary for Part 11 compliance, including user management and authentication, functions to prevent tampering or loss of electronic records, access restrictions, and audit trail functionality, all provided via an application programming interface (API). By integrating this API, users can utilize ASDAMS' regulatory compliance features. Additionally, the data registered in ASDAMS can use the analytical instrument's proprietary file format directly, which helps reduce the development effort required for Part 11 compliance in analytical instrument software.

Connections have already been established with the high-performance liquid chromatography (HPLC) software ChromAssist and the spectrophotometer software UV Solution Plus, and ASDAMS will continue contributing to Part 11 compliance for products in the pharmaceutical field into the future.

(Hitachi High-Tech Analysis Corporation)

SDAMS				0 (	Analytical Solution Service Logo
Home System Status	Home				
Organization Management Authority / User / Group / Pessword	Project List Project Name	Client-Server Status			
Project Management	Diff Test Stress Test_240628	Automatic Update Cycle:		300 seconds	Update
USB Device Management	Stress Test_240625 Stress Test_240624	System Configuration: Server Status:		C/S System	
USB Device Settings	Stress Test_240622 Project6	DB Storage Available Capacity:		212 G8/ 500 G8	
Instrument Configuration Manag Instrument Configuration Settings	Stress Test Project3	Server Information:	Server Information:		History
Various Settings Basic Settings / Reason (Comment)	Project2 Project1				
Maintenance Active / Betrieve		Device(Compute HHS2723	er) User	Instrument	Status Power ON
backp / Deve Data		HHS2724 HHS2723	Analytical Solution Service		Power ON User Logged in
Display / Approval		HHS2724	Analytical Solution Service		User Logged in
					Detailed Status

#### [04] Home Screen of "ASDAMS" Support Software for FDA 21 CFR Part 11

#### 5. Polarized Light Microscopy Technique for Thermal Analysis Instruments

Thermal analysis instruments are widely used across various fields to evaluate thermal properties in the research and development of materials as well as quality control. Hitachi High-Tech Science has enabled more detailed analysis by developing sample observation technology that uses a camera to visualize the sample's state during measurement.

As an advanced version of this sample observation technology, the newly developed polarized light microscopy option for thermal analysis instruments features improved camera resolution and support for polarized observation. When combined with a thermal analysis instrument, it enables the capture of high-resolution polarized images while varying the sample's temperature, thereby allowing for the observation of microscopic crystalline state changes. This enables thermal analysis at the microscopic level, which was challenging with conventional instruments, facilitating fundamental research on crystal orientation in samples, analysis of microscopic defects in polymer films, and evaluation of the physical properties of ultra-thin multilayer films.

Moving forward, Hitachi High-Tech Science will further expand applications and provide this technology for analytical instruments that support everything from advanced material research and development to quality control for customers across a wide range of industries.

[05] Real View Polarized Light Microscopy Option



(Hitachi High-Tech Science Corporation)

#### 6. High-resolution Schottky SEM SU3800SE/SU3900SE Series

A scanning electron microscope (SEM) is an instrument used to observe the fine structure of material surfaces, and is widely utilized across various industries in fields such as nanotechnology and biotechnology, with applications from research and development to manufacturing and quality control. Among them, the demand for high-resolution Schottky scanning electron microscopes, or field emission SEM (FE-SEM), which enable higher-magnification observation, is increasing for applications such as observation of fine particles, analysis of microscopic foreign substances, and elemental analysis.

In recent years, SEM has been utilized for controlling the fine structure of various materials to enhance functionality and performance, as well as for foreign matter and defect inspection to improve quality. There is growing demand for further improvements in operability, such as streamlining the acquisition of large amounts of data and simplifying the process of finding the field of view during wide-area observations, as well as for reductions in the labor required for inspection tasks. [06] High-resolution Schottky SEM SU3800SE/SU3900SE Series



The SU3800SE/SU3900SE series is equipped with an automatic optical system adjustment function that helps reduce the user's operational burden. In addition, the optional "EM Flow Creator" feature supports the automation of operations such as continuous image acquisition. Users can perform automated observations tailored to their specific purposes by executing the recipes created by this feature.

(Hitachi High-Tech Corporation)

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