Review

HORIBA's Biohealthcare Technologies Supporting Drug Discovery, Diagnosis, and Treatment

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The healthcare journey, which covers prevention, diagnosis, treatment, and prognosis management as a continuous process, is facing a strong need for transformation due to the pandemics such as COVID-19 and the rapid aging of society. Fast and simple testing methods, early detection of diseases, the development of new biopharmaceuticals and cell therapies, and advanced process technologies for their stable production and supply are all essential. This article introduces HORIBA's biohealthcare business from two perspectives—diagnostic devices and analytical instruments—and presents the technologies it has developed to date, their future directions, and how they will contribute to improving the quality of the healthcare journey.

Keywords
liquid biopsy, biopharmaceuticals, process monitoring

Introduction

The healthcare journey—from prevention to diagnosis, treatment, and prognosis management—is entering a major period of transformation due to the global spread of COVID-19 and the acceleration of population aging and declining birthrates. During COVID-19, large numbers of patients presenting with fever and fatigue emerged, creating an urgent need to deliver medical care while preventing droplet/aerosol transmission; this situation exceeded the assumptions underlying the healthcare system at that time. Challenges in healthcare response to pandemics became evident, including the supply of in vitro diagnostic testing analyzers and reagents; the provision of locations and opportunities for testing, clinical care, and emergency patient care; the early provision of vaccines and therapeutics; and the monitoring and control of outbreaks. Consequently, nationwide efforts are underway to prepare for the next pandemic. At present, Japan is also facing increasingly severe problems such as soaring medical expenditures and strain on the healthcare delivery system due to the rapid progression of population aging and declining birthrates. Medical expenditures have increased year by year (Figure 1). As the elderly population grows, the burden on the working-age population becomes even heavier and further increases in medical expenditures may undermine the sustainability of the social security system. Structural challenges, including shortages of physicians and healthcare workers and their uneven distribution between urban and rural areas, are also intensifying. In small- and medium-sized hospitals, there are increasing cases in which deteriorating management makes it difficult to maintain emergency medical care systems. Addressing these issues is an urgent matter.

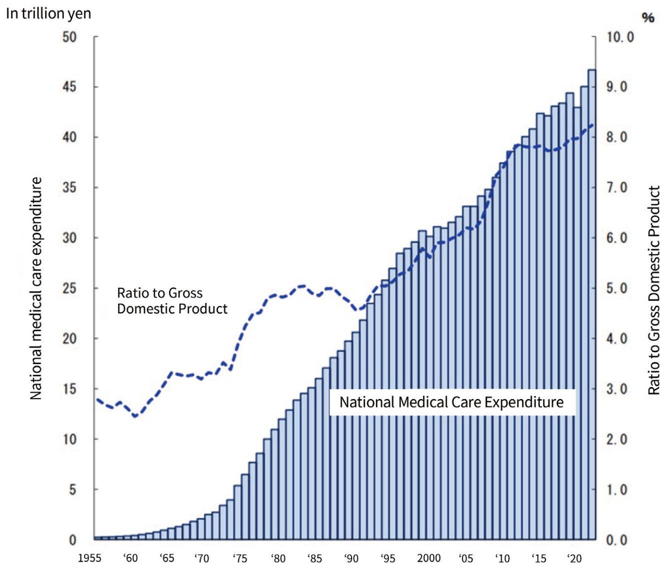

Figure 1 Annual trends in national medical expenditures and the ratio to gross domestic product.
Source: Ministry of Health, Labour and Welfare, "Overview of National Medical Expenditures in FY2022 (Summary of Results)" [1], [2].

In this social context, there is a growing demand for measurement technologies that enable simple testing without large systems or specialists and that contribute to rapid and accurate diagnosis, as well as analytical technologies useful for developing new therapeutics and vaccines and measurement technologies that support their stable, highly efficient production and supply. The following sections introduce HORIBA's initiatives and future developments in its biohealthcare business related to these needs.

HORIBA's Biohealthcare Business Initiatives

HORIBA's biohealthcare business comprises two domains: "medical devices used for diagnosis" and "analytical systems used in drug development." The former contributes by supporting clinical settings, whereas the latter contributes by supporting research and development settings.

HORIBA's medical devices are primarily deployed as clinical laboratory systems for hematology, immunology, and clinical chemistry. Through the provision of compact Point-of-Care Testing (POCT) systems for clinics (including pediatrics), laboratories in small- and medium-sized hospitals, and bedside use, HORIBA supports routine clinical practice.

The Hematology and CRP analyzer (Figure 2) was developed 27 years ago as system capable of simultaneously measuring complete blood count (CBC) and C-reactive protein (CRP[*1]) using whole blood samples. Subsequently, it has achieved specimen miniaturization, shorter turnaround time (TAT), reduced infection risk for operators, and downsizing of the device, and it is now widely adopted, particularly in clinics. Because it can simultaneously measure different test items that are important for infectious disease screening, it provides data that support rapid on-site decision-making in screening tests aimed at differentiating viral infection from bacterial infection in febrile patients.

*1 CRP (C-Reactive Protein): a type of protein that increases in serum when acute inflammation or tissue injury is present in the body.

Figure 2 Automated Hematology and CRP analyzer.

Figure 3 Glucose analyzer.

Figure 4 Centrifugal blood analyzer.

Figure 5 Laser diffraction and dynamic imaging particle size and shape analyzer.

Figure 6 Raman microscope.

In Japan, the prevalence of chronic diseases such as diabetes has increased, and there is a growing need to measure blood glucose and HbA1c[*2] not only at specialized facilities but also under the care of primary care physicians. HORIBA provides a solution that enables in-house diabetes testing by combining the glucose analyzer "ANTSENSE" (Figure 3) with the centrifugal blood analyzer "Banalyst" (Figure 4), which measures HbA1c with high accuracy using µTAS technology. In addition to enabling measurement of whole-blood samples through simple operation, shorter TAT makes it possible to efficiently conduct diagnosis and prognosis monitoring of chronic diseases within the limited time available for outpatient practice.

*2 Hemoglobin A1c (HbA1c): hemoglobin bound to glucose in the blood, representing the average blood glucose level over the past 1–2 months.

In recent years, with the widespread adoption of Electronic Medical Records (EMR), HORIBA has developed solutions not only for analyzers themselves but also for automatically integrating and linking data to EMR. These solutions support improvements in the quality of medical care by streamlining testing operations, reducing input errors, and centrally managing historical data. Such "analyzer + data integration" initiatives also constitute an important foundation for work-style reforms and for coordination in home care, both of which are being promoted in clinical settings.

Meanwhile, HORIBA's analytical systems originated from its founding product, the pH meter, and have been widely used from basic to applied research through pH measurement of various solutions in laboratories. Subsequently, HORIBA expanded into the particle measurement field and achieved particle size distribution measurement over an extremely wide range—from several tens of nm to several mm—by combining multiple measurement principles such as laser diffraction and dynamic light scattering. In particular, the laser diffraction and dynamic imaging particle size and shape analyzer (Figure 5) has been used to evaluate particle size distributions of raw materials for pharmaceuticals, foods, cosmetics, and other products, and has made substantial contributions to optimizing particle design that directly affects formulation uniformity and dissolution properties.

In addition, Raman microscopes (Figure 6) and transmission Raman spectrometers leveraging spectroscopic technologies have supported quality improvement of tablets by visualizing the dispersibility of specific components in small-molecule drug tablets and evaluating crystal polymorphs, thereby ensuring content uniformity.

In recent years, in response to increasing societal demands for medical safety, the importance of ensuring data integrity (DI) for manufacturing and quality control data has further increased. Because pharmaceutical manufacturers require systems that ensure data authenticity and consistency, HORIBA, in addition to providing analytical instruments, has deployed "HORIBA PLATINALINK" as a DI-compliant platform that can be utilized across HORIBA products, thereby ensuring data traceability and preventing falsification, among other measures.

Future Business Initiatives

In recent years, the forms of diagnosis demanded in clinical settings and of drug development and manufacturing have been changing substantially. In the diagnostic domain, earlier detection of diseases such as cancer is expected to become increasingly important. Accordingly, in addition to conventional pathological examinations that collect tissue, a shift toward liquid biopsy—using body fluids such as blood that is simpler and less invasive—is expected to progress.

For example, research on early diagnosis targeting miRNA (RNA that plays a role in regulating gene function) in exosomes released from cancer cells, as well as prognosis management and monitoring of treatment effects through analysis of trace amounts of Circulating Tumor Cells (CTCs) present in blood, has been advancing. These approaches are expected to provide important clues for future applications ranging from early cancer diagnosis to treatment monitoring.

To contribute to such future healthcare, HORIBA is leveraging technologies cultivated in medical devices and analytical instruments. For instance, HORIBA is also engaged in technology development related to liquid biopsy, including analysis of exosomes using the simultaneous multi-laser nanoparticle tracking analyser "ViewSizer 3000" (Figure 7), which applies particle tracking—one of the particle size distribution measurement techniques—and capturing CTCs by applying blood sampling technologies cultivated in hematology analyzers. These technologies are currently utilized mainly for research purposes; however, in the future, it is expected that, by integrating them with diagnostic medical devices, they will evolve into next-generation diagnostic solutions that can also be used in clinical settings.

Figure 7 Simultaneous multi-laser nanoparticle tracking analysis system.

In the domain of drug development and manufacturing, the development of biopharmaceuticals and vaccines using proteins such as antibodies and nucleic acids has been accelerating. Biopharmaceuticals mainly consist of macromolecules with molecular weights ranging from several thousand to several hundred thousand, and their manufacturing differs substantially from that of small-molecule drugs based primarily on chemical synthesis, as it depends on cell culture processes. Minor fluctuations in raw materials, culture conditions, and cell states can significantly affect the quality attributes of the final product. Consequently, compared with small-molecule drug manufacturing, biopharmaceutical manufacturing places greater importance on thorough process design as well as real-time control and management. Among pharmaceutical manufacturers and Contract Development and Manufacturing Organizations (CDMOs), there is a strong demand not only for final product quality evaluation but also for continuous monitoring of in-process conditions and for initiatives to enhance visualization and control of manufacturing processes.

Manufacturing and quality control technologies that precisely analyze products and medium components during cell culture are important for achieving both improved production efficiency and stable quality of biopharmaceuticals. The importance of the concept of QbD (Quality by Design), which realizes product quality through manufacturing processes designed to meet quality requirements, and of PAT (Process Analytical Technology), which visualizes and analyzes manufacturing processes in real time and builds quality through process control, has been increasing in recent years.

Figure 8 Process Raman.

Figure 9 Fluorescence spectroscopy analyzer.

To address these needs, HORIBA is advancing the deployment of process measurement solutions aimed at implementation in production environments, not only for research and development purposes, based on its core technologies such as Raman spectroscopy and fluorescence analysis. In particular, the process Raman system "PI-200 series" (Figure 8) and the Fluorescence spectroscopy analyzer "Veloci A-TEEM BioPharma Analyzer" (Figure 9) monitor, in real time, product and raw material concentrations, glucose, lactate, and other metabolism-related components in cell culture, thereby contributing to optimization of culture conditions. This contributes to improved production efficiency, while initiatives are also underway to support the design and verification of manufacturing processes by leveraging the acquired data.

Conclusion

HORIBA's biohealthcare business is also at a major turning point. In the field of diagnostic devices, HORIBA has thus far provided value primarily through screening tests in clinical settings; however, going forward, through integration with advanced analytical and measurement technologies cultivated in analytical systems, HORIBA will evolve toward next-generation diagnostic solutions that support prevention, early diagnosis, and monitoring. In the field of analytical systems as well, HORIBA will promote the development of process measurement technologies that consistently support the drug development environment not only in basic research and formulation evaluation but also from basic research through to actual production processes.

HORIBA's biohealthcare business aims to contribute to qualitative improvements across the entire healthcare journey—from diagnosis to treatment and prognosis management—and to create new value. In subsequent articles, as specific examples, we will introduce in detail the centrifugal blood analyzer Raman analytical technologies supporting culture and manufacturing processes, the fluorescence spectroscopy biopharma analyzer, and the fluorescence lifetime imaging microscope.

* Editorial note: This content is based on HORIBA's investigation at the year of publication unless otherwise stated.

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