# RFID Solutions for the Medical and Pharmaceutical Industries

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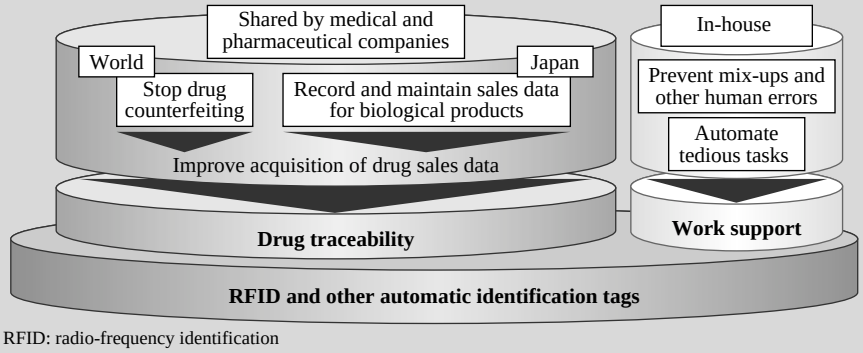
*OVERVIEW: In recent years, there has been considerably progress in leveraging RFID in many different areas. The pharmaceutical industry in particular is looking to RFID as a reliable way to detect and deter counterfeit drugs and medicines. As a fundamental solution to the problem of bogus drugs, the FDA (Food and Drug Administration) of the U.S., the country accounting for close to 50% of drug and medicine sales worldwide, recommends RFID tagging of prescription drugs, and some manufacturers have begun to tag their pharmaceuticals at the individual package level. Adoption of RFID is also expected to greatly reduce human errors when dispensing drugs at hospitals and pharmacies, and a number of pilot studies and trials are now in progress. Hitachi, Ltd. has proposed a number of innovative RFID solutions based on the company's achievements developing systems for the medical and pharmaceutical industries, RFID-related research and development, and substantial expertise gained through participation in government and ministry sponsored IC tag pilot studies and trials.*

## INTRODUCTION

RFID (radio-frequency identification) is expected to play a significant role in the healthcare industry not only for identifying counterfeit drugs but also for improving traceability, for streamlining the movement of products in and out of warehouses and inventory management in the pharmaceutical wholesale industry through batch reading of multiple units, and for reducing mix-ups and other errors at hospitals and pharmacies.

Yet in this environment confined to drug manufacturers, wholesale distributors, and medical institutions, it should be pointed out that systemization of control systems based on GMP (good manufacturing practice) guidelines in the case of drugmakers and other ministerial ordinances has been given priority and made significant headway, while there has been a tendency to defer systemization of stock control and history control that so far have been less subject to ministerial ordinances. But through adroit application of RFID and other IT (information technology) solutions, we should bring down costs while improving efficiency of these latter operations as well. Here, the latest RFID-related developments in the medical and pharmaceutical industries in Japan and other countries are first reviewed, then recent Hitachi Group RFID initiatives addressing these needs are described (see Fig. 1).




RFID: radio-frequency identification

*Fig. 1—Roles of RFID in the Medical and Pharmaceutical Industries.*
*Traceability systems for capturing drug sales data as well as systems to reduce tedious tasks and human errors work more effectively using RFID.*

## ISSUES FACING THE MEDICAL AND PHARMACEUTICAL INDUSTRIES

The WHO (World Health Organization) has estimated that the proportion of counterfeit drugs on the world market has risen to 10%, and sales of bogus drugs are close to US$40 billion in 2006 alone. Counterfeit drugs frequently contain unsanitary or contaminated ingredients, and there is a high risk of contracting a contagious disease or suffering some kind of adverse side effect from fake drugs. And even if the counterfeits simply do not contain any efficacious medicine, patients' lives are at stake and this represents a grave social concern.

### Situations in the US

In the US, there is a large number of secondary distributors between the big three pharmaceutical distributors controlling 90% of the drug market and healthcare institutions, so the distribution system is complicated with multiple distribution routes, thus making it relatively easy for counterfeit pharmaceuticals to slip into the supply chain. In 1999 the FDA (Food and Drug Administration) announced that secondary distributors would be required to create and maintain records including addresses and the lot number of all drugs purchased (Pedigree). The FDA initially suspended enforcement of the pedigree requirements because of the enormous backlog of documentation in paper form and merely recommended that wholesalers voluntarily adopt drug tracking, but finally made the requirements mandatory on December 1, 2006 as the number of counterfeit drug incidents continued to increase. According to FDA figures, there were about 10 incidents of bogus drugs a year up to the year 2000, but this has more than doubled to an average of 20 incidents a year since 2001.

### Situations in Japan

The situation in Japan is quite different from that of the US, with virtually no traffic in counterfeit drugs. Concerned about drug traceability, Japan's revised Pharmaceutical Affairs Law that was partially adopted in 2003 clearly defines record-keeping obligations for dealing with biological products: the authorization holder is required by the law to record and maintain the source, the product name, lot number, and other information about the product, distributors are required to provide the authorization holders with detailed records about who they sold the biological products to, and healthcare institutions are required to record and maintain records about the patients who are the end recipients of special biological products. The law stipulates that, as of 2007, prescription drugs must be labeled with a product code and barcode at the sales package level. More specifically, biological products must be labeled at the sales package and case levels with product code, expiration date, and manufacturing number; while special biological products must also be labeled at the dispensing package level with barcode product code, expiration date, and manufacturing number.

## RFID APPLICATIONS

### Drug Manufacturers

After announcing the pedigree requirements in 1999, the US FDA advocated item-level RFID tagging of drugs. Because the RFID tag provides a unique identifier that is extremely difficult to counterfeit, the FDA determined that this approach would be very effective for suppressing the manufacture and distribution of bogus drugs. The pharmaceutical companies are not just directly harmed by the loss of sales to the counterfeits; the availability of fake drugs also reflects badly on their corporate images making it appear that they cannot provide drugs that are safe and secure. Pfizer Inc. spent $5 million to implement an RFID system for tracking Viagra*[1]. Moving in a similar direction, Purdue Pharma L. P. began RFID tagging OxyContin*[2], and GlaxoSmithKline plc is conducting an RFID pilot study to tag Trizivir*[3]. Note that all of these drugs are expensive and/or popular, so the availability of counterfeits would have a major adverse effect on patients. So far, Japan's domestic drug makers have not begun to market RFID-tagged prescription drugs, but the pharmaceutical companies with significant sales abroad that are subject to the FDA's pedigree requirements are stepping up research and pilot studies of RFID-based traceability systems.

### Wholesalers

The major US pharmaceutical wholesalers are also pushing ahead with RFID pilots, and plan to link their systems to the traceability systems of the drug manufacturers in the first half of 2007.

In Japan we have seen some applications of RFID to prevent mix-ups in the course of manual picking work at distribution centers. This is implemented in one of two ways: either the RFID tag is bestowed on

*1 Viagra is a registered trademark of Pfizer Inc., USA.
*2 OxyCotin is a registered trademark of Purdue Pharma L.P., USA.
*3 Trizivir is a registered trademark of GlaxoSmithKline plc, UK.

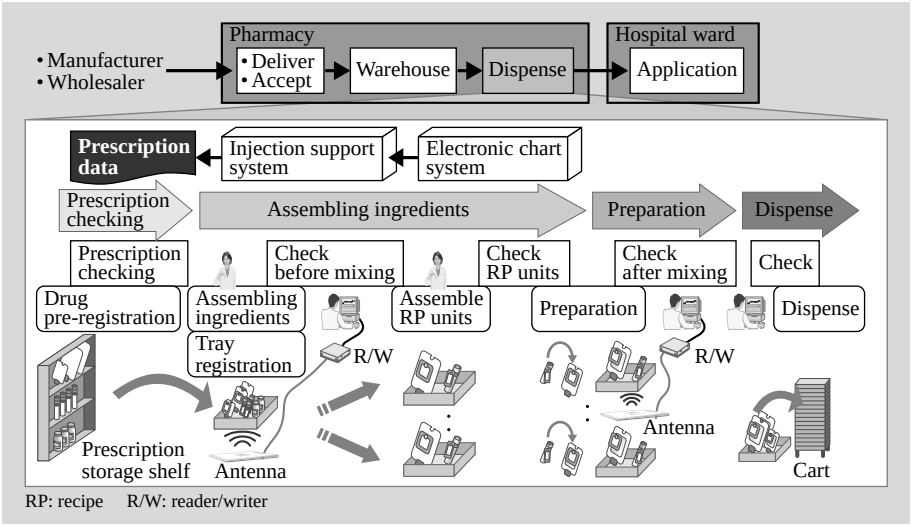



*Fig. 2—Schematic of Pilot Dispensing Support System Sponsored by MEXT (Ministry of Education, Culture, Sports, Science and Technology).*
*Automates checking tasks when mixing anti-cancer drugs and high-calorie infusions in pharmacies.*

the picking worker and work instructions are indicated, or the RFID tag is bestowed on a basket and instructions show which items are to be picked up. In both of these schemes the RFID tag is not attached to the drug itself, but some distribution centers have reported a remarkable 30% reduction in work time based on these methods.

### Healthcare Institutions

Hospitals and pharmacies are now starting to use a variety of RFID-based systems including a system that prevents the dosage of wrong drugs by matching RFID-tagged drugs with the patient's RFID-tagged wristband when drugs are administered to patients and an RFID-based system that assists dispensing of drugs which prevent mistakes in mixing and assembling drugs. Most of these systems here in Japan and worldwide are still in the pilot study phase.

Akita University Hospital has actually implemented such a system that has practically eliminated mistakes by matching the medication to be administered with the RFID tags embedded in the nurse's ID (identification) badge and the patient's RFID-tagged wristband.

A number of RFID-based drug dispensing support systems are now being evaluated in pilot projects sponsored by the METI (Ministry of Economy, Trade and Industry), the MIC (Ministry of Internal Affairs and Communications), and the MEXT (Ministry of Education, Culture, Sports, Science and Technology). The trial conducted by MEXT in 2006 involves automatic RFID checking of assembly, mixing, and dispensing of anti-cancer drugs and high-calorie infusions where a dispensing error could have fatal consequences. The system was found to be highly effective (see Fig. 2).

## PROPOSED RFID SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY

### Drug Tracing System

Drug traceability is becoming increasingly important not only to detect and deter counterfeit drugs but also to track and trace biological products. A drug tracing system provides integrated end-to-end management and control of drugs from the manufacturer and distributor, through intermediate wholesalers, to the healthcare institutions that prescribe drugs, and ultimately to the patients who receive the prescriptions (see Fig. 3).

The ability to identify individual items by barcode or RFID automatic identification tags is required to implement product traceability across different kinds of businesses and companies, but RFID-based tags are generally more effective because they can store substantial amounts of data and they also permit additional data to be added along the distribution route if necessary. RFID tags also vary in size and they are affected by liquid, metal, noise, and other factors, and therefore should be selected to meet the requirements — shape, content, and purpose — of different drugs to be traced.

Integrating individual item identification and the tracing system, Hitachi Group implemented highly efficient and precise history control at drug manufacturers and wholesalers by combining manufacturing and distribution control systems that the company developed earlier. And turning to the healthcare institutions, Hitachi implemented a centralized environment for managing tracing data

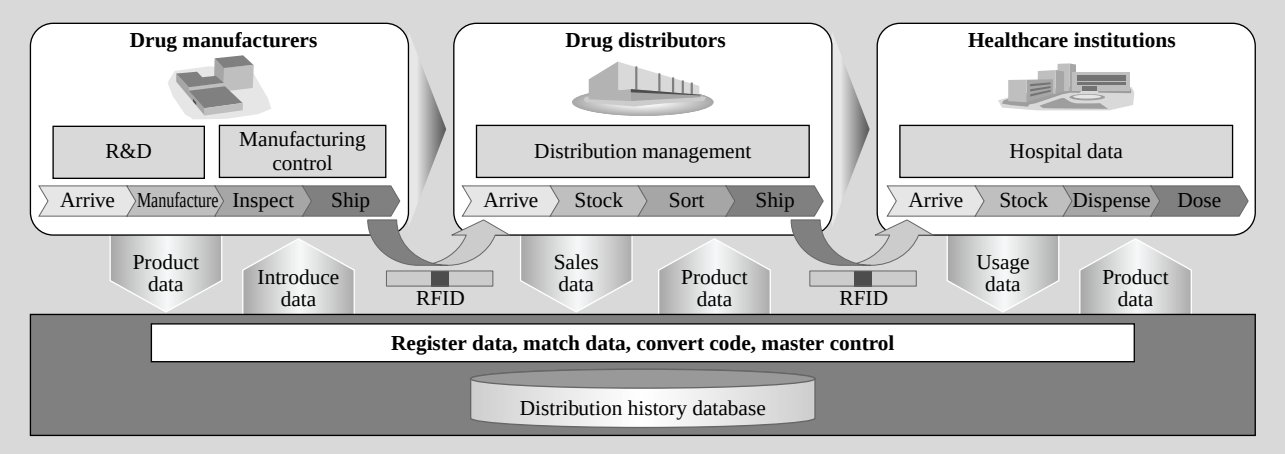



*Fig. 3—Drug Tracing System.*
*A drug tracing system has been implemented by leveraging RFID and other individual item identification technologies in combination with corporate traceability based on conventional solutions.*

right up to administration of medications to patients by upgrading onsite input functions, ensuring careful pre-treatment matching, and entering actual results.

Establishing end-to-end traceability from upstream to downstream will enable collection of medication results data, more accurate estimates of demand for drugs, and also permit the production of drugs tailored to actual usage patterns.

## Proposals for In-house Use of RFID

For in-house use, Hitachi has come up with a number of proposed solutions that fully exploit those advantages of RFID.

### Research and development

The development of new drugs often involves the storage of many specimen tubes and plates containing different compounds for screening in a refrigerator, and it is not uncommon to visually misidentify a plate number because it is obscured by frost when first taking the sample out of the refrigerator. Even when barcodes are attached for ID purposes, samples are sometimes misidentified due to frost. This led us to develop a fail-safe system in which a tiny μ-chip or Coil-on-Chip tag is attached to sample containers or plates, so samples are automatically and positively identified as soon as they are placed on the dispenser (see Fig. 4). RFID technology was also used to develop an effective location management system for pinpointing specific sample compounds in a cabinet that contains a vast number of samples. This will sharply reduce the picking time, eliminate the problem of picking the wrong samples, and significantly alleviate the work load, except for the actual experimental work itself.

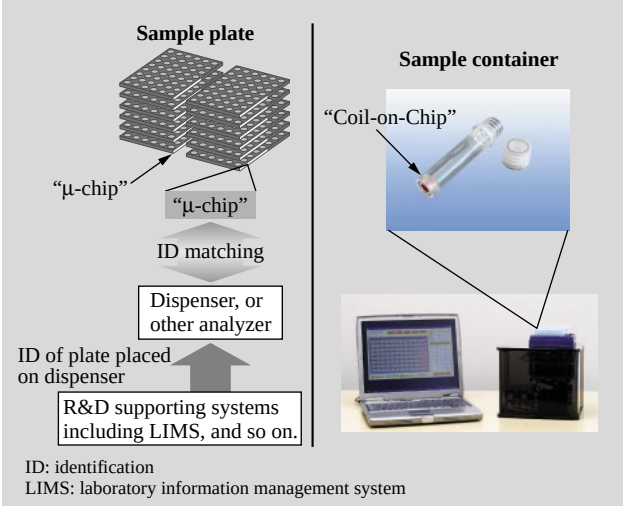



*Fig. 4—Compound Control System.*
*Matching to verify prepared as prescribed when plate is placed on the analyzer (left). Sample container with built-in miniature Coil-on-Chip RFID device made by Maxell Seiki, Ltd. on the bottom (upper right), and reader/writer that complies with The SBS (Society for Biomolecular Screenings) standards (lower right).*

### Distribution departments

In order to comply with new mandatory history control requirements for biological products, the distribution departments of drug manufacturers and distributors have had to quickly implement control and tracking at the lot unit level and are struggling to find ways to lessen the increased administrative and work loads. If the product is palletized or packed in boxes, Hitachi's standards-compliant μ-Chip Hibiki RFID tags that communicate over a fairly long distance can

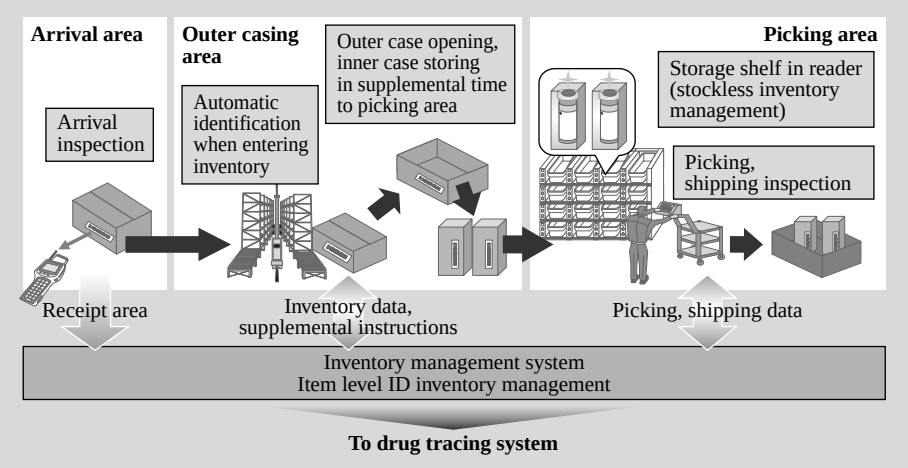



*Fig. 5—Distribution Department Management.*
*Inventory control in lot units is supported while operations work is alleviated using RFID and other automatic identification technologies.*

be used for batch recognition to ensure packing, picking, shipping, and other product requirements are met exactly as specified. Here again, the technology can be used for location management purposes by attaching RFID tags containing the shelf number to shelves in warehouses. And by attaching a read antenna to the shelves, it becomes very easy to verify inventories almost instantly right on the spot, and to take inventories (see Fig. 5).

### Quality assurance

There are some drug products that the quality can only be ensured if the product does not spend longer than a specified length of time under certain temperature conditions during the manufacturing process. The quality of such products can be better ensured, say when drugs are being conveyed from one point to another and cannot be constantly monitored by humans, by using Hitachi's sensor, a kind of active tag (battery-powered RFID tag), to periodically collect and record and transmit temperature, vibration, and other pertinent data. And by mounting the sensors in proximity to the shelves where drug products are stored, it is easy to measure actual conditions and implement more finely tuned temperature control in cold storage warehouses.

## CONCLUSIONS

This paper highlighted the latest RFID-related developments in the pharmaceutical industry and described some of Hitachi's RFID solutions that are tailored for medical and pharmaceutical industry applications. While there are a numerous challenges and it is going to take some time to build an integrated end-to-end tracing system that cuts across different players in the drug industry, the Hitachi Group is making good use of this time to familiarize itself with the potential of RFID technology, to propose a wide range of RFID-based solutions, and contribute to overcoming the challenges faced by both the medical and pharmaceutical industries.

## REFERENCES

(1) FDA Pedigree Requirements in 21 CFR Part 203, Dec. 2006
(2) A. Hotehama et al., "Traceability Solutions for Food, Drug and Medical Instruments," *Hitachi Hyoron*, Vol. **88**, No. 4, pp. 354-357 (Apr. 2006)
(3) Federation of Pharmaceutical Manufacturers' Associations of Japan, "New code display guidelines for prescription drugs," (Nov. 2006)

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