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AIDC is A Sign of Things to Come: Part I

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What is AIDC and How Will it Impact Pharma Manufacturing?

In 1974, a pack of Wrigley's chewing gum became the first retail item to be scanned with a Universal Product Code (UPC). IBM and the retail industry led the development and implementation of the UPC, but the healthcare industry did not embrace standardized bar coding.

And this continued into the 21st century. In 2006, a senior healthcare executive told me that automated identity and data capture (AIDC) in healthcare "would never happen in his lifetime." He is still alive.

Enter the regulators and the legislators. In 2013, two U.S. regulations, the Unique Device Identifier (UDI) regulation and the Drug Supply Chain Security Act (DSCSA), set standards for AIDC in healthcare ***(1,2).*** A major selling point of both regulations was that AIDC would help avoid counterfeiting and facilitate recalls. Since 2013, deadlines for both have been extended. Potential uses and effects of AIDC in healthcare are slowly taking shape and are far broader than the initially stated regulatory objectives due to the growing digitization of the industry.

The AIDC legislation and regulations enabled, and even required for the first time, future widespread use of more informative AIDC in the U.S. healthcare industry. The National Drug Code (NDC), which has been used on drugs and some devices for many years only contains manufacturer and product names in a linear barcode. For years, lot (or batch) and expiry text has been required on manufacturer healthcare labels, but there was no standardized AIDC format for this information. The limitations of and administrative issues related to NDC codes severely restricted product control and cost-saving possibilities.

The 2013 regulations require encoded lot and expiry information and even serialization as well as mandates on entering company and product identifiers into databases accessible to government agencies, such as the U.S. FDA's Global UDI Database (GUDID), and for prescription drugs product transfer reporting requirements.

There is no cost or pricing data in the FDA databases; however, providers and others are leveraging the GUDID and similar databases abroad to build very sophisticated databases. These will prove to be useful in contracting functions.

AIDC: Inevitable Part of Digitization

Retail is far more fully digitized than healthcare. Before UPC barcodes, individual merchants had to place stickers on products. Digitization of healthcare is inevitable, and AIDC is coming to healthcare as part of digitization. As in retail, AIDC marking at source will limit the addition of labels, aka "stickering," elsewhere in the supply chain.

For manufacturers not to make the most of the AIDC technology seems a terrible waste. While I firmly believe that AIDC can enable healthcare services, production and distribution automation, data integration, and cost savings over the long term, the path forward clearly is not simple.

GS1, the issuing agency for the UPC and one of the U.S.- and EU-accredited issuing agencies for UDI and DSCSA symbologies, along with RxTrace, have been good sources for information on DSCSA and UDI as interpretations have evolved.

Greg Bylo, U.S. Vice President, Healthcare, GS1, who is leading the initiative to drive the industry's adoption and usage of GS1 standards, characterizes the issue as follows:

> "Most companies ask themselves [what path to follow] and struggle with determining the correct decision and the value that would result from a serialization effort," says Bylo. "So the question is: 'Do I do nothing; do I use a lot/batch approach; or do I serialize my products?'"

Bylo further points out that each option offers different possibilities with different cost implications. He lists the questions a company should ask for each option:

1. How much **control** of my products in the supply chain should I have?

2. How expensive are my products? Does tracking my products afford me better control of these expensive assets?

3. How much risk can we assume if something goes wrong? With lot/batch I will have one level of risk; with serialization I will have significantly less risk, since I will be able to bound the issue in smaller groups and not an entire batch/lot.

4. How do I want to handle a recall? With lot/batch how many products will be impacted versus serialization controls where a company can bound the recall by serial number.

The choice is ultimately one of risk and cost. At the same time, AIDC presents some challenges that may make manufacturers wary to fully embrace it. These are:

- *Complexity.* The United States has led in healthcare AIDC implementation, but the task has proven far harder than anticipated.

- *Resistance to change.* Healthcare is fragmented. Many competing interests have resisted change. Some may fear transparency.

- *Concerns about data security.* These are valid. The Finance industry had the same concerns about data security as digitization became common. But this industry developed preventive measures just like pharma can.

- *Cost.* The initial costs of implementation are high. Marking products with AIDC symbologies is only the first step; the IT costs are usually far greater. The resulting efficiencies, opportunities and returns on investment will only be realized beyond the short term. Some companies fail to consider potential offsetting benefits. Many vendors and consultants offer services to assist. Good help is not cheap.

- *Lack of clarity.* Regulations are evolving in very uncertain business and political environments. In the United States, some hope for a healthcare regulatory reversal. They hope that value-based purchasing and accountable care will simply go away. This is not likely given the need to resolve out-of-control healthcare costs, economies of scale for large entities and already heavy investments in AIDC.

- *Differences in drug and device regulatory requirements.* In the United States, drugs, biologics and devices are covered by different sets of regulations and FDA centers. There are similarities, but also major differences. Even differences in the language used in drug and device regulations can cause difficulties. Product names and risk classes are not well standardized. Combination products present their own issues. Many companies manufacture both pharma and devices.

Differences in regulatory systems from country to country. Harmonization of requirements is desirable. Marking requirements seem to be moving toward similar endpoints. Products are in different classes in different countries. Risk classifications abroad differ from those in the United States. Full harmonization of data requirements seems impossible. Abroad, the pace of adoption is even more uncertain. Some healthcare trusts in the United Kingdom have begun mandating the adoption of the Pan-European Public Procurement On-Line (PEPPOL). PEPPOL requires AIDC marking and submission of manufacturer, product and cost data. While the implementation timing has been postponed, currently Classes 3 and 2 A&B will have to be in the PEPPOL system by March 31, 2018. Adoption of PEPPOL in healthcare across much of Europe and beyond is predicted. How the differences in UDI implementation dates would be viewed in CE audits is another open question.

Serialization is essential to having granular information to manage products. It allows the manufacturer, a manufacturer's subcontractor, or others to identify a specific product as it moves through the supply chain and to associate that specific product with the user and other factors in near real time.

Certain product changes may not normally occasion a lot or batch number change by a product manufacturer or marketer. Lot or batch numbers are often not sufficient for managing because distributors, as well as drug packaging, software and excipient vendors, might not record or report some potentially meaningful changes. Some examples of these types of changes (which some might consider inconsequential, but may actually be important) could be component processing changes, raw material lot changes or "minor" procedural changes.

Distributors do not record the lot or batch numbers distributed to every customer. Therefore, having only lot or batch numbers can result in unknowns and unnecessarily large recalls. By knowing what specific (serialized) product a specific customer received can validate the appropriateness of a return for credit. Serialization also enables limitation of grey market activities.

It is difficult to know how much to include in such a 40,000-foot overview. I hope this information stimulates thought. In Part II, I discuss serialization challenges and opportunities for combination products.

This article contains opinions and is not regulatory guidance. The author and his clients have interests in the use of AIDC in healthcare.

References

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2. "Are you ready for the Drug Supply Chain Security Act?" U.S. FDA.

About the Author

Napoleon Monroe's expertise includes product development, licensing, regulatory processes, risk management and international marketing, with experience managing business relationships in more than 30 countries.