China

Implementing UDI on medical devices in Shenzhen – benefiting healthcare regulation and delivery.

Challenge

There are increasing efforts to promote and implement the use of UDI for medical devices in China, but the scale involved is challenging. In Shenzhen alone, three separate regulatory departments are involved (Shenzhen Administration for Market Regulation, Shenzhen Health Commission and Healthcare Security Bureau of Shenzhen Municipality). Adding to the complexity in that in Shenzhen city there is a total of 1,549 medical device manufacturers (14,095 medical device SKUs), 75,975 medical device distributors and 5,780 healthcare providers. This means the medical device supervision and traceability chain is long and challenging.

Approach

Shenzhen Administration for Market Regulation has established one data platform for UDI, collected data from two sources (suppliers and healthcare providers), in a project led by three departments. model of "one platform as the foundation, two areas to make efforts and three department collaboration.

Shenzhen's UDI promotion involves multiple departments and numerous entities, creating a complex medical device supervision chain.

Due to the presence of numerous device manufacturers, distributors, and healthcare providers, Shenzhen faces a complex and extensive device supervision chain.

The foundation of Shenzhen Administration for Market Regulation's model is based on one platform.

Introduction

Work has been underway since 2019 to promote and implement the use of the Unique Device Identifier (UDI) in Chinese healthcare. Shenzhen Administration for Market Regulation and Shenzhen Institute of Standards and Technology have fruitfully explored UDI policy, standard, technology and application throughout this period, and work to popularise the implementation of UDI has led to a tipping point. On 14 October 2021, the Shenzhen UDI tracing platform was officially launched. The platform is used to collect the information on the production, circulation, and clinical use of medical devices, using UDI as the main key. Currently, the platform has collected over 72,000 products (UDI-DIs) from more than 300 Shenzhen manufacturers and more than 500,000 pieces of clinical use information from 15 large tertiary hospitals in Shenzhen. The use of UDI is being gradually expanded. Increasing numbers of healthcare providers will participate in pilot projects and more data collection methods are being developed. Ultimately, there will be full life cycle medical device tracking throughout Shenzhen.

Since 2019, the National Medical Products Administration, the National Health Commission and the National Healthcare Security Administration of the People's Republic of China have jointly published several documents aimed at vigorously promoting the implementation of UDI. By 1 June 2022, UDIs were in place for all class III medical devices. From 1 June 2024, 103 varieties of class II medical devices will also be required to use UDIs.

Shenzhen has taken the lead in building a comprehensive medical device traceability system based on standards, industry promotion, enterprise training and platform application. All this work has been in strict accordance with national and provincial and municipal policies and related requirements and has led to marked achievements in UDI promotion and implementation.

Innovation in working model

The working model being used in Shenzhen is "one platform as the foundation, two areas to make efforts, three department collaboration".

The "one platform" is the Shenzhen UDI tracing platform, the first platform in Guangdong province. It provides technical support for accurate and smart supervision.

The "two areas" relates to collecting data from two sources – manufacturers and healthcare providers. In addition, some stakeholders whose data is more advanced have been selected to participate in a pilot, to achieve closed-loop data management.

"Three-department collaboration" describes the three departments jointly involved in the work: Shenzhen Administration for Market Regulation (AMR), Health Commission of Shenzhen Municipality and Healthcare Security Bureau of Shenzhen Municipality. These jointly promote the work to implement UDI across the medical device supply chain.

Figure 1: The launching ceremony for Shenzhen UDI tracing platform on 14 October 2021.

In line with global and national standards

In 2021, Shenzhen AMR issued an UDI implementation guideline based on GS1 standards, which are recognised around the world. Four local standards were released, including DB4403/T 218-2021 Implementation Code for Unique Device Identifier, DB4403/T 219-2021 Design and Application Code for Unique Device Identifier Traceability System, DB4403/T 220-2021 Distribution Rules for Unique Device Identifier Products, and DB4403/T 277-2022 Specification for Unique Device Identifier Data Interface.

Shenzhen Institute of Standards and Technology has provided technical advice and support services throughout including face to face and online training. More than 10 training activities have been held and over 1,000 people have attended the training in past two years. These measures help manufacturers not only meet the compliance requirements both at home and abroad, but also reduce the export risk. Manufacturers can also choose GS1 China's value-added services, to synchronise the UDI data to China UDID through GDSN.

Figure 2: Hybrid UDI training co-hosted by Shenzhen Institute of Standards and Technology and GS1 China.

Figure 3: UDI training for healthcare providers jointly hosted by Shenzhen Administration for Market Regulation, Shenzhen Health Commission and Healthcare security bureau of Shenzhen municipality.

Accurate traceability throughout the whole life cycle

A framework of whole life cycle monitoring platform for medical devices has been established, and UDI has been used to connect the information of each link, from manufacturer to distributor, healthcare provider and eventually to the patients. The chart below shows the tracing chain of medical device in production, circulation and use, and shows the flow of medical device in the whole life cycle dynamically, which helps to empower smart supervision and improve patient safety.

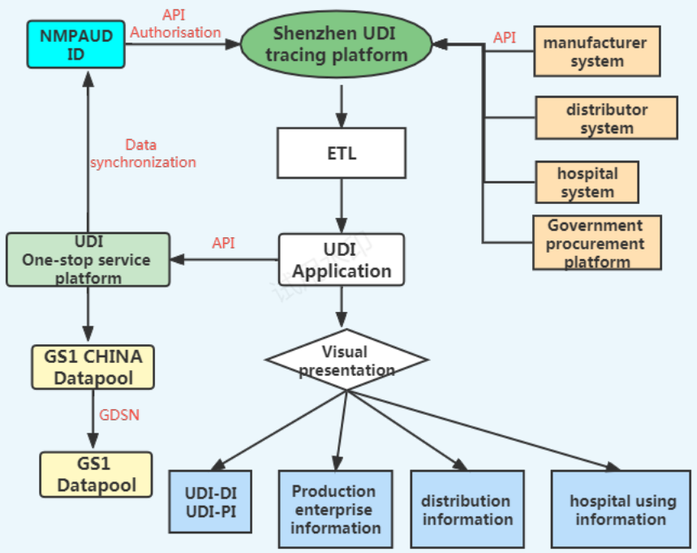

Figure 4: Demonstration of data flow between platforms

Regulators in Shenzhen have also increased the implementation scope and selected some stake-holders with advanced data to participate in a pilot, to explore a production-to-use closed-loop data management.

As of early June 2023, the platform has collect-ed over 72,000 products (UDI-DIs) from more than 300 Shenzhen manufacturers, and more than 500,000 pieces of clinical use information from large Shenzhen tertiary hospitals...

Figure 5: Infographic of the whole life cycle of medical devices

Figure 6: Site investigation at hospital warehouse

Next steps

Shenzhen AMR is actively expanding the data collection methods between the platform and stakeholders. The department will also continue to improve the UDI platform, expanding the implementation scope, increasing the number of healthcare providers in the pilot and enriching data collection methods. It is intended that this will establish the platform as a key means to use UDI in regulation, purchase, use, payment and monitoring of medical devices, and realise data sharing on medical devices. This will include information on regular regulation, purchase flow, clinical application.

Conclusion

In strict accordance with the relevant UDI policies and requirements of the state and provincial governments, Shenzhen regulators have taken the lead in exploring and establishing a traceability system for medical devices. Efforts have been focused on standard development, publicity, implementation and training, promotion and application, and platform construction. The UDI platform can be used to trace medical devices and lower the cost and improve the regulation efficiency; for the health department, it can enhance the management of clinical use and promote the use of big data in healthcare; for the medical insurance department, it can accurately identify medical devices in the government procurement, increase the transparency of payment and combat fraud and abuse.

About the author

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Ms Fan is a director of Medical Device Safety Supervision Division, Shenzhen Administration for Market Regulation. Mainly responsible for drafting and organizing the implementation of specific measures and methods for the management and use of medical devices. To supervise the implementation of medical device management, use quality management standards. To organize and implement supervision and inspection, sampling inspection of medical device management and use, monitoring of medical device adverse events and handling of medical device emergencies.

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Ms Xu is a Director of GS1 China Shenzhen branch, professor level senior engineer. As the project leader, she presided over 15 national and provincial research projects and participated in the formulation of more than 40 national, local or group standards. Familiar with the application of coding technology to solve the information construction in food safety traceability, imported cold chain food traceability, food validity management, medical equipment, e-commerce and other fields.

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Yong Sun has engaged in coding technology research and application promotion, standardization, information construction and other related work, as the main project leader and standard drafter completed a number of provincial and ministerial topics, ISO standards, national standards, industry standards, etc. He is currently a Chinese registered expert on two technical committees of ISO/TC 249 and ISO/TC 215.

About the organisations

Shenzhen Administration for Market Regulation.
To be responsible for comprehensive market supervision, market order supervision and unified registration of market entities, to be responsible for the supervision of agriculture, animal husbandry, food and drug, medical equipment, cosmetics, equipment safety, standardization, intellectual property rights and other fields, and to coordinate the quality construction in Shenzhen.

https://amr.sz.gov.cn/

Shenzhen Institute of Standards and Technology.
Shenzhen Institute of Standards and Technology (SIST) was founded in 1984, directly under the Shenzhen Administration for Market Regulation, is the only professional standardization research, service and application of quasi-public scientific research institutions in Shenzhen, attached to the GS1 China Shenzhen branch and other national technical institution brands.

https://www.sist.org.cn/