Taking an Industry Leadership Position in UDI Adoption

GHX®

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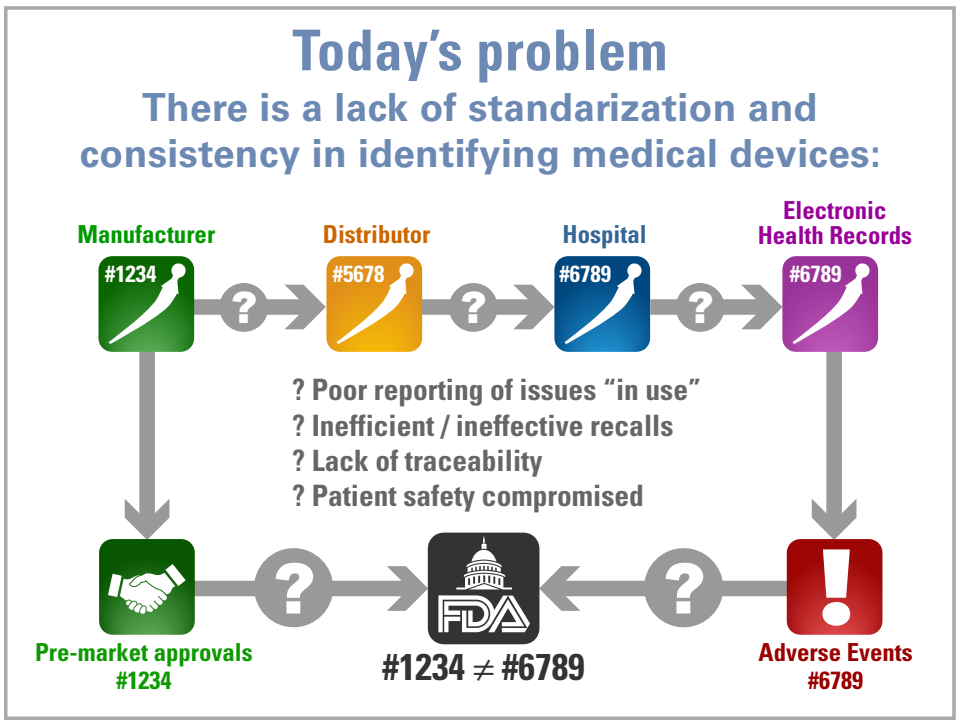
The objective of this document is to help ensure that a medical device company's strategy for UDI adoption will position them for the greatest benefits now and in the future. UDI adoption can benefit the healthcare industry from a much broader perspective if the scope of adoption goes beyond just submitting UDI data to the FDA Global Unique Device Identification Database (GUDID). Medical Device companies have an opportunity to leverage UDI product attribute data from the point of manufacturing to the point of use so that patient outcomes and safety can be improved while reducing operating costs throughout the supply chain. There is substantial value to be realized if the scope of UDI adoption is taken far beyond just meeting the FDA mandate. The scope of a comprehensive UDI adoption strategy has regulatory, data sharing, and process implications. Taking the time to understand what is required now and what will be required in the future is an important first step as you define your approach to UDI adoption.

At GHX, we advocate that medical device manufacturers broaden their strategy for UDI adoption beyond the submission of UDI data attributes to the FDA GUDID. Doing UDI 'right' is critical to avoid frustrating rework. We have developed our technical solution and consultative services approach based on a mindset of getting the most value from UDI adoption by ensuring all trading partners can leverage UDI data across clinical and supply chain processes. We help manufacturers disseminate their UDI product attribute data from a regulatory and commercial perspective by leveraging our best-of-breed UDI submission solution which publishes UDI data to the FDA GUDID and also to a GDSN-certified data pool, Health Connexion. Sharing UDI data attributes with providers via a GDSN-certified data pool should be viewed as a critical component of a manufacturers UDI strategy so that the UDI product data can be captured on a patient's electronic health record.

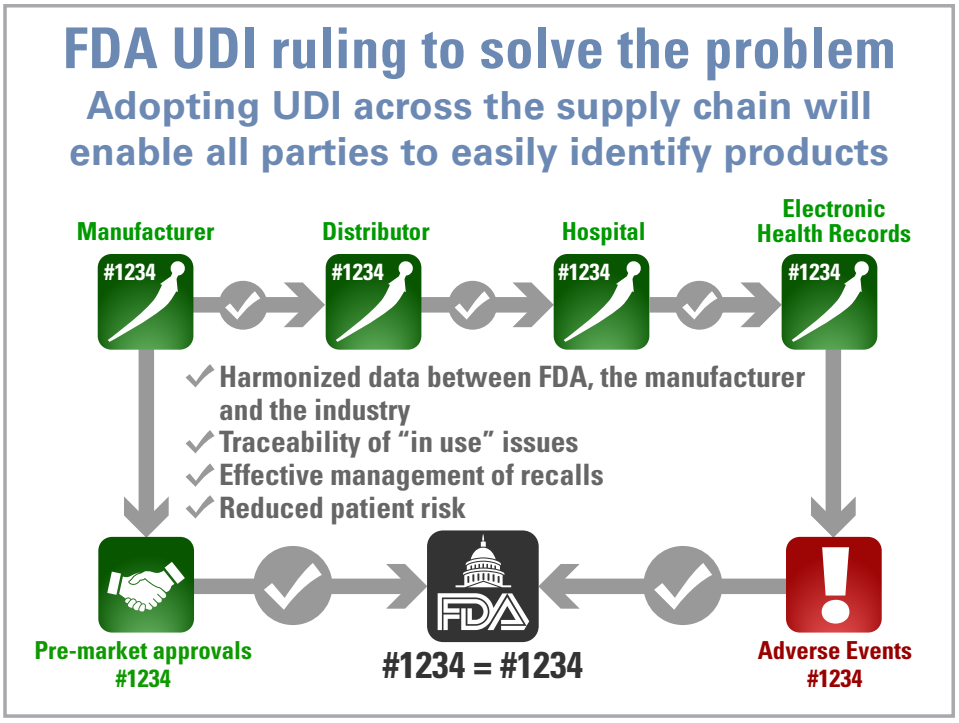


Why is UDI important?

Today, there is a lack of standardization and consistency in identifying medical devices. This inconsistency makes it impossible to track what products are being used where, which results in poor reporting of issues, ineffective recalls, and patient safety concerns.

The FDA UDI regulation requires medical device manufacturers to label their devices so that the UDI is available at the point of use and it also requires the manufacturer to load the UDI and data attributes to the FDA GUDID. The objective of

the legislation is to enable consistency across all trading partners in the supply chain and most importantly at the point of use. **Let's drill down into specifically what is required from a regulatory, data sharing, and process perspective.**



Regulatory perspective

UDI compliance requires the creation of an entirely new quality management system. This is not a once and done project. This is a new quality system that you need to maintain on an ongoing basis. In the final guidance document from the FDA it states that 21 CFR part 11 compliance is a requirement. Basically any system that is utilized to store the data, manage changes to the data, and manage the submissions of the data to the FDA – should comply with 21 CFR part 11. All systems that support manufacturing, labeling, quality processes etc. need to be validated. UDI submission is another regulated process that needs to be managed with the same scrutiny as a manufacturing or labeling system. There needs to be an audit trail for changes, access to human readable records, system security, training of processes and most importantly, change management procedures.

Just like your manufacturing processes you need to ensure that any changes to data are managed through a reliable process and there is appropriate documentation. An FDA inspector will audit your UDI submission solution just as they would audit your manufacturing systems and processes. The audit will include an audit of your change management processes and training records. You need to put into place the appropriate SOPs and train teammates to manage the data in a sustainable way. The audit will also include managing change control of system changes in test and production environments. Finally as you define your scope and approach to manage your data submissions to the FDA, make sure you have an audit trail of your changes and acknowledgements in an archive in the original submission format and human readable format.

Data sharing perspective

We believe that you need to have a broad vision as you define and implement your UDI submission solution. That vision needs to take into account the management and dissemination of both your commercial and regulatory product data from a global perspective. From a data sharing perspective, we have seen several GPOs and hospitals send requests to manufacturers to submit their UDI data attributes to them via a GDSN-certified data pool. This is quickly becoming the preferred mechanism to share product attribute data with trading partners and adoption is growing significantly. Global regulatory agencies around the world are also actively working to define their requirements for UDI. We anticipate that there may be some similarities to the FDA—but at a minimum there will be different attributes to account for different languages. The specific communication protocols also have not yet been defined. You should define your approach broadly to include dissemination of all commercial and regulatory product attribute data.

When you define your approach for an industry UDI solution, take a step back to ensure you are solving for all of your needs to disseminate product attribute data. You will need much more than an FDA submission solution. Your UDI solution will need to manage submissions to the FDA, future global regulatory bodies, and GDSN-data pool

trading partners. As an example, at GHX, we have created a single pipe solution where a manufacturer populates a 'superspec' of product attributes that are then parsed out within our UDI solution to trading partners and regulatory agencies, as needed.

Process perspective

In the future, UDI data will be able to be used to improve adverse event reporting, track and trace, recall management, post market approvals, and surveillance while also improving order to cash processes. Getting your UDI in the FDA GUDID is just step one. You also need to include your UDI in your systems used to track product technical complaints and adverse events. Having a vision for how your company will utilize UDI to improve your business processes is important as you define your project scope and approach. As an example, if you plan to use UDI to improve your order to cash processes you need to think about where UDI needs to be included in your ERP system and your end-to-end supply chain processes.

Why take an industry leadership position in UDI adoption?

Since 2000, GHX has continuously collaborated with healthcare business partners, standards bodies and regulatory agencies, to promote the adoption and generation of value from the use of global data standards in healthcare. We have seen a lot and we have learned a lot as the level of adoption has begun to take off across all players in the healthcare industry. We believe the manufacturers, distributors, providers, and payors that are taking a leadership position in their adoption of UDI are best positioned to maximize their value longer term. Those that approach UDI adoption as more than just an FDA mandate and use the project as an opportunity to leverage UDI data to realize internal and external process benefits could create a unique and sustainable competitive advantage for themselves and their customers.

The proven path for global UDI database submission

Creating, transmitting, and tracking your GUDID submission data to meet the FDA's new UDI rule—that's your immediate need, and GHX can get you there. Our UDI Submission solution not only meets the FDA's requirements but also the future requirements of global regulatory bodies and your commercial trading partners. Our solution allows you to submit your data through a single pipe that drives all your UDI data attributes to regulators, healthcare providers, distributors, and group purchasing organizations (GPOs) directly or via a GDSN-certified data pool. For more information, contact us below.

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