Top 10 UDI Submission Pitfalls

GHX®

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The FDA's UDI rule passed in September 2013 aims to considerably reduce the instances of patient injury and death that result from the misidentification of medical devices. The UDI rule requires healthcare manufacturers to label covered products with a unique device identification code and provide additional information about their products to a UDI database. The first UDI compliance deadline for high-risk Class III devices was September 24, 2014.

Based on lessons learned through its work with regulatory agencies, standards organizations, and medical device manufacturers, and its success submitting medical device data to the FDA's Global UDI Database (GUDID), GHX has developed this guide for preparing and publishing data to the GUDID.

Approximately 10 percent of products fall under the first deadline for Class III products, while the remaining 90 percent of medical devices sold in the U.S. have yet to be impacted by the regulation. **As outlined in the US UDI Regulatory timeline below, this September, all implantables, as well as products determined to be life-saving and life-sustaining devices must be in compliance, with all remaining Class II devices the following year. Class I devices must comply by September 2018.**

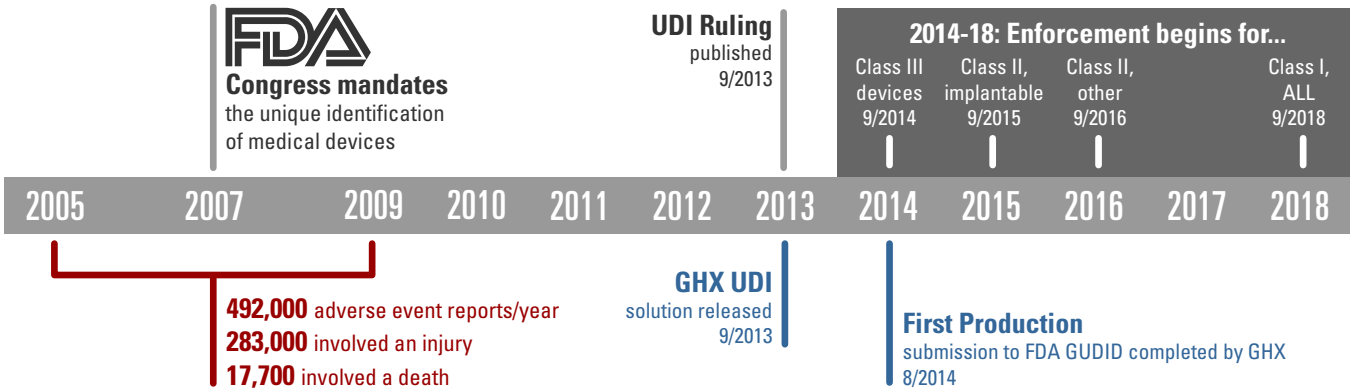
Lessons Learned and Mistakes to Avoid When Submitting to the FDA GUDID

1. Thinking it's easy: Many manufacturers believe the labeling requirements for UDI are the greatest challenge and product data submission to the GUDID is the easy part. The reality is that GUDID submission is much more complex than many originally thought. In most companies, data is spread across multiple departments and stored in dispersed locations with varying degrees of availability so the process of locating and compiling data can be especially challenging.

Additionally, the format required for GUDID data submission is not intuitive, and FDA acknowledgements indicating if a submission has been successful, can be difficult to decipher. Furthermore, systems and processes used to submit data to the GUDID must be validated to comply with the following: Part 11 of Title 21 of the FDA Code of Federal Regulations, Electronic Records, Electronic Signatures (21 CFR Part 11), as well as Parts 820 and 830. UDI compliance is not a simple matter of gathering and submitting data. It requires a well-thought-out process validation strategy.

2. Waiting to start: Because Class III and Class II life sustaining manufacturers are first required to comply with the FDA's UDI rule, some manufacturers of products in other classes have chosen to take a "wait and see" approach.

US UDI Regulatory Timeline



FDA UDI Regulations require:

- Supplier to uniquely identify their devices
- Label the device according to the UDI regulation
- Load Unique Modifier and associated attributes to the FDA database (GUDID)

The problem is that UDI preparedness takes a lot longer than most realize. During UDI readiness engagements, the GHX consulting team has found it takes manufacturers an average of nine months to prepare product data for submission to the GUDID, with some global manufacturers spending years on their UDI implementations. Additionally, major U.S. health systems are setting their own deadlines for receiving standardized product data from their suppliers, some requiring manufacturers to supply product attribute data via a Global Data Synchronization Network (GDSN) certified data pool in late 2014 and early 2015. With thousands of manufacturers required to comply with the FDA UDI rule through 2018 and increasing demands from healthcare provider organizations for standardized product data, it's in a manufacturer's best interest to begin their UDI preparedness efforts now.

3. Not fully understanding the full scope of UDI product attributes: A critical step to success is to verify the superset of data attributes required by the FDA and your commercial community, and the workflow and process requirements that will be needed at your company to source, maintain, and publish product attribute data to your recipients.

Manufacturers that have enumerated their products with GS1 Global Trade Item Numbers (GTINs) and are sharing this data with customers and business partners through a GDSN-certified data pool may believe they can submit the same data in the same format to the FDA's GUDID. The reality is that GDSN and GUDID data submissions are not the same. There are subtle differences in the required data attributes, how they are formatted, and the processes for submission. Manufacturers need to understand the specific data attributes that the FDA requires and the format in which the data needs to be stored for submission to the FDA. As an example, the FDA GUDID requires two latex questions:

- Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)
- Device labeled as "Not made with natural rubber latex"

Your submission to the FDA requires these two attributes be submitted. Knowing this is a requirement upfront will allow you to set up your data repository appropriately and avoid missing data elements or incomplete submission records. To meet all of your recipient's needs, ideally you should establish a single pipe solution where all product attributes that are needed can be parsed out within your UDI solution to trading partners and regulatory agencies as needed.

4. Submitting data before it is verified: This may seem obvious, but GUDID submissions need to be approached with the mindset that you will submit data only when you know it's perfect. Don't rush to submit before you're ready. Once the data is ready, we recommend you verify your data prior to FDA submissions. The GHX solution has a submission simulator, based upon errors that have been sent back from the FDA. As an example, the FDA requires that the product attribute for sterilization method be included for all disposable Class III products. The submission simulator validates that the appropriate data attributes are populated based on product classification type. Our solution allows the user to see where the FDA may have issues with the data before submitting to the test and production FDA environments. This saves time and effort because the FDA may take several days to review and return failed submissions. The simulator allows the user to immediately see which data attributes could fail so they can be addressed ahead of time.

For example, submissions have been rejected for the following issues:

- PMA Number not 7 digits
- Labeler DUNS not 9 digits
- "Kit Product" is a required field. It must be marked either "yes" or "no"
- Device Identifier Publish Date is a Required Field
- Contact Phone Numbers must follow prescribed format
- Improper GMDN Term Code
- Non Matching DUNS numbers (DUNS number xxx is not a valid submitter for DUNS number yyy)
- FDA Listing and Supplement Numbers incorrect
- GMDN and FDA Preferred Term Codes don't align

5. Inability to handle data attribute volatility: The FDA has changed attribute requirements twice and is expected to continue to do so. Be prepared to manage changes from the FDA and global regulatory agencies, while maintaining the system in a validated state. Given the volatility of the requirements, you need to ensure your technical solution will be able to be maintained in compliance now and in the future.

6. Inability to support global UDI requirements: As they look towards FDA compliance, many medical device manufacturers have not considered the global regulatory requirements that will be mandatory in the near term. Several regions and countries are moving forward with UDI-like requirements including the European Union, Korea, Japan, Canada, China, Brazil, and Argentina. Your UDI solution architecture should be set up to support future global regulatory requirements. The database needs to be structured around managing multiple submissions, verifying data prior to submissions, and tracking multiple unique country requirements.

7. Inability to decipher errors on acknowledgements: Once your data is prepared and ready, it's time to submit to the FDA test environment. Once the FDA 'approves' your data, it can be submitted to the production GUDID. If your data is prepared properly and you are truly ready, these last two steps will be simple. Be prepared to receive and decipher the acknowledgement messages from the FDA. The key here is understanding what needs to be done to correct the errors as you receive the FDA acknowledgements. Below is an example of an FDA failed acknowledgement containing an embedded error message stating the approved product labeling indicates the product contains rubber latex; however, the submission to the FDA did not flag this appropriately on the submission.

8. No plan to archive data: Archiving submissions and acknowledgement receipt is the final critical component of any GUDID solution. Each submission transmitted to the FDA is individually tracked and all acknowledgements are captured and associated back with the submission data. The submission data, the human readable representation of the submission, and the acknowledgements need to be archived so that they become the revision controlled UDI regulatory record for that product.

9. Taking a piecemeal approach: With industry attention on the FDA's long-awaited UDI rule, some manufacturers are choosing to focus their time, resources, and efforts solely on how they can draw the necessary data out of their systems for a one-time submission to the FDA's GUDID. What many fail to realize is that the UDI rule is just one of many emerging global regulatory and industry demands for standardized product data. The FDA envisions broad applications for UDI and is planning to use it to improve the visibility and identification of medical devices across the Center for Devices and Radiological Health (CDRH). This is just the beginning, UDI will soon become *the* way the FDA and other global regulatory

FDA failed acknowledgement

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bodies identify devices. In our work with medical device manufacturers in preparing for GUDID data submissions, GHX has found those that implement more holistic, sustainable master data management strategies—designed to not only meet their current needs but also to address future requirements—get the most out of their UDI investments in terms of greater operational efficiency and lower costs.

10. Thinking that a one-time technology implementation is all that needs to be done: Some suppliers subscribe to a data pool or UDI solution expecting that the technology will solve the issue; but that is only part of the challenge. Through years of experience GHX knows that data pool and UDI technology solutions are vital to success, but the strategies surrounding their implementation are equally, if not more important. Adopting a new technology is arguably the easiest part of UDI implementation. The real challenge lies in being able to effectively and efficiently manage the data attributes, inter-company connectivity, and sustainable processes that generate the subject matter being submitted to a data pool or the FDA GUDID. The longest duration of time will be establishing the related processes, data identification management, and implementation strategy that will be used to optimize the data pool/UDI technology. Manufacturers that will be most successful in their UDI implementations are those that view GUDID submissions as a new business process. This includes change management processes for managing the status of submissions, maintaining an archive with a complete audit trail, and maintaining the accuracy of their data end-to-end over time.

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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