FDA Unique Device Identification (UDI) System
Readiness and Beyond
UDI: Global Scope

In 2007, the US Congress passed legislation directing the Food and Drug Administration (FDA) to develop regulations establishing a unique device identification (UDI) system for medical devices. **On September 24, 2013 the final FDA rule took effect in the US.** Comparable legislation that is expected from other areas of the world will set up the potential for a global system for UDI.

A globally consistent system to track medical devices will benefit public safety by reducing medical errors and improving post-market surveillance of devices, enabling manufacturers and regulators to identify product and safety issues more quickly and precisely. The system should also ease the complexity of international product registrations and eventually provide a foundation for a global, secure distribution chain, helping to reduce counterfeiting and creating supply chain efficiencies for manufacturers, distributors and end users.
Requirements and Expected Timeline

In the US, implementation will follow a risk-based approach over several years with the highest risk devices taking effect one year after the final ruling is finalized. Lower risk devices will be distributed over the subsequent years. A compliant UDI program needs to address three areas: **Label & Packaging, Direct Marking (DM) and a UDI Database.**

**FDA Compliance Timeline**

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<tr>
<th>Year</th>
<th>Class III</th>
<th>Class I-II*</th>
<th>Class II remainder</th>
<th>Class I remainder</th>
<th>Class II</th>
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*Implantables and Life-sustaining / Life-supporting
**Multi-use devices that are intended to be reprocessed before each use
Think You’re Ready?  
Key Considerations

Complying with UDI requires your organization to fully understand the nuances of the FDA regulations and how they will impact your organization. As you prepare to define your organization’s approach to implementing UDI, key factors and questions to consider include:

1. **Our Regulatory Affairs, Research & Development and Supply Chain functions are all impacted.**
   - Who will champion this in our organization?
   - Where will the budget to implement be allocated?
   - How do we use UDI to drive added benefit across our enterprise?

2. **Barcoding and labeling are not standardized across our manufacturing facilities.**
   - Which barcoding standards are best for our needs?
   - Without common labeling systems, how do we efficiently move to a common label format?
   - What is the impact to our operations (e.g. Manufacturing, Warehousing and Logistics)?

3. **Our products are highly engineered.**
   - Does directly marking multi-use products add complexity to my design inputs and development plans?
   - Will it complicate manufacturing and execution systems?
   - What will be the impact on time to market?

4. **Our data and information is dispersed across many diverse “systems” including desktops, file shares and enterprise-wide systems.**
   - What data are really required to satisfy the requirements?
   - Can we locate it and is it in an electronic data format?
   - Is it complete and accurate?

5. **FDA’s UDI requirements will likely evolve; international regulatory bodies will create their own requirements**
   - How will we keep track of changing requirements?
   - How will we interact with regulatory agencies to understand the evolving requirements?
   - How can we build our systems to flexibly accommodate future requirements?

6. **Our UDI plans are not developed.**
   - How long will it take to scope, plan and implement?
   - Can we be ready in time?
   - What is our contingency plan?
Evaluate Your Readiness Level

UDI compliance begins with a comprehensive assessment of your organization’s readiness across **four key areas:**

- **Organizational Awareness and Alignment**
  - Assess organizational awareness of the UDI ruling and preparedness for implementation requirements
  - Align on goals and expectations

- **Product Portfolio Impact Assessment**
  - Identify the profile of current product offerings across global channels
  - Assess timing and volume of products impacted by labeling, packaging, DM and database reporting

- **Operations Impact Assessment**
  - Align on Device Identifier and Barcoding standards and strategies to implement consistently across enterprise
  - Assess DM impact and technology options, and products exempted from DM requirements
  - Identify current data and application architecture and the sources for required UDI database elements

- **Implementation Planning**
  - Assess completeness and identify gaps
  - Develop a high-level roadmap for UDI implementation, including threads and activities for processes, technology, organizational change and program management
Develop Your Plan

The UDI changes are new, so leading practices are just emerging. Companies should focus on assessing their individual situations and defining a plan based on exposure and risk tolerance. Your plan of action depends on your company’s situation and should be tailored to address gaps in your own level of readiness. Plotting your readiness assessment across the various impact categories (as illustrated below) helps companies understand and develop a personalized plan.

## Impact Categories

<table>
<thead>
<tr>
<th>Readiness Level</th>
<th>Organization Awareness</th>
<th>Portfolio</th>
<th>Labeling</th>
<th>DM</th>
<th>Data &amp; Applications</th>
<th>Implementation Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Senior management team aligned on mandate</td>
<td>Majority of products Class II or exempt</td>
<td>GS1 or equivalent standards implemented</td>
<td>Majority of products single use or implants</td>
<td>Well integrated master data strategy with good data integrity</td>
<td>UDI program formed and funded</td>
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<tr>
<td>Medium</td>
<td>Cross functional engagement across organizational units</td>
<td>Broad mix of products</td>
<td>GS1 or equivalent program in progress</td>
<td>Limited products are multi-use devices</td>
<td>PLM, Labeling and Regulatory Systems available</td>
<td>Segmented efforts proceeding</td>
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<tr>
<td>Low</td>
<td>Siloed efforts focused on limited functions</td>
<td>High volume of Class III Products</td>
<td>Standards not consistently defined</td>
<td>Majority of products subject to direct marking</td>
<td>Limited systems, dependent on disparate sources and personal stores</td>
<td>Preliminary Scoping</td>
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Deliver More than Compliance with your UDI Program

Medical device manufacturers are smart to focus first on UDI compliance: put in place the systems, processes and governance to ensure you achieve compliance with the new UDI regulations prior to pursuing other strategic benefits. Continued market access for your products is at stake.

But companies that look over the horizon will understand that UDI can be an enabler for many benefits beyond compliance. These benefits could include:

- **Improved Patient Safety**: More accurate and timely responses to adverse events; Reduced medical errors; Improved post-market surveillance; Improved responsiveness to medical recalls

- **More Secure and Efficient Supply Chain**: Fewer errors in order management and fulfillment; Reduced counterfeiting; Improved inventory control

- **Improved Internal Efficiencies**: Streamlined labeling operations; Simplified product numbering schemas and manufacturing execution; Tighter integration between other business systems

- **Accelerated International Access**: Improved product registration process; Increased visibility into global product configurations

- **Better Responsiveness to Customer Requirements**: Global product classification; Certified data pools and Synchronization of accurate data

The trick will be to implement your compliant UDI system with enough ‘hooks’ to enable these future downstream benefits – without allowing the program to get sidetracked by building the initial system to be everything for everyone.
UDI is now a mandate, but it is also an opportunity to innovate with your business and operations. Kalypso is focused on helping our medical device clients realize optimal product development performance and sustain real, lasting results. Our team has the industry expertise and UDI experience necessary to help your organization navigate this complex ruling and position you for the future and beyond.

Are you ready for UDI?
Do you feel Intrigued? Uncertain? Panicked? …then get in touch.

For more information on how to assess your organization’s readiness for UDI contact:

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