

Medical Device UDI/Data Standards Adoption Network

Group Charter

January, 2010

Current State

(This is based on the UDI Conference held the week of October 20, 2009 in Orlando)

Regulation Status – This is a GLOBAL issue

- The US UDI Regulation is not yet finalized, and no date for formal release of the regulation was provided. We were told it would be “soon,” and some speculate the proposed rule could be made public as early as Q1 2010. The hold-up is working through the numerous unique situations that exist in trying to assign unique identifiers to EVERY medical device. Examples of specific standards that are expected to qualify are GS1 (the GTIN – Global Trade Identification Number), HIBCC and NDC. A significant amount of work is also being done to get agreement on the “attributes,” or specific data, that will also be required along with the actual identifier.
- Regardless of the current state of the rules, it will in fact become a regulation. This will not die during the process as has happened with some similar initiatives in the past. You should assume that you will be required to put a unique identifier on all your products and that you will need to provide all the required attributes.
- There is also an initiative called the Global Harmonization Task Force (GHTF) that is working to drive global standards. The objective is to help ensure that what is required by the FDA meets the requirements of other countries, and vice versa.
- The US regulation will state that companies can choose which standard they will use. Around the world, most regulators are not letting manufacturers and providers choose. Most countries are requiring use of a single standard. To the best of my knowledge, nearly every country that had made or is in the process of making a decision is choosing the GS1 standard. In addition, every manufacturer that I have spoken to is moving or planning to move to the GS1 standard. Some companies have previously implemented HIBCC, and they are in the process of determining when they will convert to GS1. GS1 IS BECOMING THE GLOBAL DATA STANDARD.
- There are a handful of manufacturers that have been driving working to establish global standards through their active involvement in GS1 Global for several years. They include Abbott, Alcon, B Braun, Baxter, Becton Dickinson, Covidien, Medtronic and J&J (I’m sure there are some I have forgotten). While much of the work has already been done, there are still opportunities to get involved.

Adoption Status

- Do not assume that the class of your device will drive when adoption will be required. Also, do not assume that because you sell physician preference items that you will be able to avoid the requirements. Adoption timing is being driven by:

Medical Device UDI/Data Standards Adoption Network

Group Charter

January, 2010

- GPOs and leading Providers - See the memos that have been issued to date by Premier, Novation, Amerinet and major providers such as Sisters of Mercy ROI and Intermountain Healthcare that are beginning to provide sunrise dates by which they will require GS1 standards for product and location identification be used in their contracts. While these initiatives do not specifically mention UDI, their approach is consistent with the information currently published by the FDA regarding UDI.
- Governments and Providers outside the US
- Do not avoid moving toward adoption because “providers will not use it” or the information is too difficult to gather. This will be an unacceptable response in the eyes of the regulators around the world.
- If you are not familiar with the US Hospital GPO “Sunrise Dates,” you need to get up to speed. This is the current thinking relative to implementation dates.

Level of Effort

- Based on my observations from the Conference and discussions that I have had with specific organizations, a majority of companies are just beginning to focus on this effort. It is not yet a corporate priority. And there is, in general, a TOTAL LACK OF UNDERSTANDING OF THE LEVEL OF EFFORT REQUIRED to implement these standards.
- THIS IS NOT JUST A REGULATORY ISSUE. IT IS AN ENTERPRISE-WIDE ISSUE. You will be impacting your product identification, product data management, production data, customer data management, product labeling, tracking, contracts, invoicing, information systems, etc... A “SLAP & SHIP” solution will not suffice.
- I do not have the exact statistics, but I would estimate that at least 75% of the conference attendees were either Regulatory/QA or IT. Operations and Supply Chain were not well represented. While Regulatory may help make this a corporate priority, THE MAJORITY OF WORK REQUIRED TO IMPLEMENT WILL FALL ON OPERATIONS/SUPPLY CHAIN.
- Because no one has “done it all” yet, there is nowhere to go to get the “playbook” to guide implementation. It reminds me of the early days of SAP/ERP.

Outcome from our hosted Workshop following the Conference

- We had around 50 attendees representing roughly 25 companies, in some cases with representatives from multiple divisions with companies. Roughly half of the attendees came from Medical Device Supply Chain Council member companies.
- Our focus was exclusively on UDI Adoption. We did not get involved in standards definition, or other initiatives such as GLN implementation. For purposes of the meeting, we focused on GS1 standards.
- We provided an opportunity for people to hear from “thought leaders” who have been involved in the process for an extended period of time and to learn for their experiences.

Medical Device UDI/Data Standards Adoption Network

Group Charter

January, 2010

- Attendees were generally mid- to lower- level employees and managers who have been given responsibility for this initiative.
- The following are my conclusions from our Workshop:
 - The attendees found the meeting VERY beneficial. The attendees saw great benefit to talking to thought leaders and industry “peers” who are in similar roles. They now know much more about what they are getting into than they did before the Conference and our meeting.
 - In general, there was a lack of understanding of the regulation, the status of the regulation, the global reach of the standards, the tools that are available to facilitate adoption, the scope of the initiative and level of effort required. This is not a one person job.
 - While most attendees say their organizations have made the commitment to UDI compliance, most are preparing for or just getting started.
 - There is a lot of frustration with the lack of granularity of the Regulation and data requirements at this point. While it is natural to want to wait for the final rules to be issued, the cost of implementation will likely be higher if you do not begin to your assessment and mobilization processes. There is a desire to avoid false starts (based on past experiences) and rework based on changing requirements.
 - Very few (if any) organizations have an overall implementation plan.
 - Attendees acknowledge that it is difficult, if not impossible to find all the available information (e.g., the data for the attributes) within their own systems and to stay up to speed on the changing global landscape. There was a general lack of awareness of what information and tools are available to facilitate adoption and implementation.
 - Everyone wanted to continue this group and, in fact, grow it. The more companies we have involved, the better chance we have of driving global adoption.
 - Involvement will NOT be limited to our Council member companies. We will need to find a way for non-members to help fund this effort. We do not anticipate any additional expense for our Council members beyond individual travel and lodging for future meetings.

Medical Device UDI/Data Standards Adoption Network

Group Charter

January, 2010

The Charter

Group Mission – “The UDI/Standards Adoption Network”

Our mission will be focused on increasing adoption of data standards across the global universe of medical device manufacturers. This includes the ability to articulate, identify and capture the business value from adoption.

- We will focus exclusively on Manufacturer adoption. We understand what is being done with Healthcare Providers, GPO’s, Distributors and other relevant organizations. We will NOT focus on driving adoption by these other supply chain participants
- We **WILL NOT** get involved in setting standards - we leave this to GS1 and other standards bodies. We **DO NOT** want to replicate the activities of other groups or recreate materials - reuse and leverage of existing intellectual property is key.
- We will integrate with other relevant associations and service providers as much as possible to leverage learnings and work done by these groups.

We believe our focus should be on the following areas:

- Provide a forum for individuals from Medical Device Manufacturers who have responsibility for this initiative to stay up to date on the current state of GLOBAL standards.
- Document the “case for change” based on global regulatory and customer requirements, and working to identify the business benefit for Device Manufacturers (e.g., improved and streamlined business processes, easier management of recalls, supporting attainment of “perfect orders,” etc.)
- Communication to the broadest audience possible. The adoption message must be communicated to as many global Manufacturers as possible.
- Provide easier access to the information and tools available to facilitate adoption and implementation.

Participation

Participation in this group will be open to all Medical Device manufacturers and selected third parties. This will not be a sales forum for third parties, so their participation will be limited and controlled. This effort will be driven by the industry and supported by third parties based on industry needs.

We will use some of the existing thought leaders as an “Editorial Board.” This group will provide guidance regarding the collection and dissemination of information. The proposed members include:

Medical Device UDI/Data Standards Adoption Network

Group Charter

January, 2010

- Mike Wallace – Abbott
- Tom Werthwine – Johnson & Johnson
- Dennis Black – Becton Dickinson
- Grant Hodgkins – Alcon Labs
- Jackie Rae Elkin – Medtronic
- Corwin Hee – Covidien
- Jay Crowley – FDA

The group will be facilitated by the Medical Device Supply Chain Council.

Preliminary Initial Activities

1. Establish an on-going Communication Forum for participants
 - Based on our last meeting, we are assuming that there will be a need for on-going communication regarding global standards and adoption. While the focus will be on UDI, because we are assuming a GS1 solution, we will also talk to other solution components (e.g., GDSN, GLN)
 - These communications will be through meetings, webcasts and ad-hoc information distribution.
 - The timing, frequency and scope of these events will be determined by the Leadership Group.
2. Create a Repository that will be a “one-stop shop” for Standards information

The site will provide a link to all known relevant information. Much of the information will be provided through linkages to other sites, such as GS1 and the FDA. Examples of topics include:

- The latest available information on specific data standards and legislation
- Reference materials, including but not limited to:
 - Business Case examples - internal presentations used to “sell” standards initiatives internally
 - Industry communications
 - Information on pilot initiatives
 - Education materials
 - Global standards information
 - Implementation checklists
 - Case examples

Medical Device UDI/Data Standards Adoption Network

Group Charter

January, 2010

Cost of Participation

For corporate Members and Sponsors of the Medical Device Supply Chain Council, the cost of meeting participation will be covered by current annual Council Membership and Sponsorship dues. There will also be no meeting charge to participants who serve on the GS1 leadership group. For non-members, there will be a charge of \$150 per attendee per meeting (assuming two meetings in 2010) to support operating costs for this group. Each attendee will be responsible for their individual travel and lodging. There will be no charge for participation in other activities such as webcasts. At the end of the year, these charges can be credited toward a Medical Device Supply Chain Council Membership or Sponsorship for 2011 where appropriate. (Selection as a Council Member or Sponsor is at the sole discretion of the Council. Participation in this group does not guarantee acceptance as a Member or Sponsor.) Additional information on Council memberships can be provided upon request. If there are significant changes in scope or level of effort based on the needs of the group, we will revisit the cost structure as necessary.