



GS1 Healthcare Response to GHTF UDI – Questionnaire

Draft policy ideas related to a Global Unique Device Identification System for Medical Devices

GS1 Healthcare appreciates the opportunity to provide feedback and comments on the GHTF's UDI Questionnaire. We commend the GHTF for their approach to seek a global definition for UDI as it will be important for all stakeholders that a harmonised approach towards identification of medical products is taken.

About GS1 and GS1 Healthcare

The GS1 global Healthcare User Group is a voluntary and open group formed by leading global pharmaceutical and medical devices companies, wholesalers, hospitals and trade associations from around the world. Its primary objective is to enhance patient safety worldwide through accurate and standardised product identification. The group is striving for global standards for automatic product identification. More information can be found at www.gs1.org/healthcare

The GS1 System of Standards is the most widely used identification numbering and data carrier system throughout the world. Over 1 million users across 145 countries and across more than 24 industry sectors have adopted what is today known as the GS1 System of Standards. It is recognised by organisations such as the International Standards Organisation (ISO), the American National Standards Institute (ANSI) and the European Committee for Standardisation (CEN).

The GS1 Healthcare group has chosen the GS1 system as the sole system of standards in healthcare and strongly supports and recommends the adoption and use of GS1 standards in this global UDI initiative.

The standards being finalized under the GS1 Healthcare initiative are the only global set of holistic solutions available today that address all 3 key portions of a potential UDI solution:

GS1 AIDC Standards

- GS1 is the leading source of AIDC standards used by over 1 million member companies in virtually every country in the world, and enables over 5 billion AIDC-assisted transactions per day
- GS1 Healthcare has completed the standards development for the AIDC data carrier and the data required for every type of Healthcare item at every packaging level, which is currently in the 'Global Standards Management Process' (GSMP) for cross-industry approval

GS1 GDSN Standards (Global Data Synchronization Network)

- GDSN is a set of standards with supporting software systems *in use today* to exchange product data between trading partners
- GS1 Healthcare has completed the extensions of the existing standards and systems to more completely support the specialised needs of Healthcare products, which is currently in the 'Global Standards Management Process' (GSMP) for cross-industry approval

GS1 Traceability Standard

- A set of standards defining the messaging protocols and associated data and information requirements to support end-to-end traceability
- GS1 Healthcare has completed the extensions of the existing standards and systems to more completely support the specialised needs of Healthcare products, which is currently in the 'Global Standards Management Process' (GSMP) for cross-industry approval

The GS1 network of 108 Member Organisations worldwide ensures the local reach for future implementation, facilitating pilot studies and government funded programmes, training, working with local regulators and associations etc.

UDI - Questionnaire

Draft policy ideas related to a Global Unique Device Identification System for Medical Devices

On 8 October 2008, the GHTF Steering Committee has established an Ad-Hoc-Working Group on Unique Device Identification (UDI).

In the era of global economy it is desirable to address the traceability of medical devices at a global level. Traceability paves the way of market surveillance of the medical devices. This is why the introduction of a UDI system appears to many regional regulatory authorities and to industry at large as an effective tool to protect more efficiently public health. It is mainly for patient safety reasons that

it is advised to develop UDI for medical devices. It will also enhance the work of market surveillance authorities in case of recalls and for the fight against counterfeiting. In addition, the development of an international approach will make the trade of medical devices more secure for the stakeholders (health authorities, hospitals, manufacturers, distributors, etc).

For the GHTF regional jurisdictions, it is of great importance that a globally applicable UDI system without regional adaptations is developed. Therefore, the design and construction of a UDI mechanism should be addressed in a forum like GHTF, to encourage the use of a harmonised UDI system by all regulatory jurisdictions.

What is UDI?

The UDI system for medical devices will consist of a unique identification code using a globally accepted standard format. This code will allow the use of automatic-identification systems in the field where medical devices are sold, stored, installed, used, maintained etc. In order to be able to accommodate all methods of labelling, marking, identifying products and software (one-dimensional linear barcode, two-dimensional barcode, RFID or other Automatic Identification and data capture media), UDI should be technology neutral.

Due to physical reasons the information provided in the code is limited. For the purpose of improving patient safety, market surveillance and efficiency of the public health sector etc. it will be necessary that the manufacturer must be able to create a link between the CODE and additional information related to the product and needed by other stakeholders in the field. Currently developing concepts of a global UDI envisage the creation of a (with a long-term perspective global) UDI-database which includes these information.

The following Questionnaire is intended to sample the expectations of regulators and industry with regard to a UDI.

In the first part the Questionnaire is focussed on the label and the CODE on the product (e.g. sterile pack, sales package, etc.). The second part is related to the additional information to be provided by the manufacturer and transferred to a UDI-Database. Finally, the last part concerns the implementation of the UDI into the GHTF Model.

Name: _____ [GS1 Healthcare Leadership Team](#)

Organisation: _____ [GS1 Healthcare](#)

Country: _____ [Worldwide](#)

I. UDI – LABEL

- Requirements on the UDI-label (minimal content of information provided with the UDI-label) and types of relevant MD/IVD MD

1. What do you consider as the practical state of the art (3-5 years deployment window) for automatic identification and data-capture systems (AIDC) for the different types and classes of MD?

a) One-dimensional barcodes (or linear barcodes, respectively)

b) Two-dimensional barcodes

c) RFID (radio frequency identification device)

d) Others

Like

e) Or do you consider (while keeping the character of technology neutrality) that the specific UDI technology should be determined by the characteristics of the device.

If Yes, provide examples (e.g. use of RFID for a specific device)

GS1 Healthcare recommends the choice of linear bar codes where possible, 2D when necessary due to print space or pack size and to see RFID as a possibility for the future, in addition to bar codes. The choice of AIDC technology should be left to the discretion of the brand owner and/or manufacturer to most effectively balance these differences in packaging, and to best meet the needs of the supply and dispensing chain. The data requirements of the UDI also need careful consideration; a risk based approach to the data intensity (inclusion of Serial Number, Lot number or expiry *[use by]* date) must be proportional to the level of patient safety risk thus ensuring economic viability of the application. Finally, deployment timescale needs to also take account of capital equipment depreciation to enable further investment in UDI technology integration.

Currently there are several barcode systems for AIDC available (like GS1 128, GTIN 13, UPC, CODE 39, MSI, Data-Matrix-Code, SEMACODE, Vericode, etc). While many scanners and barcode readers are currently able to read multiple barcodes and/or tags, at least the structure of the information provided with the barcode and/or tag could be different. Therefore,

2. Should a global UDI-system limit the number of used barcode systems or AIDC-standards

a) NO

b) YES

In case of yes, How many?

No, the AIDC Application Standards developed by GS1 Healthcare represent the optimal balance between standardised markings / standardised data, and the flexibility to choose alternative AIDC data carriers to solve challenging marking problems.

There are many different AIDC data carriers in existence for one good reason - each brings specific strengths to bear in solving challenging marking problems. The GS1 AIDC

Application Standards represent a multi-disciplinary solution to marking the maximum number of products with the maximum level of standardisation. Limitation would be detrimental to the needs of Healthcare; flexibility in today's complex environment is vital. The suite of GS1 Identification Keys, symbologies and carriers enables the widest possible usage of UDI.

Why do you consider a limitation as necessary or unnecessary?

See above.

3. Should the numbers of barcodes and/or tags on the devices (or package) be limited?

a) NO

Why?

b) YES

Why, how many?

NO. The number of bar codes [and/or RFID tags] should be applied in conformance with the GS1 Healthcare AIDC Application Standards to satisfy the intended use of the product. This standard defines when it is necessary or desirable to have more than one AIDC marking on a product, while striving towards only one AIDC mark per packaging level. This also leverages GS1 rules regarding whether the information should be concatenated into a single bar code or split into 2 or more bar codes.

For example, a medical device (or pharmaceutical) that is sold in both retail and hospital settings may require at least 2 bar codes to meet the needs of these very different stakeholders - a UPC or EAN code may be needed to enable point-of-sale scanning to support retail users, while potentially coexisting with a GS1-128 or Data Matrix barcode containing extended information to support hospital or provider users. (Note: all symbology mentioned above are part of the GS1 solution).

4. AIDC systems are still fast developing technologies. It is predictable that new technologies will be available in the future. In principle a UDI should be technology neutral, but it could be necessary to require interoperability at least during the transfer period to the new AIDC. If a new technology is promising, should the existing technology (specified by UDI requirements) be the minimal requirement, until the time voluntary marking and scanning/reading of the new technology is pervasive?

GS1 Healthcare believes that a more scalable approach is to create guidelines which

allow any GS1-approved AIDC data carrier to be utilised, and that the brand owner and/or manufacturer should retain the flexibility to choose the appropriate data carrier.

The standards bodies routinely ensure forward and backward compatibility as part of the new technology introduction process while providing flexibility to adopt new technologies as they are developed, without need for constant regulatory changes every time a new technology is developed.

5. Currently available CODING systems (e.g. like GS1 Application Identifiers or HIBCC Coding) provide a lot of possibilities to add specific information (like article or catalogue number, expiry date, lot number, weight and measure, serial number, etc.) into the barcode. That is useful and necessary since such codes are voluntarily used for a lot of different purposes (like specific internal or external tracking systems, for logistics etc.). A global UDI which has the goal to improve the patient safety and the post market surveillance must define the minimum content of information provided with the code on the device. In the interest of practicability (size of barcode) and ergonomics of the use of coding systems the information provided with the CODE should be minimised to absolute necessary.

What information should be part of the UDI – label and so automatically readable?

What information should be provided to a UDI-Database?

The GS1 AIDC Application Standards Team addressed the details of AIDC marking requirements for all Healthcare items, including Medical Devices.

This work team recently completed Phase 1 work (addressing over 90% of Healthcare items) and is now actively working to address Phase 2 items and markings .

This cross-functional, global team of 90+ members has worked for the past 2 years to define a risk-based approach to marking of Healthcare items, with the amount of data carried in AIDC proportional to 'risk' and to the intended use of the product, and further segmented by what markings are required by which supply and dispensing chain participants (for instance, hospitals may need to apply additional marks such as asset identifiers unless there is a UDI marking present which meets their needs). This Phase 1 work has now moved into the standards approval process (GSMP) and will ultimately be integrated into a new revision of the GS1 General Specifications document.

The current repository for the recommended / required AIDC markings is contained in the AIDC Product Marking Grids; a copy is attached for reference.

One key principle of the GS1 system is that the AIDC data is simply a pointer to a record in a data base, the amount of data to be carried should be the minimum needed to look-up and access that data. Therefore, the data carrier should carry only the 'necessary' information, while the 'supplementary' information can be referenced elsewhere.

Please specify if the answer below is provided for all Medical Devices or for a specific type of Medical Device (e.g. AIMD, IVDs, Instruments, etc.)

(Note: The UDI will not be a substitution of existing labelling requirements. The UDI will be an additional labelling requirement to allow the broad standardized use of automatic-identification systems in the field of Medical Devices (through distribution and use).

Information 1. encoded in <u>UDI-Label</u> (e.g. so called GS1-Application Identifier) Or 2. information to be provides into a <u>UDI-Database</u>	1. UDI-Label YES or NO (necessary UDI-label on the device, and/or, package)	2. UDI-Database YES or NO	Why do (don't) you consider the specific information as necessary for the UDI-LABEL and/or for the UDI-Database
a.) manufacturer	NO incorporated in part of UDI	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications
b.) device name	NO	YES: suggest using Brand Name in this field	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications
c.) make, model, size	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications
d.) article or catalogue number	NO incorporated in part of UDI	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications
e) country of origin/ manufacturer	NO	NO	Need to precisely define what country of origin means; final assembly, customs definition; etc.
f.) serial or lot number	Depends on type of device	NO	Should only be encoded in AIDC for specified types of products as shown in the GS1 AIDC Team grids
g.) best before or expiration date	Depends on type of device	NO	Should only be encoded in AIDC for specified types of products as shown in the GS1 AIDC Team grids

Information 1. encoded in <u>UDI-Label</u> (e.g. so called GS1- Application Identifier) Or 2. information to be provided into a <u>UDI- Database</u>	1. UDI-Label YES or NO (necessary UDI-label on the device, and/or, package)	2. UDI- Database YES or NO	Why do (don't) you consider the specific information as necessary for the UDI-LABEL and/or for the UDI-Database
h.) storage conditions (e.g. needs to be refrigerated)	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications. The definition of what is meant by 'storage conditions' must be clearly articulated. Values and requirements must be globally harmonised or storage conditions cannot be reasonably added to the database. Must also deal with multiple storage condition parameters, excursion value and duration, etc. This is very complicated and should be considered for a Phase 2 implementation.
i.) nomenclature, classification (e.g. GMDN / UMDNS / UNSPSC)	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications. The number of classification schemes must be kept to one standard - there should be one common scheme before this element is required. Need to clarify what the classification scheme is to be used for - what are the business requirements.
j.) packaging level/number of items	NO packaging level (indicator digit) is incorporated in part of UDI	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications
k.) labelled as single use or reusable	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications
l.) sterility	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications

Information 1. encoded in <u>UDI-Label</u> (e.g. so called GS1-Application Identifier) Or 2. information to be provides into a <u>UDI-Database</u>	1. UDI-Label YES or NO (necessary UDI-label on the device, and/or, package)	2. UDI-Database YES or NO	Why do (don't) you consider the specific information as necessary for the UDI-LABEL and/or for the UDI-Database
m.) contains known labelled allergen (e.g. latex)	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications. There must be a globally harmonised list of expected values expected from GHTF (Latex etc.) or the value of inputting this data and querying it from the database is impossible.
n.) Regional authorised representatives	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications. Should be limited to the Primary authorised representative only, not a list of all authorised representatives.
o.) Global Unique Identification number (like GTIN, LIC...)	YES	YES	The UDI number is the minimum marking required, and should be applied to all products where possible
p.) National Product catalogue number	NO	NO	This is too vaguely defined; it is not practical that every national product catalogue number for every in-scope country would be stored in the database, and it constantly changes.
q.) National License or Registration number	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications.
r.) others MRI compatibility	NO	YES	Should be looked-up in the database; no compelling need to use this static data field in AIDC applications.
s.) others			

6. Do you consider that a UDI system should be based on the level of risk:
- a) Yes, for “High risk” Medical Devices only
 - b) Yes, for all Medical Devices, with common rules irrespective of the risk.
 - c) Yes, for all Medical Devices, but with risk proportional application rules.

(C) GS1 Healthcare fully endorses and supports the concept of a global UDI for all medical devices, based on the risk proportional application rules developed by industry and regulators within the GS1 AIDC Application Standards work team.

7. If the goal of a UDI for medical devices is a better traceability for better market surveillance and consequently better patient safety, it would be necessary to be specific about the intended level of traceability of devices. In case of implants for instance, it could make sense to require that every single product is made automatically identifiable until the time of implantation. For some other less critical devices e.g. mass-produced consumable products (syringes, plasters etc.) it would be technologically difficult and economically very expensive to require the same level of traceability. In these cases it could make sense to require automatic-identification only on the level of batches, lots, dates of production etc.

Should the UDI define different levels of traceability?

YES. See the previously attached GS1 AIDC Application Standard Product Marking Grids for details.

Which kind of products should be traceable up to the level of the single product (serial number)?

ONLY the highest risk products, in general, should be traceable to the single product (item) level. See the previously attached GS1 AIDC Application Standard Product Marking Grids for details.

For which products would it be sufficient to require a lot or batch number?

ONLY the Enhanced-risk products, in general, should be traceable to the Lot or batch level. See the previously attached GS1 AIDC Application Standard Product Marking Grids for details.

For which devices is it physically impractical and economically unreasonable to require any level of traceability?

GS1 Healthcare believes that there are some limited exceptions that cannot be marked

with AIDC using current technology. For instance, very small reusable instruments such as cannulas, probes, needles, and other delicate instruments used in Ophthalmology and Neurosurgery would be virtually impossible to directly part mark with current technology.

We encourage the GHTF to include guidelines to provide for a manufacturer to request an exemption to product marking, including the evaluation criteria for determining when an exemption would be granted.

We further encourage the GHTF to consider identifying and excluding certain classes of medical devices such as Ophthalmic and Neurosurgical reusable surgical instruments from the direct part marking requirements for the initial implementation phases, as current marking technology is not capable of applying marks to many of these products. When technology improves, these exclusions could then be removed.

See the previously attached GS1 AIDC Application Standard Product Marking Grids for details.

8. Many medical devices are custom-made devices (manufactured for a specific patient). The requirement that medical devices must bear a specific UDI label can have an enormous economic impact for small and medium sized medical devices enterprises. Having in mind that in case of custom-made device the tracking of the product should not be a problem, it could be discussed if such devices shall be excluded from a future UDI requirement.

Should custom-made devices be excluded from a future UDI-requirement?

If, no why

GS1 Healthcare believes that given the amount of work to be done in implementing an effective, global solution to UDI, that items such as custom-made devices should be excluded at this time in order to focus effort and regulatory support on marking the 80-90% of products that can readily carry AIDC markings.

Additionally, there is little value in having these individual patient-specific items in the global database.

These excluded devices could be addressed at a later time when the overall system is operational and the majority of products have been addressed.

What other devices or groups of devices could also be excluded from the UDI-requirement?

Why?

In keeping with the comments and thought process in the previous question, GS1 Healthcare also encourages the GHTF to also exempt convenience kits from marking requirements until a later date. There are a number of significant issues related to the

marking of kits that must be understood and worked through.

For instance:

- The term 'kit' or 'convenience kit' must be thoroughly defined so there is no confusion about scope - is a group of items shipped together as a pricing bundle considered a kit? Or only those items that are subjected to some distribution related value add process?
- If every item within the kit is marked with UDI, does the kit also require UDI?
- If the kit contains a drug, which UDI rules apply? Device rules or Pharma rules or both?
- If some items in the kit require UDI containing Lot and/or Serial Number, does the overall kit have to carry that level of UDI, or some other level?
- If kits are composed of items inside the kit and outside the kit, how are UDI rules applied?

Since convenience kits represent a relatively small segment of the market, focusing on marking the items that can be more easily marked first would yield more immediate benefits.

9. The current available standards for AIDC Systems are working on the basis of a registration *of owners* of the e.g. specific barcode. In general the owners must register themselves at non-for-profit organisations (like GS1, HIBBIC) and have to pay for the use of the numbering system which is expressed in the barcode.

The *owner* of a barcode must not be a "*legal*" *manufacturer*. There are currently no standardised or regulatory rules regarding the data to be recorded (and checked) by the non-for-profit organisation, or with regard to who can use a medical devices barcode, or who has (or if Authorities do have, respectively) free and fast access to these registration data.

- a) Do you consider a need to clarify and/or specify what data of the future owner of a UDI-barcode must be recorded by the non-for-profit AIDC-Standard-Organisations (GS1, etc.)?

Yes or No

Why?

The GS1 system provides interoperability across many industry sectors - there need not be a specific UDI prefix/derivation specifically for Healthcare items. In fact, this would be counterproductive - since many Healthcare items cross-over into at minimum the retail and non-retail supply and dispensing chains, a mandate for specific Healthcare UDI schemes would require at minimum 2 different product markings using 2 different schemes which invites errors at all levels of the supply and dispensing chain.

- b.) What data shall be recorded, checked and made accessible (by the above mentioned non-profit organisations) for the purpose of national market surveillance authorities?

- 1.)
- 2.)
- 3.)
- 4.)

Why shall these data be recorded?

See above.

10. In contrast to pharmaceuticals or food, many medical devices are not consumable products with a relatively short lifetime. Many products like instruments are reusable or have a long lifetime for several years. They will be cleaned, re-sterilised, refurbished, disinfected, maintained, repaired etc. during their lifetime. These procedures could impact and damage the UDI-label.

Is it necessary that the UDI-label of re-useable Medical Devices must be readable during the whole lifetime of the device?

YES. The UDI label (or direct part marking) should remain readable throughout its *intended* lifecycle. We emphasise 'intended' lifecycle, as some medical devices that are intended for single-use are reprocessed and re-used - this is not in accordance with manufacturer's specifications, therefore the UDI label (or direct part mark) should not be required to remain readable for these off-label uses - the entity responsible for this type of off-label reprocessing should have the responsibility to assure continued readability of the UDI throughout this post-use lifecycle.

If yes, what technologies are currently available and appropriate to protect the UDI-label of devices during use etc.?

11. While it seems to be necessary, that many devices shall be traceable up to the level of use, it could due to ethical reasons and existing rights of privacy be necessary to implement UDI rules to avoid misuse of automatic-identification, e.g. avoiding that patients with implants can be unauthorised identified by third-persons.

Do you see a need to implement rules to avoid misuse of AIDC?

YES.

1. Security of the UDI database is a key source of compromised security. Strong, effective security practices with continuous monitoring and threat response is an absolute must in the UDI database system.
2. In our opinion, Privacy rights directly related to the AIDC carrier become an issue when all of the following events are present:

- a. there must be a valid, real privacy concern present and there must be a definition or other means to determine what is a real public health-related privacy concern
 - b. the AIDC must be capable of being interrogated without the consent or knowledge of the individual having the privacy right concern
 - c. there must be enough information in the data carrier to enable a malicious party to uniquely and unequivocally identify the product
 - d. there must be a mechanism to associate the identified product to a particular individual person by that malicious party
3. There are certainly some specific exceptional situations where privacy is a real concern; however we believe that there are no privacy issues with the majority of AIDC technologies related to the medical device field.
 4. We recommend that any guidelines developed to address privacy matters should be limited in scope to ONLY those products identified by the manufacturer as having the need for extra precautions to protect privacy.

If yes, for which products and which rules could be implemented?

See above.

II. ADDITIONAL INFORMATION REGARDING THE UDI DATABASE (to be created and maintained by the manufacturer and to be provided into a UDI-database)

As the UDI-label provides a possibility to identify a specific product in the market by using automatic-identification technologies, there is a need of manufacturers, users, hospitals, distributors, insurances and regulatory authorities to get additional information in relation to the coded products.

This information is currently widely spread in the field. They are available at the different stakeholders. Currently, there are several initiatives on regional levels underway to create databases which contain the information needed by the different stakeholders.

The operators of these databases are Authorities, National Agencies, Insurances or Universities etc. As the operators of these databases are very different, the purpose of the databases are not the same. A database which is mainly focused on patient safety, traceability and market surveillance is not available yet.

To improve the patient safety etc. the UDI-label on the device itself must be supported with a kind of a database or an information network, so called UDI database.

The UDI database shall allow the use of an existing globally accepted data exchange process (such as the GS1 Global Data Synchronization Network (GDSN)) to harmonize the exchange of device safety information. It could use a globally accepted nomenclature (such as GMDN, UMDNS). Once a "UDI-CODE" is allocated to a medical device, the manufacturer shall transmit this code and some additional related information to one or more databases. The UDI databases centralise all the UDI-CODES required by the regulatory authorities.

12. For the purpose of improving safety and market surveillance what information must a manufacturer provide together with the specific product code to such an UDI-database in view of a regulatory authority? Please justify your choice. (see also table on question 5)

We believe that all the fields in the Question 5 table marked with YES in the Database column are valid and appropriate for the manufacturer to communicate to the UDI database.

13. What additional data are needed (or are wished) by other stakeholders? (Note: In some regions national product catalogues are established and require specific information from the manufacturers etc.)

None, see above.

14. Based on your experiences with national/regional databases, product catalogues etc. are the current available international standards developed by HL7, GS1, CEN, ISO etc. sufficient to establish and maintain a globally accepted and compatible data exchange system or is it necessary to require the compliance with a specific standard. Please justify your choice.

GS1 Healthcare believes that the current and evolving GS1 Healthcare standards for GDSN, Traceability and AIDC Markings are the only truly global and holistic solutions in existence today to support the needs of a global UDI database.

These GS1 Standards address the key infrastructure and operational transaction sets needed for end-to-end traceability, while providing the possibility to leverage this compliance framework for future business value within our organisations.

No other standards address all aspects of this solution, from the catalogue features (GDSN) to the product markings (AIDC) and finally the transaction network infrastructure and messaging (EPCIS and eCOM). This complete coverage is essential to enabling the end-to-end solution envisioned and advocated by GHTF. Moreover, if there is an agreement on ONE set of guidelines, then as additional EU Member States or other countries wish to participate, the timescale and effort to bring them into this network is substantially reduced.

We believe that if the framework for the solution is not specified and one set of guidelines is not chosen, then a proliferation of approaches will emerge with no mechanism to assure interoperability between each solution. This would ultimately require the deployment of not one set of solutions, but a number of different solutions, at each and every point in the

supply and dispensing chain by every participant. Witness what is happening on the Pharmaceutical side of the business, with completely different solutions in existence today for Turkey, Florida, France, Italy and Belgium, just to name a few. This lack of standardisation is delaying every implementation (California delayed now twice, with the latest delay stretching out 6+ years), requiring multinational players to invest in completely different technologies and solutions for each jurisdiction, and providing NO mechanism to interoperate between jurisdictions.

We applaud the efforts of the GHTF in working to prevent a repeat of this situation on the medical device side of the business.

III. IMPLEMENTATION OF THE UDI into the GHTF-model

According to the GHTF-model medical devices manufacturers are obliged to monitor the safety and performance of their devices in the post production phase. In general that is done as part of the quality management system. For some low risk devices the manufacturers have to be in compliance with some specific regulatory post-market surveillance requirements.

It could be argued that the use of automatic-identification-technologies is the state of the art to perform adequate post market surveillance. Therefore the requirements to label the device with a UDI and to provide information to the UDI-database could be included into the GHTF-model by adding them to the Essential Principles of the product (e.g. labelling requirements) and to the obligations of manufacturers and authorities.

The UDI-label and a UDI database would require from the manufacturer the creation of a link between the UDI-label (and/or tag) on the device and additional product information. That will probably result in the establishment of an internal database of the manufacturer. The need to establish such an internal database can be considered as a necessary tool to keep control of the processes on the manufacturing side and as part of the quality management system. Specific requirements on a kind of such an internal database can be established in the future by changing the relevant quality management standards, or by new standards and specific requirements formulated in the GHTF model.

The intention to create on the basis of the information provided by the manufacturer a UDI-Database could be integrated into the GHTF-model by revising or rethinking the GHTF-guidance on medical devices registration systems.

15. What would be the best way to implement a UDI-System into the GHTF model?
 - a) UDI label → new essential principles in the GHTF model → Standard bodies create specifications

UDI database → requirement for manufacturers as part of the QM system → Structure and Format developed by standard bodies (ISO based) → Establishment (or rebuilding) of National and International compatible regulatory (or other) MD-Databases

OR

b. Alternatives: