Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli (1523)

USDM Simplify, Unify, Optimize
Life Science Compliance for Regulated Systems

UDI 2.0
What have we learned – and where are we going…

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US Legislation (FDAAA 07; FDASIA 12)

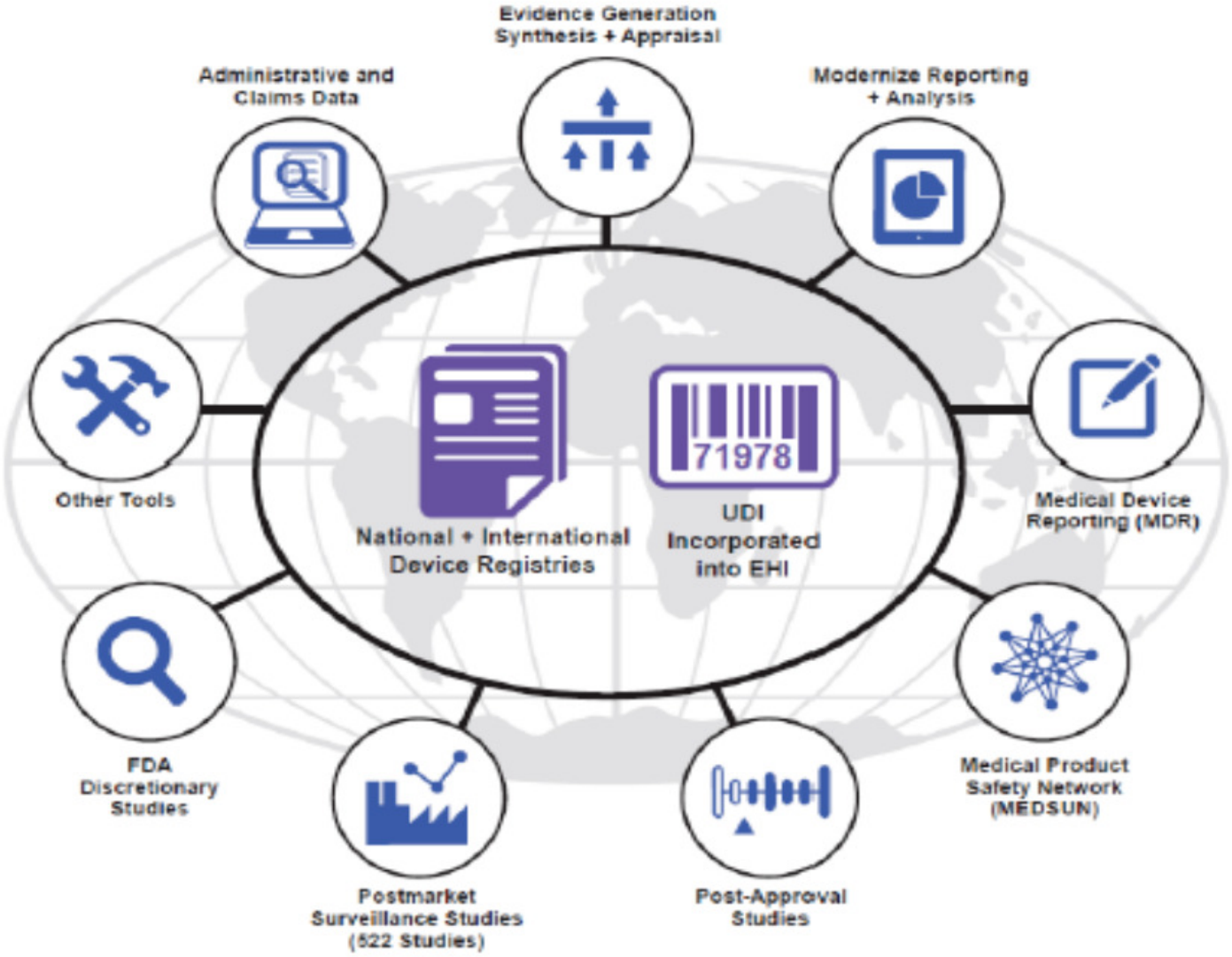
Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. ***The unique identifier shall adequately identify the device through distribution and use***, and may include information on the lot or serial number. *The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.*

Public Health Benefits

The UDI system provides global visibility and supports:

- Medical device recalls
- Adverse event reporting
- Tracking and tracing
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Reduction of medical errors (e.g., bedside scanning)
- An easily accessible source of device information for patients and clinicians

US FDA UDI Rule Intent/Objective



UDI and Traceability

UDI is intended to support traceability through identification of a specific device throughout its distribution and use and over its entire life.

Compliance Dates

Implementation (compliance) timeframes – September 24:

- 2014: class III and devices licensed under PHS Act
- 2015: class II/I implants and life-supporting/sustaining
- 2016: rest of class II
- 2018: class I

For Direct Marking:

- Compliance dates are extended by 2 years
- except for FDASIA (year 2) devices – still at year 2.

UDI “Compliance” is Really Hard

But not for obvious reasons:

- Many manufactures have grown by acquisition (silos, multiple SOPs, ERPs/PLMs) – different approaches which need to be centralized
- Using UDI to make all sorts of other label changes (name, address) and sku rationalization
- Uncertainty about global UDI
- UDI rule is tried to balance costs/risks – but there is a lot of (maybe too much?) flexibility and ambiguity
- Many see UDI as (primarily) a regulatory activity – don’t see internal and external benefits

UDI has uncovered…

- Many business practices that are no longer sustainable (e.g., orthopedic trays/sets, private label)
- Opportunities to leverage UDI to solve business problems – asset management, loaners
- Rule provides flexibility for individual manufacturers – is leading to inconsistency across market
- Many exceptions are not aligned/do not support downstream business practice (e.g., SUD exception)
- That different country's/regulator's needs are going to create significant implementation issues (e.g., what is a device, device class, meta-data needs, actors)

Unexpected Issue…

1. Is it a device, drug, combination product…?
2. Is it an accessory or component – or “spare part”?
3. How did it get to market and what is its procode?
4. Who is the “manufacturer”(labeler)? OEM/3rd party
5. How many (finished, US) devices do I distribute?
6. How do I package it?
7. Where is all the data I need for GUDID?
8. Where am I going to store and how am I going to submit data to the GUDID?
9. Barcode verifiers/quality barcodes?
10. How am I going to maintain visibility/traceability?

What do you produce…?

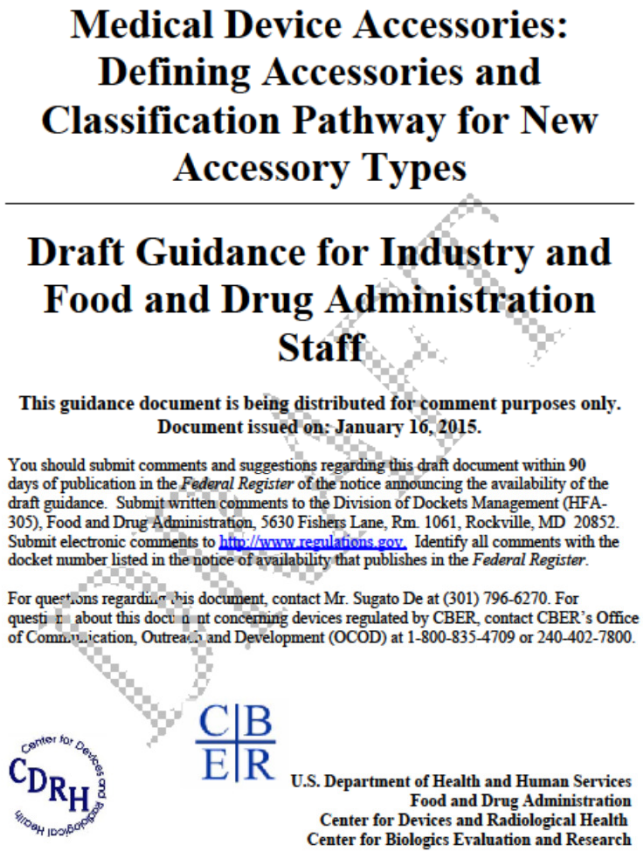
- What is your product portfolio – detail all active SKUs (of “finished” medical devices)?
- Is product a regulated medical device (US vs OUS)?
- What is its risk class (US vs OUS) – vs premarket path (which drives compliance dates)?
- What is its procode – drives FDASIA and SUD exception?
- Is it a component, accessory or spare/service part?
- Devices with no independent premarket path?
- How do you identify/mange configurable devices?
- Combination products (esp. NDA) – may have no clear device classification? What about those with an NDC?

What is a medical device?

A device is … "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, **including a component part, or accessory** which is… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals….

Which means that accessories and components are in and of themselves medical devices – subject to UDI.

What is a medical device?



Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types

Draft Guidance for Industry and Food and Drug Administration Staff

This guidance document is being distributed for comment purposes only.
Document issued on: January 16, 2015.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Mr. Sugato De at (301) 796-6270. For questions about this document concerning devices regulated by CBER, contact CBER's Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Accessories <….> of Parent Devices

- ***support*** the performance of a parent device by enabling or facilitating that device to perform according to its intended use.
- ***supplement*** the performance of a parent device if it adds a new function or a new way of using the parent device, without changing the intended use of the parent device.
- ***augment*** the performance of a parent device by enabling the device to perform its intended use more safely or effectively

What is NOT an Accessory…?

"It is important to note that articles that do not meet the definition of an accessory will not be treated as accessories simply because they may be used in conjunction with a device." [FDA]

"Spare parts supplied for replacement of existing components of a device, the conformity of which has already been established, are not medical devices. If spare parts, however, change significantly the characteristics or performances of a device with regard to its already established conformity, such spare parts are to be considered as devices in their own right." [EC]

Who is the “labeler”…?

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REF FMF02

Who is the “labeler”…?

- How does this affect your OEM/private label/contract manufacturing relationships?
- Who will have responsibility for which parts?
- What will this look like in the GUDID?
- How will this play out globally?

“Labeler” is any person who causes a label to be:

- applied to a device with the intent that the device will be **commercially distributed**; or
- **replaced or** modified with the intent that the device will be commercially distributed.

Who is the “labeler”…?

- EU definition “The manufacturer is any natural or legal person who is responsible for designing and manufacturing a product with a view ***to placing it on the Community market "under his own name"*** (or trademark).”
- GHTF/IMDRF definition of manufacturer – “…any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of ***making the medical device available for use, under his name***; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).”

How do you label/package it?

- Where is the “label” – regulatory concept?
- Is date in standard format – even exempt levels/devices?
- How many label templates do you have? Are any labels produced off-site?
- Do you need UDI on label/package below the orderable/shippable unit?
- How many levels of packaging do you have?
- Are you packaging the same device in different packages?
- Do you understand the difference between the UDI Label and the Direct Marking requirement?
- Are you applying UDI the same/different than others?

Do you have quality barcodes?

- Deconstruct barcode – correct and formatted data.
- All issuing agencies require barcode quality of grade C or better.
- You need barcode verifiers!
- The rule … amends the Quality System Regulation by requiring examination of the accuracy of the UDI as part of the scope of the labeling inspection, that the device history record include any UDI …

How do you describe it?

- Have you captured, normalized and verified (and successfully submitted) the GUDID attributes?
- Brand name?
- Model/version (regulatory) vs catalogue number?
- Packaging hierarchy
- DUNS numbers
- DM/DPM
- Organizational challenges – workflows, process validation, SOPs, people, education

“Convenience” kits…?

- “A medical procedure kit is either a convenience kit, if it contains only medical devices, or a combination product, if it contains both a device and a drug or biologic. The final rule excepts a device packaged within the immediate container of any convenience kit or within the immediate container of a combination product from bearing a UDI on its label provided, as long as the kit or combination product is labeled with a UDI…”

“Convenience” kits…?

But… UDI on kit/CP assumes that:

- Manufacturer has traceability/visibility into all of the components
- All of the components are consumed (or discarded) when opened/used

If not – then need to reconsider use of kit exception (at least for some components)

- “Orthopedic procedure kits are a well-known example of a medical procedure kit.”

Direct Marking (DM UDI)

- In addition to the label requirement – a "permanent marking" UDI is required on the device itself if:
  "…the device is intended to be used more than once and intended to be ***reprocessed before each use***."
- DM DI can be same of different as label DI.
- Can be AIDC or HRI – or both.
- DM Exceptions part of rule – manufacturers document in DHF.

What is a Reprocessed Device…?

A reprocess device is one that is initially supplied:

- As sterile and requiring the end user to process the device after initial use (i.e., cleaning and disinfection or sterilization) ***prior to the subsequent patient use.***
- As non-sterile to the end user, and requiring the end user to disinfect or sterilize the initial packaged device and to subsequently reprocess the device after initial use.
- As a non-sterile SUD to the end user, and requiring the end user to sterilize the device prior to its use.

Conforming Amendments

Adds to each the requirement to use UDI:

- Part 803 – Medical Device Reporting
- Part 806 – Reports of Corrections And Removals
- Part 810 – Medical Device Recall Authority
- Part 814 – Premarket Approvals
- Part 820 – Quality System Regulation
- Part 821 – Medical Device Tracking Requirements
- Part 822 – Postmarket Surveillance

Conforming Amendments

803.52 Manufacturers must include the UDI on the device label or on the device package in individual adverse event report submissions.

806.10 The manufacturer or importer must include on reports of corrections and removals: the UDI that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

806.20 Records of corrections and removals not required to be reported to FDA shall contain the UDI, or the device identifier, UPC, model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

814.84 The holder of an approved pre-market approval shall identify in its periodic report each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report.

Conforming Amendments

820.184 Device history records must include any UDI or UPC, and any other device identification(s) and control number(s) used.

820.198 Manufacturers must include in their complaint files any UDI or UPC, and any other device identification(s) and control number(s) used.

820.200 Service reports that represent an event that must be reported to FDA must include any UDI or UPC and any other device identification(s) and control number(s) used. 821.25 A manufacturer of a tracked device must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of these devices.

822.9 Class II and III device manufacturers required to conduct postmarket surveillance must include both premarket application/submission number and device identifiers in the postmarket surveillance plan submission.

820.120 Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct UDI or UPC, expiration date, control number, storage instructions, handling instructions, and any additional processing instructions.

Are you really compliant…?

- Have you documented use of any exceptions, updated relevant SOPs, trained staff, etc, etc…?
- Do you know where your existing inventory is?
- Have you addressed the conforming amendments?
- Is your solution extensible to other countries?

- Systemic activity – include all relevant players – see all conforming amendments

IMDRF and US FDA Differences (1/2)

- IMDRF has a significant label space constraint exemption – allows UDI on next higher package level. FDA does not.
- IMDRF limits the single use device packaging exemption to risk class A and B devices – FDA has no limitations (though narrower definition of how it can be used).
- IMDRF allows any “non-prescription medical devices exclusively for retail Point of Sale (POS) do not need to encode Production Identifiers in AIDC on the point of sale package.” – FDA limits this to class I devices.
- IMDRF states that if constraints limiting both AIDC and HRI on the label – the AIDC format shall be favored (certain environments, such as home care, may warrant the use of HRI over AIDC) – FDA always requires both.

IMDRF and US FDA Differences (2/2)

- IMDRF allows GMDN to be optional – FDA requires it.
- IMDRF requires "serial numbers for active implantable devices" – FDA does not.
- IMDRF requires the UDI of the implantable device must be identifiable prior to implantation (e.g., tear-away tag, peel-off label) – FDA has no such requirement.
- IMDRF requires medical devices within a kit to have a UDI – FDA exempts all contents of the kit from UDI.
- IMDRF has "guidance" for how UDI is applied to configurable medical device systems and stand-alone software – FDA has no rules (at least yet).
- FDA has exempted completely from UDI all GMP-exempt Class I devices – IMDRF does not have anything similar.
- FDA has an "existing inventory" exemption – IMDRF not.

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Thank you!

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