Challenges and Opportunities With UDI Implementation

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Is it 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…. 
Accessories <> of Parent Device

• **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.
Accessory vs Spare Part

“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]
Active SKU List…?

• What is your product portfolio?
• Is product a regulated medical device (US vs OUS)?
• What is its premarket path, procode and risk class?
• What about 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?
• Stop doing crazy things with SKUs…!
• Opportunity to do sku rationalization…
Who is the “Labeler”…?
Labeler vs Manufacturer

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).”
OEM/Private Label

• Review all contracts/supplier/quality agreements.
• 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?
What/where is on your label…?

• Where is the “label” (regulatory concept)?
• What is currently on the “label” – and why?
• Is date in standard format – even exempt levels/devices?
• How/where are labels/templates produced?
• UDI on label/package below the orderable/shippable unit?
• Why do we include manufacturing date, symbols, other…?
• Label has evolved over many years – this is an opportunity to review what is on the label and …
How do you package it (and why)?

- What do users actually do with the device/packaging?
- How many levels of packaging do you have?
- Are you packaging the same device in different packages?
- Are you applying UDI the same/different than others?
What about the UDI exceptions...?

- Single Use Device PACKAGING
- “Convenience” kit
- Existing inventory
- Custom – really?
- Class I – no PI(s) – but…?
- Combination products…?
- DSCSA…???
SUD Packaging Exception

UDI *can* go on SUD next higher level of packaging when:

The individual single-use devices (SUDs) are:
1. distributed together in a single device package,
2. intended to be stored in that package until used, and
3. which are not intended for individual distribution.
   - Can *not* be used for implants (?)

Need to document above.
-- And Unit of Use (UofU/"virtual") DI required in GUDID
“Convenience” Kit Exception

“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” Kit Exception

But… UDI on kit/CP assumes that:

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

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

- Finished devices manufactured, packaged and labeled prior to compliance date
- Existing inventory – regardless of where it is located
- Consignment is considered your inventory
- Continue to put into commercial distribution +3 years past compliance date to use w/out UDI
- Where is at all…?

BUT – need process to identify and manage inventory
Direct Marking (DM DI)

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 –document in DHF.

Need to understand the difference between the UDI Label and the Direct Marking requirement!
GUDID Data Elements

• “When a GUDID attribute appears in the medical device labeling [on the label], the values submitted to the GUDID should match the value in the labeling.”

• Therefore – some “optional” fields are “conditionally required” – kit, combo, HCT/P, size, storage and handling

• Some are truly optionally (description, catalogue number) – but, should you leave them blank…?

• Model/version (regulatory) – new DI trigger…

• Brand Name – name used in labeling or in the catalog.
UDI Requires Solid Infrastructure

- Talk to your downstream trading partners and customers!
- Many manufactures have grown by acquisition (silos, multiple SOPs, ERPs/PLMs) – need for centralization
- Rule provides a lot of flexibility (and ambiguity)
- Many see UDI as (primarily) a regulatory activity – don’t see internal and external benefits
- Some exceptions are not aligned/do not support downstream business practice (e.g., SUD exception)
- UDI is a Program – not a project…
Next Steps

- Understand what you actually make/distribute – and why.
- Understand whether it is a regulated medical device.
- Understand its regulatory path to market, procode, etc.
- Understand how you label it – and why.
- Understand how you package it – and why.
- Understand the exceptions – and whether you can AND should use them.
- Is your UDI and associated meta-data used/useful?
Thank you!

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