What Did We Learn From Class III Implementation…?

Jay Crowley, VP and UDI Practice Lead, USDM
Email: jcrowley@usdm.com
Direct: +1-850-880-2591
Cell: +1-443-438-0608

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
- Uncertainty about global UDI
- UDI rule is tried to balance costs/risks – but there is a lot of (maybe too much?) flexibility and ambiguity
- FDA – and not the "user" – is the arbiter of correct
- Many see UDI as (primarily) a regulatory activity – don't see internal and external benefits

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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)

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#1 – what do you produce…?

- What is your product portfolio – detail all active SKUs?
- 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 product code (procode) – drives FDASIA and implant (SUD exception)?
- Is it a components, accessories or spare/service part?
- What to do when there is no independent premarket path (e.g., part of PMA)?
- Combination products (esp. NDA) – may have no clear device classification? What about those with an NDC?

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#2 - Who is the "labeler"…?

#2 – 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.

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#3 – how do you label/package it?

- Where is the "label" – regulatory concept?
- 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 product in different packages (in 1-in-1 and in 5 pack)?
- Do you understand the difference between the UDI Label and the Direct Marking requirement?
- Are you applying UDI the same or different than other manufacturers?
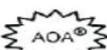
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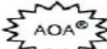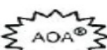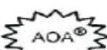
#4 – Are you really compliant…?

- Have you documented use of any exceptions, updated relevant SOPs, trained staff, etc, etc…?
- Do you know where your existing inventory is?
- Have you captured, normalized and verified (and successfully submitted) all the GUDID attributes?
- Have you addressed the conforming amendments?
- Do you have quality barcodes (labeling inspection, barcode verification, etc.)?
- Is your solution extensible to other countries?
- Do you have visibility and traceability with your non-sterile implants distributed in trays and caddies?

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GS1-UDI Application Example

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HIBCC-UDI Application Example

ICCBBA-UDI Application Example

Conforming Amendments

803.32 User facilities must include the UDI on the device label or on the device package in individual adverse event report submissions.

803.33 User facility must submit in annual reports the UDI that appears on the device label or device package.

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

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.

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Conforming Amendments

810.10 FDA will include the UDI that appears on the device label or on the device package in its cease distribution and notification order.

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.

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.

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.

Conforming Amendments

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.

821.30 Persons other than device manufacturers and distributors must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device.

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.

IMDRF and US FDA Differences (1/3)

- Manufacturing date exemption – IMDRF yes, FDA no.
- Significant label space constraint exemption – UDI on next higher package level – IMDRF yes, FDA no.
- 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.
- For RFID, IMDRF also requires linear or 2D barcode on the label." – FDA does not.

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IMDRF and US FDA Differences (2/3)

- 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 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 exempts orthopedic trays whose contents are configured for a specific order – FDA has no exemption.

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IMDRF and US FDA Differences (3/3)

- IMDRF requires medical devices within a kit to have a UDI – FDA exempts all contents of the kit from UDI.
- IMDRF has "rules" for how UDI is applied to configurable medical device systems – FDA has no rules (at least yet).
- IMDRF has "rules" for how UDI is applied to stand-alone software (IMDRF uses the term Software as a Medical Device (SaMD)) – more detail than FDA currently has.
- 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 does not.

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