Lessons Learned from U.S. FDA UDI Rule Implementation for Class III Medical Devices

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UDI IMPLEMENTATION LESSONS LEARNED
SUMMARY

Get GS1 Organized
– Understand GS1 Company Prefix assignments
– GTIN implementation helped tremendously for UDI program
– GDSN strategy was very, very beneficial -- UDI submission was a natural extension

Get Organized
– Senior Level Executive Support
– Detailed project planning

Teams and Teamwork
– Standards and UDI Rule Education
– UDI has many aspects and many skills are needed
UDI IMPLEMENTATION LESSONS LEARNED
SUMMARY

UDI is NOT just a Project, it’s a way of life
  – UDI is also about implementing processes
  – New policies/procedures need to be written

Data Source(s) and Collection
  – Determine data attribute owners
  – Build data collection into the product launch process
  – Determine and organize DUNS numbers
  – Validation required from source systems to GUDID

DO NOT OVERLOOK
  – Report 830.360
  – Quality Systems Requirements

START NOW!
life. to the fullest.