

# 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!



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