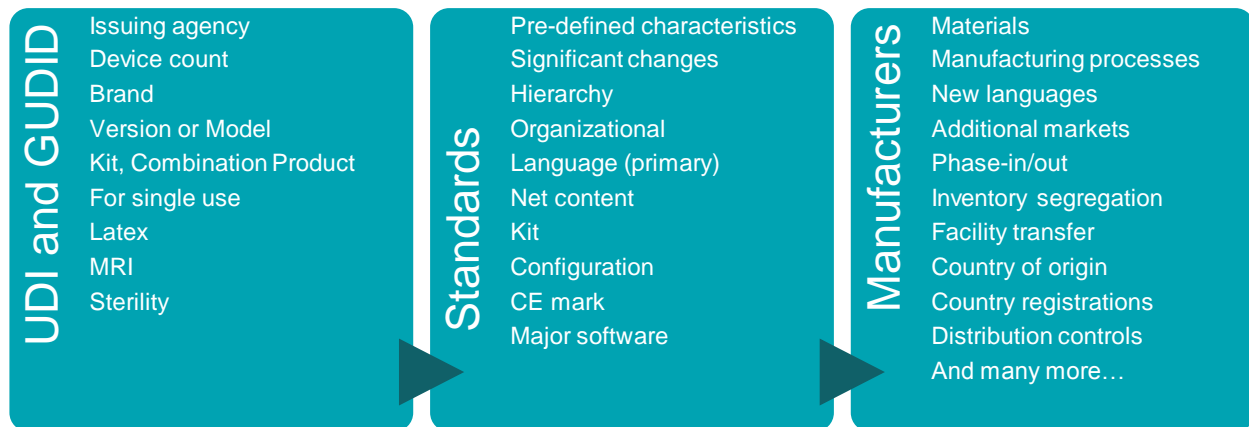# LEARNING UDI COMMUNITY WORK GROUP TOPIC PROPOSAL

PROPOSED WORK GROUP TOPIC: (e.g., what problem or issue will this proposed group address?)

The objective of the Unique Device Identifier (UDI) system is to create assignment of Unique Device Identifiers to medical devices. Each UDI is composed of Device Identifier (DI) and Production Identifiers (PI). The expectation is that a given version/model of a given device would have only one DI, however multiple DIs have been assigned for a given version/model of a device as evidenced through conversations with UDI Capture case studies participants and the recent Data Quality Initiative. This is introducing challenges for provider systems that would like to import and use data from Gobal Unique Device Identification Database (GUDID). The three boxes below require assignment of a new DI when the value of the data element changes.

UDI and GUDID	Standards	Manufacturers
Issuing agency Device count Brand Version or Model Kit, Combination Product For single use Latex MRI Sterility	Pre-defined characteristics Significant changes Hierarchy Organizational Language (primary) Net content Kit Configuration CE mark Major software	Materials Manufacturing processes New languages Additional markets Phase-in/out Inventory segregation Facility transfer Country of origin Country registrations Distribution controls And many more…

The above list need to be reviewed, evaluated to ensure if the change should require a new version/model and catalog number and how should a GUDID record be updated when a new DI is required.

WHY THIS TOPIC IS IMPORTANT: (brief descriptions, e.g., what impact is it/will it having/have on adoption of UDI, patient safety, costs or barriers to compliance or adoption, etc.)

The UDI system is not useful unless the data collected in GUDID is a trusted source of truth for providers. Since this is a problem that is stopping adoption of this data set in provider systems, it needs to be reviewed and resolved.

AFFECTED/REQUIRED STAKEHOLDERS: (who are the critical participants that are affected/need to be included in this proposed work group, e.g., manufacturers, providers, technology companies, clinicians, etc. – *please be specific as needed, e.g., types of manufacturers, roles, functions, etc.)*

Group Purchasing Organizations

Manufacturers

Health Care Providers

FDA UDI team

BRIEFLY DESCRIBE, IF APPLICABLE, ANY WORK THAT HAS BEEN DONE ON THIS ISSUE PREVIOUSLY:

FDA UDI team has performed analysis of existing data and have verified the problem. We are contacting and communicating with some of the entities that have been reported to us as data quality issues.

EXPECTED OUTCOMES/DELIVERABLES OF THE WORK GROUP: (guidance, case studies)

A clear understanding of when a new DI should be allowed for a device and what to do with the DI record that was originally entered in GUDID. Ideally the best practice should be a 1-1 relationship between a DI and catalog number (version/model).

PROPOSED TIMEFRAME TO DELIVERABLES:

6 months from start of project.

INDIVIDUALS PROPOSING TOPIC:

Mike Schiller, Senior Director, Supply Chain, AHRMM