



# UDI Impacts on Recall Management Work Group Charter

## **WORK GROUP FOCUS:**

UDI Impacts on Recall Management – Evaluating clinical and supply chain operational, and patient safety impacts and benefits of using the UDI to enhance the recall process. The work group is expected to build upon prior work by the AHRMM LUC Benefits of UDI Work Group and Strategic Marketplace Initiative (SMI).

## **WORK GROUP EXECUTIVE CHARTER:**

The mission of the UDI Impacts on Recall Process Management workgroup is to: 1) define the value to multiple stakeholders (suppliers, providers, patients, etc.) re: the use of UDIs in the recall process; 2) collect information on current level of usage of UDIs in the recall management process, and 3) make recommendations to increase usage of UDIs to maximize value.

## **WORK GROUP LEADERS:**

Barbara A. Strain, MA, CVAHP, Director of Value Management, University of Virginia Health System.

Richard A. Perrin, CEO/Principal, Active Innovations, LLC.

## **AFFECTED STAKEHOLDERS:**

The workgroup will be diligent in gathering validated perspectives from different stakeholders involved in the product recall processes for their organizations. As such, the workgroup will seek input and participation from across the healthcare supply chain including:

- Manufacturers
- Distributors
- Hospitals and other healthcare settings
- Clinicians
- Patients
- Technology vendors\*
- FDA
- Associations, e.g., SMI, AdvaMed



**Note** – Technology vendors will include recall and inventory management systems vendors as well as others that may provide important perspectives, e.g., AIDC systems, ERP/MMIS systems, content management systems, eProcurement systems.

## **BACKGROUND:**

Research has shown an increasing number of medical device recalls. The number of recalls issued in 2018 was the highest in five years, while the average number of Class I units recalled per quarter increased more than 64 percent from 2016 to 2017. According to a 2017 McKinsey report, a major recall can have a negative impact on perceived manufacturer shareholder value, not to mention the significant risk to patient safety if the devices in question are not removed from the market and patients treated with those devices, especially implantables, cannot be identified.

The ability to better manage medical device recalls was one of the primary drivers behind the UDI regulation. Still, the use of UDIs in recall notices by manufacturers remains limited.

This workgroup will seek to identify and evaluate different practices across the medical device supply chain and make recommendations to improve patient safety and increase efficiencies through increased use of UDI in the recall process.

## **Key elements to be considered by this workgroup include:**

- Data and process for submitting recalls to the FDA (including UDI-DI [Device Identifier(s)] and UDI-PI [Production Identifier(s)])
- Processes and systems used to manage recalls (by suppliers, healthcare system supply chain and clinical teams, FDA, and technology systems)
- Data required to effectively manage recalls by various stakeholders
- Information and workflow related to the recall management process
- Current processes, reasons and levels for generating medical device recalls

One anticipated recommendation is to increase the number of recalls that include UDI-DI and UDI-PI and to clarify the structure and format of recall data that would best meet the needs of those managing recalls – both industry and healthcare systems.

## **PROCESS & DELIVERABLES:**

- A three-pronged approach is planned for this workgroup's efforts:
  1. Place a call for formal case studies from organizations highlighting their operational and patient safety benefits from incorporating the UDI into their recall process,
  2. Develop and distribute survey(s) to gather data on current practices, capabilities and use of UDI in recalls, and
  3. Develop recommended practices showing the value for use of UDIs in recalls management.
- Develop educational materials to be shared with FDA and other clinical and supply chain participants on best practices and impacts of UDI use in medical device recalls.
- Develop recommendations to be shared in various communities to enhance product recall effectiveness using GUDID UDI information.



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## **COMMUNICATION PLAN:**

The following approaches are projected to be used in communicating results of this workgroup:

- Review, validation and dissemination of relevant information gathered from surveys, interviews, business communications, etc.
- Submission of recommendations to AHRMM Learning UDI Community and FDA including posting(s) to AHRMM LUC webpage.
- Preparation of White Paper regarding UDI Impacts on Medical Device Recalls.
- Distribution to AHRMM LUC, AHA, HFMA, ARHMM, HIDA, HIMSS, HDMA, HSCA, IAHSCEM, SMI, HPN, HHN, Beckers, etc.