



# **UDI/Standards Adoption for Medical Device Manufacturers**

Hosted by the **Medical Device Supply Chain Council**

**October 22, 2009**

# Meeting Agenda

7:00 *Continental Breakfast*

7:30 *Welcome*

**Mike Wallace;** Abbott Labs

7:45 *Opening Comments and Introductions*

**Kevin Stout;** Medical Device Supply Chain Council

8:15 *Implementation Strategy and Experience*

**Grant Hodgkins;** Alcon Labs

**Jackie Elkin;** Medtronic

9:00 *A Global Perspective*

**Volker Zeiner;** B. Braun

9:20 *Global Harmonization Task Force (GHTF) Update*

**Tom Werthwine;** J&J

# Meeting Agenda (continued)

9:40 *GS1 Overview, Information & Tools*

**Ulrika Kreysa;** GS1 Healthcare Global Office

**Dennis Harrison;** GS1 US

10:30 *Open Discussion, Q&A*

12:00 *Close Meeting*

## Meeting Objectives

- Identify ways to facilitate broader Medical Device manufacturer adoption.
- Provide a basic understanding of current adoption initiatives (company and industry), and what tools are available to manufacturers to support adoption.
- Provide a global perspective on standards adoption versus UDI legislation compliance.
- Identify obstacles to adoption and what can be done to overcome them based on the knowledge and experience of the meeting participants (lessons learned).
- Identify specific needs from the Medical Device manufacturer community and opportunities to address those needs.
- Networking!!!

## Current State

- There is a general understanding across the healthcare and medical device industries that the current complexities and associated costs are not sustainable. Data standards are a fundamental building block toward achieving improvements in supply chain efficiency, reduced operational costs, improved regulatory compliance, and improved clinical outcomes.
- There is a basic level of understanding of the current data standards and associated US legislation. The knowledge of broader global standards initiatives and local legislation is much more limited. Companies are in reaction mode when the phone rings and they are informed of regional/country based dictates.
- The level of awareness relative to standards initiatives for smaller and mid-sized companies is limited. Activity toward adoption for these companies generally ranges from limited to non-existent.
- A number of companies have taken the lead in driving standards development. In some cases, corporate involvement in standards initiatives through third parties (e.g., GS1) has been limited due to cost and/resource constraints.

## Current State - continued

- A focus on industry-wide adoption has been much more limited to date, though focus on adoption is increasing.
- Many companies are following a “late adopter” strategy. They will act when dictated by regulatory bodies (US and global) and/or major customers. They are waiting to be told what to do by when.
- There is a lack of understanding across the industry of what it means to “achieve compliance.” How does a company define success relative to data standards?
- Because no one has implemented everything wall-to-wall, there is a general level of understanding of what is involved to become “compliant.” This lack of documented successes and the associated data makes selling a corporate-wide standards initiative to the executive level challenging, if not impossible. While the executives generally understand the need, elevating standards initiatives is difficult without a clear understanding of resources, costs, timing and benefits (e.g., ROI). This is particularly challenging given the current economic environment. An even harder sell is to position these initiatives based on achieving a “competitive advantage.”