HUG

Standards Implementation/ Regulatory Affairs

Minneapolis MN
Jackie Rae Elkin and Tom Werthwine

The global language of business

www.gs1.org

Standards Implementation/ Regulatory Affairs

Activities to Date

Regulatory Activity :
Meeting with FDA CDRH
Meeting with UK Dept of Health National Patients Safety Agency

Customer Feedback

How does HUG develop positions ?
The need for a governance model

Roadmap for success

Regulatory Activity

Standards Implementation/ Regulatory Affairs

Meeting April 24, 2006

AdvaMed
Advanced Medical Technology Association

FDA
Food and Drug Administration

GS1 HUG

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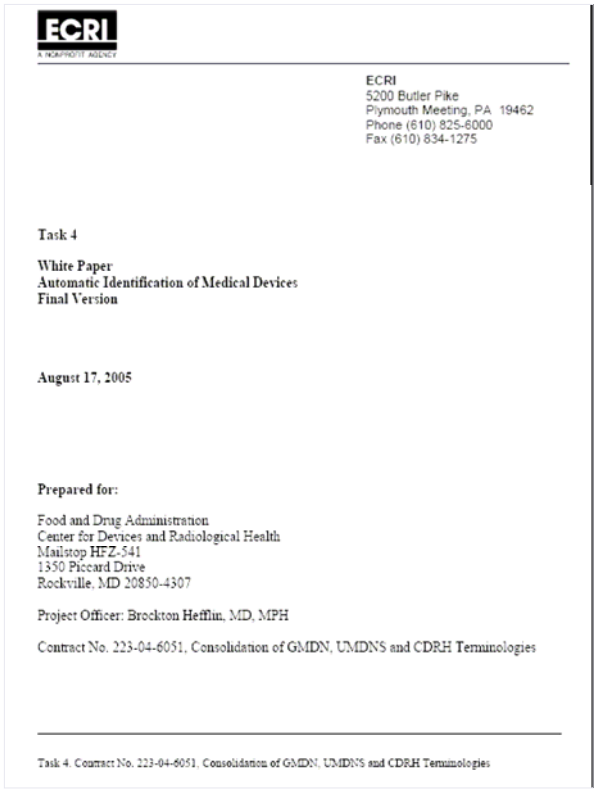
Food and Drug Administration



ECRI
A NONPROFIT AGENCY

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Plymouth Meeting, PA 19462
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Task 4

White Paper
Automatic Identification of Medical Devices
Final Version

August 17, 2005

Prepared for:

Food and Drug Administration
Center for Devices and Radiological Health
Mailstop HFZ-541
1350 Piccard Drive
Rockville, MD 20850-4307

Project Officer: Brockton Hefflin, MD, MPH

Contract No. 223-04-6051, Consolidation of GMDN, UMDNS and CDRH Terminologies

Task 4, Contract No. 223-04-6051, Consolidation of GMDN, UMDNS and CDRH Terminologies

FDA meeting with industry to discuss the value of medical device serialization April 2005.

- Track devices being recalled
- Deter counterfeiting
- Find critical devices to accelerate clinical care delivery
- Prevent transmissibility of disease and infection
- Post market safety analysis

GS1 HUG

Ensuring the Safety of Marketed Medical Devices

Dan Schultz, MD

Director, Center for Devices and Radiological Health

January 4, 2006

Adverse Event Reporting Challenges

- Adverse events are widely under-reported by users
- Numerous reports with inadequate information about how the device was used and what may have caused the problem
- Difficulty in identifying the specific device involved
  - Health care providers generally do not document device use in patient records
  - Devices lack unique identifiers
  - Manufacturers continually produce modified versions of their products.
  - Device firms are often purchased by other companies
- Devices are often used “off-label”
- Shift to home use
  - Non-professionals are using these products

United States Department of Health & Human Services — FDA — CDRH Center for Devices and Radiological Health

9

Attendees

Jay Crowley, FDA

David Racine, FDA

Jeff Secunda, Advamed Staff (teleconference)

John Roberts, GS1 US Staff

Jackie Rae Elkin, GS1 HUG and Advamed member

Peter Tomicki, GS1 HUG and Advamed member

Tom Werthwine, GS1 HUG, EPCglobal HLS, and Advamed member

Can you summarize the reports from the GS1 Healthcare User Group meeting in Italy?

Primary focus was on pharmaceuticals and the Italian healthcare sector. Rome was chosen as the site so that we could engage the Italian Ministry of Health and discuss the Bollini initiative. Dr. Walter Bergamaschi invited the GS1 HUG “to find an agreed solution to standardize the ID system and to propose technical solutions for Traceability in agreement with all supply chain participants”.

How does the GS1 data structure account for items like serialization, RFID, kits consisting of several devices components, drug/device combinations, software versions in devices?

The GS1 bar code system identifies data elements through the use of application identifiers. AI (01) introduces the Global Trade Item Number (GTIN). AI (21) introduces the serial number. When used together they are called the SGTIN.

Upcoming meeting with UK Department of Health to include GS1 HUG, GS1 UK, and Eucomed

Customer Feedback

Standards Implementation/ Regulatory Affairs

Hello all,

I am interested in finding out how Operating Rooms conduct Verification of implants during their Time-Out process. What types of implants are included or excluded? Who initiates or conducts the verification of the implant, as the "correct" implant? Do you consider a "wrong implant" a Sentinel Event? In reviewing the JCAHO standards, it identifies "wrong patient, wrong site, wrong procedure" as WRONG SITE SURGERY, but does not mention "wrong implant" specifically. Thank-you for your imput!! Mary

National Patient Safety Listserv
May 31, 2006

Patient Safety Consultant
Midwest US Hospital

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. -- Oregon Association of Hospitals and Health Systes web site

Governance

Organization Considerations

Need a glossary that defines offices and membership.

Chair :
Leadership team member:
Board of Governors / Founding Members:
Work team leader:
Work team member:
Plenary member:
Attendee:

Organization Considerations

Chair Position criteria

Company or individual appointment ?
Length of term and term limits ?
GS1 subscriber or member org ?
Duties ?

Organization Considerations

Membership Criteria

Subscribe to one or more GS1 offerings:
GLN, GTIN, EPC

Strive for balance among geographic regions, Pharma, and medical devices, comprehensive market presence - competitors welcome

Organization Considerations

The external face of GS1 HUG

All meetings shall include GS1 staff to preclude collusion

Need to differentiate individual, corporate, HUG, and GS1 positions.

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Workstream

How do we mitigate the “silo effect” of current workteams ?

How do we ensure GSMP acceptance of GS1 HUG proposals ?

Develop roadmap

Develop “quick wins”

Points to Consider

Or

“Quick Wins”

Suggested Process

1. Prioritize
2. Organize by expertise - align with GTIN allocation and surgical instrument marking
3. Align terms and assumptions
4. Gather requirements E.g. France and AU e-catalogues
5. Develop
6. Review and revise
7. Communicate

Roadmap for success

Identification

Organize WG according to Roadmap priorities to support Identification
- Application Standards Development
  - Unique Application Scope Statement

Data Selection – Mandatory/Optional
- Carrier (what bar code or tag) Selection
- Carrier Specifications (size, conformance, placement, text)
- Rules (data rules, allocation rules)

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Classification

Begin after business/regulatory requirements for classification in HUG are determined and a gap analysis against existing standards takes place

Data Align

Begin after business/regulatory requirements for data alignment in HUG are determined and a gap analysis against GS1 Global Data Dictionary http://gdd.gs1.org/gdd/public/default.asp takes place

Data Synch

Need for education and business case development

Business Messaging

Begin after business/regulatory requirements for business messaging in HUG are determined and a gap analysis against existing standards takes place

HUG

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