

Standards Development Work Team: Final Results

20-22 September 2006

Paris, France

Peter Tomicki

The global language of business

www.gs1.org



Work Team Objectives

Part I – Process optimisation for healthcare

- Gather input from Healthcare Industry (HUG)
- Review existing process to develop standards (GSMP)
- Implement appropriate changes to GSMP for HUG standards development
- Represent HUG in GSMP community through official position

Part II – Forecasting model for future standards needs

- Develop framework and forecasting model
- Generate a first forecast within framework



Part I - Optimisation

HUG Input into GSMP Renovation

- Input gathered from HUG was reviewed by various levels within GS1
 - New HUG Standards Development processes endorsed by GSMP and GS1
- Monitored for inclusion in GSMP renovation

Two points to continue to pursue:

- Standards lifecycle management: adoption, review, decommissioning
- Audit mechanism: will require resources and a certification process
- HUG Leadership Team represented in established GSMP organisation
 - Peter Tomicki elected to represent HUG in GSMP Process Group

Next steps for WT:

Part I - Complete



Part I – Optimised Process HUG+GSMP

Interim Process

- Focused on Packaging and Marking standards indicated in Roadmap
- Ends when HUG AIDC Application Standards are entered into GSMP
- Healthcare lags other industries in adopting and integrating GS1 standards

Permanent Process

- All other standards not included in Packaging and Marking
- Begins when the development of these standards are driven by the HUG
- Healthcare is relatively mature in development and deployment
- No change suggested to current process built by other industries in GSMP



Part I – Interim Process HUG+GSMP

Interim Process Flow

- 1. HUG Leadership Team (LT) creates a Work Team (WT) to address need
- 2. WT generates two key deliverables with support of allocated GS1 staff:
 - Business case for proposed standard
 - Document outlining modifications/additions to existing GS1 standards
- 3. Proposed standard document reviewed by HUG and extended GS1 staff
- 4. Document finalised by WT and voted by HUG to enter GSMP
- 5. Document, business case and GSMP Change Request (CR) submitted
 - GSMP Change Request includes HUG specific addendum
- GSMP Process Group uses submission to classify CR as "complex" or "simple"
 - If "simple": submission is returned to LT for final HUG membership vote
 - If "complex"...





Part I – Interim Process HUG+GSMP (con't)

- GSMP adopts WT as "healthcare champions" of HUG proposed standard
- 8. GSMP initiates a "Call To Action":
 - Stakeholder team created:
 - WT + non-healthcare potential standards users or stakeholders
 - Technology and solution providers consult as directed by GSMP
 - Short period of public review driven by stakeholder team
- GSMP assesses input and determines whether a pilot is necessary
 - If a pilot is necessary:
 - Stakeholder team collects pilot participants
 - Pilot executed
 - Results reviewed by GSMP and stakeholder team
- 10. GSMP proceeds with a vote by stakeholder team



HUG Change Request Addendum

General (not industry specific)

- Stakeholders
- When
- Supply chain efficiency
- Stakeholder process redesign
- New technology
- Cost reduction
- Improved data transfer/communication
- Reliability
- Business transparency: transactions, sales data etc
- Data package and access
- Challenge of new system implementation
- Challenge of system migration implementation
- Database/data management
- Known legal implications eg. trademark, patent etc.

Healthcare specific

- Regulatory
- Patient safety
- Anti-counterfeiting/tampering
- Patient convenience, safety, communication, transparency, privacy
- Security
- Packaging limitations
- Product stability
- Product classifications
- Repackaging and parallel trade
- Market responsiveness for recalls, data transactions, returned product etc.
- Market specific needs
- Healthcare related existing standards to be referenced
- Exception handling
- Channel eg. retail, hospital only
- Reference/pointers eg. package inserts
- Data content
- Special product classification eg. Physician samples, clinical trial product etc.



Part II - Forecast

- Breakout session input and results from Minneapolis meeting
 - Presented at conclusion of Minneapolis meeting
- Content of framework and model
 - Designed in Minneapolis by Work Team
 - Same content as the HUG addendum to GSMP Change Request Template
 - Content be used for healthcare standards forecasting
- HUG Roadmap defines forecasted standards through January 2008
 - Currently Packaging and Marking standards only
- Business case for any additional standards to drive further forecasting
 - HUG LT prioritises development effort based on business case
 - GSMP Change Request + Addendum template is completed for forecast
 - Tools (eg. GSDN, eCom)
 - Processes (eg. data management, data classification)
 - Sub-industry classification (eg. Implants, biologics, single use devices)

Next steps for WT:

- Part II - Complete





Standards Development Working Team

Participation:

- Active HUG membership participated on WT = 11
 - Baxter, Hospira, Premier, Novartis, Pfizer, 3M, Organon
 - GS1-NZ, GS1-Head Office, GS1-US, GS1-ND
- HUG input at each meeting in breakout sessions
- Teleconference meetings
- Multi-level GS1 commitment and involvement

Budget:

No WT budget used

Many thanks to all who participated

Let's develop some standards!





Contact details

Peter Tomicki

Baxter Healthcare

T +1 847 270 5492

E peter_tomicki@baxter.com

The global language of business