HUG

Standards Development

Brainstorm Discussion Notes

29 Nov – 1 Dec, 2005

Princeton, NJ, USA

Peter Tomicki (Baxter Healthcare), GS1 HUG Team Leader

The global language of business

www.gs1.org

Process Optimization Input - Process

Initial Process

- Requirements definition stage
- Who submits request? Use templates?
  - Individual/company
  - HUG
- Need an individual as champion to follow through process
  - Needs to be a knowledge expert
  - May be drawn from HUG membership for HUG submissions
- Use HUG Communications Team to advertise/sell/publicize submission in healthcare community
- HUG to be a review layer with a periodic review process
  - Work program assessing the portfolio of submissions

Process Optimization Input - Process

Business Justification

- Document regulatory impact (any risks?)
- Document business drivers
  - Manufacturing/Channel/End Users impacted by proposed standard
    - Financial, effort/resources, etc.
  - Patient safety impact
  - Track & trace impact
  - Sustainability impact
  - Insurance/payment mechanism impact
  - Geographic impact of proposed global standard in the regions
- Focused direction to preempt scope creep

Process Optimization Input - Process

Technical Development

- Generally follow existing process for technical review with special considerations for heathcare issues
  - Examples:
    - Small size packaging
    - Direct part marking
    - Stability
    - Sterile fields
    - Regulatory requirements/impact
    - Intellectual Property
- When prepared, prior to voting:
  - Potential of pilot data justification
  - Capture appropriate stakeholder voices
    - Manufacturing, Channel Partners, End Users, Regulators etc.

Process Optimization Input - Process

Voting/Implementation

- Final HUG evaluation of submission prior to voting
- Voting to include Healthcare voice
  - Exclusive to healthcare?
    - Non-healthcare specific stakeholders (distribution, retail etc.)?
  - Voting body to be defined by HUG
    - Fixed or flexible? Need the appropriate number of voters
    - Minimum expertise required for vote
      - Expertise in technology
      - Knowledge of the submission and supporting information
    - Cross-section of stakeholders with considerations on size, scope, impact of potential standard

Process Optimization Input - Process

Publication

- Documented by appropriate body
  - AIM etc. for technical standards (eg. new barcode symbology)
  - GS1 for application standards
- Final draft evaluation by HUG prior to publication
  - Facilitate policy writing within HUG membership organizations
- Communication to other standards organizations as appropriate
  - ISO, BSA, CSA, ANSI etc.

Lifecycle Management

- Monitor/measure adoption of standard and uses of standard
  - HUG to facilitate data collection
- Implemented standard review cycle
  - Process and participation of review body?
- Enable decommissioning

Process Optimization Input – Other Factors

Scope

- Not necessary to divide healthcare industry for development process (eg. devices/pharma, implants/devices etc.)
  - Start with one process and “wait and see” if changes are necessary
- Global in scope
  - Any exceptions to global scope will require critical review

Exception Handling

- Appropriate for healthcare standards
- Added to standards publication
  - Parallel path for exceptions review to ensure standard is processed as quickly as possible
  - Included in assessments by ISO etc for further ratification
- Exceptions will require a separate rigorous review process

Process Optimization Input – Other Factors

Enforcement or Audit Mechanism

- Appropriate for healthcare standards
- Certification for healthcare industry companies and suppliers
- Additional costs/resources will be required
- HUG to create expectation in the healthcare industry to acknowledge audit results and/or certification

Medical Error Reduction

- Process may be independent of HUG goals
- Implemented standard lifecycle management and HUG review will consider HUG goals

Time

- Approximately 1-2 years for process (submission to publication)
- Sunrise dates for healthcare for adoption decided by HUG

HUG

Contact details

Peter Tomicki
Global Project Manager
T +001 847 270 5492
E peter_tomicki@baxter.com
www.baxter.com
Baxter