HUG

Vaccines and Biologics Work Team Close Out September 2006 HUG

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The global language of business

www.gs1.org

Background

Initiated the vaccine and biological work team activities at the Princeton Meeting ~ 1 year ago

Targeted our efforts on identifying the *unique needs* of vaccine and biological products

Provided updates at all HUG Meetings and solicited feedback

Close out – September 2006

Work Team Activities

Provided a forum for discussion at the Minneapolis Meeting on the Japan Proposal

Worked with the leadership team to gain consensus on a HUG response to Japan

Engaged GS1 Spain/Healthcare Committee and provided feedback

Leveraged communications between regions to share best practices

Presented at the *Bar Coding of Vaccine Products Consultative Process* meeting sponsored by the Public Health Agency of Canada

VACCINE/BIO Work Team Strategy

Leverage the common elements with pharma as much as possible

Identify key differences for vaccine and Bio products and place in an appendix

- RF Energy concern
- Cold chain requirements
- Government providers
- Specialty clinic applications
- Unique patient lifetime record keeping requirement
  (need to be permanent and transferable)

RF Energy – Unique Requirements

Work Team is not aware of data that supports the use of RFID with vaccine and biological products

(FDA compliance guide)

RFID is not a good short term Auto ID solution for vaccine and BIO products at item level

(potential for heat generated from item level tagging)

Work Team feels that 2D (other GS 1 symbols may also work) barcodes could be an efficient item level Auto ID solution

FDA is currently testing some products with RF (Biological?)

Team member to monitor this activity

Cold Chain Unique Requirements

Many vaccine and bio products require Auto ID solutions that can survive in a cold chain environment

2 – 8ºC, Frozen gels, Dry Ice (-70ºC) etc

Cold chain conditions should be integrated with the testing of tags and barcodes to EPC GLOBAL (example; impact of frost layer)

Opportunity to develop a standard for

a smart chip to monitor Temperature

develop a standard for a barcode that is Temperature sensitive

develop standards for vaccine vial monitors

Government Providers – Unique Requirements

Governments are a key customer/distributor for vaccines

Governments may seek to utilize auto ID as an enabler to supply chain visibility for stockpiles of vaccines

Specialty Clinics

Specialty atypical clinic applications may become vaccine administrators outside of the more typical supply chain.

Patient Lifetime record keeping – Unique Requirements

Immunization record keeping requirements are unique for vaccines

Data is important

- NDC or similar
- Trade name or Generic
- Manufacturer
- Lot number (required by US Law)
- Expiration date
- Name of administer
- Serial number potentially

Opportunity for multipart labels to facilitate recordkeeping

AutoID may assist in the transfer of records

Proposal For Next Steps

Summarize team findings placed in the HUG repository

Confirm/Deliver findings to applications standards team

Team members are encouraged to remain active in the HUG and confirm that the unique requirements are accounted for

Team to remain “silent” but poised to respond/engage as opportunities arise

Team members will look for opportunities to leverage the work of the HUG as is pertains to vaccine and biological products

Continue to support the Canada consultative process

Special Thanks to Workgroup Members

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