

# Standards Development

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## Standards Development

#### Part I:

Standards development process optimization for the healthcare industry

#### Part II:

Implement a forecasting model for future standards needs in the healthcare industry



### Objective

 Detail a realistic supply chain standards development process for adoption by GS1 that is optimized for the healthcare industry



#### Scope

#### References

- Global standards development organizations (ex. ISO, GS1)
- Regional/national standards development organizations (ex. BSA, ANSI, CSA)
- Healthcare industry groups (ex. PhARMA, AdvaMed)

### <u>Deliverables</u>

- Processes for standards development
- Mechanisms of adoption & enforcement
- Measures of adoption & enforcement
- Realistic framework for GS1 implementation



#### Existing Standards Development Process Review

- Determine relevant sources of existing standards for the healthcare industry, supply chain or both
- Questionnaire focusing on key factors for healthcare
  - User base (ex. geography, industry)
  - Process flow, stakeholder involvement and championing
  - Time to define, develop, ratify and adopt
  - Regulatory: responsiveness, involvement, knowledge, trust and impact
  - Industry scope: all healthcare vs. sub-industries
  - Technical scope (ex. data format, data carriers, data transactions)
  - Original source for standards vs. copycat standards
  - Review/update cycle and criteria
  - Industry uptake
  - Enforcement practices/audits
- Compile and compare results





### Develop a Baseline

- Investigate existing GS1 process
- Compare with existing standards review and user assessment
- Identify and assess gaps, additions and modifications
- Baseline GS1 healthcare process
  - Standards development process
  - Process review and update cycle
  - Enforcement/accreditation and audits
    - Within GS1
    - Healthcare industry
    - Solution providers





#### **Deliverables**

- Identify and review existing relevant standards development processes
- Compile and summarize results of review [Jan 06]
- Review standards development process user assessment
- Compile and summarize results of review [Jan 06]
- Submit first draft of GS1 "Healthcare Standards
   Development Process" Baseline for review
   [Mar 06]



#### **Objectives**

- Forecast key supply chain standards required by the healthcare industry in 2-5 years
- Create a forecasting model and process to review and update the 2-5 year forecast



#### Scope

- Supply chain standards impacting healthcare industry
  - Divide into sub-industries where appropriate
- Global
- Stakeholders along supply chain channels
- Within and outside current framework of GS1



#### **Forecast Parameters**

- Data
- Data format

- Data Transactions
- Data storage

Data carriers

Expected standards need details for model

- Rationale
  - Regulatory
  - Market/industry drivers
  - Technology advancement
- Timeframe for delivery
- Geography
- Sub-industry

Each forecast inserted into model must meet the requirements for GS1 healthcare standards development submission



#### Deliverables: First Forecast

- Review successes & failures of past standards impacting healthcare
- Review current and upcoming standards & regulatory mandates (0-2 years)
- Compile current standards & mandates [Jan 06]
- Forecast extension of standards & needs 2-5 years for "first forecast"



#### Deliverables: Forecasting Model & Process

- Define key criteria for useful forecast
- Generate forecasting skeleton [Dec 05]
- Define team & process for review of forecast
- Insert first forecast within framework [Jan 06]



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