Standards Implementation/Regulatory Affairs

Roma IT
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The global language of business
www.gs1.org
Why are we together?

Regulations can be a hurdle to implementation…
Standards Implementation/ Regulatory Affairs

Why are we together?

Single Health e-Catalogue
The Big Picture
A Phased Approach - Phase 1
18th October 2005

Regulations can accelerate implementation
Data

- Product identifier
- Lot no., Expiration date
- Unique identifier ("Serialization")
- Etc.

Carrier

- Bar Code
- RFID "Chip"
- Etc.
- Hardware to decode ("read")

Standard

- What data is included
- How data is organized
- How to decode data
Standards Implementation/ Regulatory Affairs

What do we intend to do?

Assemble a team
Plan deliverables and milestones
Do the work
Measure progress
Produce results
Team Volunteers

Amgen
Cofares
GS1 France
GS1 Switzerland
GS1 UK
Boston Scientific
Hospira
Johnson & Johnson
Medtronic
Novartis
Premier
Member Org
GS1 France
GS1 Switzerland
GS1 UK
Pharmaceutical
Amgen
Hospira
Johnson & Johnson
Novartis

Medical Devices
Boston Scientific
Hospira
Johnson & Johnson
Medtronic
GPO and Distribution
Cofares
Premier

Are we balanced?
What do we intend to deliver?

Let’s look at the HUG mission and vision…

Our **mission** is to **lead** the healthcare industry to the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.

Our **vision** is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) to seek input and **direction** for global standards in the healthcare industry.
How can we be effective?

Let’s look at the past....
In October 2001, HIDA declared EHCR is dead

(EHCR)

Efficient Healthcare Consumer Response
Is now replaced by
Electronic Healthcare Record
(EHCR)
So, we should change our focus from profit to patient

Scannable technology

*Bar coded pharmaceuticals save lives*

Research shows machine-readable product identification is key to preventing medical errors, improving patient safety, helping combat counterfeiting and lowering costs throughout the health sector. But GARY HARTLEY argues New Zealand has fallen behind the rest of the world in mandating bar codes on pharmaceuticals.
GS1 Staff suggests creating an Implementation Guide
How would our Guide be unique?

How “global” can we be?

*MVP-Seattle
Can the same guide apply to drugs and devices? *Newsweek
“It’s not about the bar code, it’s about the data.”

-- Karen Longe
How can we be effective?
Let’s look at the past and near present...

Product packaged and labeled for target market

UPC for US
EAN for Europe
FMCG bar coding for healthcare
Meat packing for healthcare
How can we be effective?

Let’s look at the future....
How can we be effective?

Let’s look at the future....

Create a work plan this week to define scope, objectives, and deliverables.

*Know when we are done.*
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