

Traceability in Healthcare II Work Group

Date: 16-February-2009

CR #: 09-000040

This is a GSMP **Call-to-Action** to recruit participants from the healthcare sector and from everywhere in the world to bring their expertise, commitment, and contribution to a new GSMP work area.

The information herein gives a general description of the new work area and the **Work Group (WG)** that is being formed to accomplish the work. For information on how to join this work area, please refer to Section 12 below.

1. Objective/Scope of the Traceability in Healthcare II WG (THII)

By mid-2010:

1. Develop a suite of Global Standards that enable Traceability in Healthcare (Process standard(s) and technical standards)
2. Develop a Standard Gap Report
3. Publish the necessary process and technical standards
4. Develop supporting products:
 - a. Guidance on enabling technologies
 - b. Migration plan for all stakeholders

That:

1. Supports compliance to the myriad of local, national, regional Regulatory requirements (see Products in scope below) and
2. Enhances the GS1 System for the Global Healthcare market
3. Does not compromise existing GS1 System and
4. Will be applicable, wherever possible, to all sectors, rather than to healthcare specifically.

2. Scope Constraints of the Traceability in Healthcare II WG

GSMP WGs and BRGs must adhere to the GS1 Standards Development Methodologies to assure their scope and deliverables, upon which the work of the other GSMP groups depends.

Generally, the team must operate within the following context:

- Develop documents that capture the business and technical requirements
- Develop documents that capture the additional considerations and concerns that were discussed during the group's calls and physical meetings.

This work effort is based off of Change Request: **09-000040**

3. Expertise Required

This is a call for healthcare supply chain stakeholders: regulators, suppliers, manufacturers, wholesalers, distributors, institutional providers, dispensers for the Traceability in Healthcare II **WG**. The experts should represent trading partners from both sides of the trading relationship, third parties and solution providers (*to be invited after the Business Requirement gathering phase has been completed*) to have proper representation on the WG. The intent is to have balanced membership from the global healthcare user community to define and establish proper global standards with the clear intention of implementation of these.

The GSMP work group model requires a minimum level of support throughout the process and to meet eBallot requirements for due process (as defined in the *GSMP Users Manual*). Failure to achieve the minimum through this CTA for due process will mean the group will not be launched.

4. Area's Affected

- GS1 Global Healthcare and its work teams
- GSMP Traceability BRG

5. Distribution for Call to Action

Please circulate this **Call to Action** packet by forwarding it to your email distribution lists. GSMP WG/BRG's are open to broad participation from any industry group, company, or region. All '**Call to Action**' packets are posted in the GS1 website at:

http://www.gs1.org/services/gsmg/involve/call_to_action.html

It is also distributed via a GSMP Community email announcement and to the GS1 Healthcare Community.

6. Timeline:

A kick off/introductory meeting will fully brief all participants of objectives and WG activities.

The first call will be held on Tuesday 31st March 2009 from 09:00 EST (15:00 CET) for 90 minutes. The overall duration of this group effort is expected to be approximately 18 months.

7. Participants:

Known Participants:

- Process Manager: John Ryu
- Sponsor:
 - Ulrike Kreysa, Director Healthcare, GS1 Global Office
 - Diane Taillard, Solutions Director, GS1 Global Office
- Chair:
 - Frédérique Fremont, C.H.I Robert Ballanger Hospital, France
 - Tim Marsh, Pfizer, USA
- GS1 Business Unit Manager:
 - Janice Kite, Traceability Director Healthcare, GS1 Global Office
- This CR is supported by the GS1 Healthcare community – Existing Traceability in Healthcare Work Team members shown below:

GS1 Member Organisations (MO) Participants:

Name		Company
Fethi	Altunyuva	GS1 Turkey
YADY	ANGULO	GS1 Australia
Bettina	Bartz	GS1 Germany
Stefano	Bergamin	GS1 Italy
Robert	Celeste	GS1 US
Christy	Chen	GS1 Taiwan
Daniel	Clark	GS1 Canada
Denis	Coleman	GS1 Ireland
Barbara	Dorner	GS1 Austria
Alicia	Duval	GS1 Canada
AHMED	EL KALLA	GS1 Egypt
Alice	Fung	GS1 Hong Kong
Douglas	Goldman	GS1 US
Sami	GRIRA	GS1 Tunisia
Michaela	Haehn	GS1 Germany
Dennis	Harrison	GS1 US
Gary	Hartley	GS1 New Zealand
Sandra	Hohenecker	GS1 Germany
Diego	Hoyos	GS1 Colombia
Zexia	Huang	GS1 China
John	Keogh	GS1 Canada
Windy	Lai	GS1 Hong Kong
Rita	Laur	GS1 Canada
Conser	Lee	GS1 Hong Kong
Anna	Lin	GS1 Hong Kong
Hans	Lunenburg	GS1 Netherlands
Giuseppe	Luscia	GS1 Italy
Ana Paula	Maniero	GS1 Brazil
Valerie	Marchand	GS1 France
Alexander	Meissl	GS1 Austria
Dorien	Mouthaan	GS1 Netherlands
Alice	Mukaru	GS1 Sweden
Esther	Peelen	GS1 Netherlands
Halim	RECHAM	GS1 Algeria
Slobodan	Romac	GS1 Croatia
Wilson	Silva	GS1 Brazil
Tania	Snioch	GS1 Australia
Marcos	Squella	GS1 Chile
Gopal	Valecha	GS1 India
Laurent	Vieille	GS1 France
Liliana	Villalpando	GS1 Mexico
Tomas	Wennebo	GS1 Sweden
Raymond	Wong	GS1 Hong Kong

Supplier Participants:

Name		Company
Nicky	Bradley	Pall Life Sciences
David	Buynak	AstraZeneca Pharmaceuticals
Scott	Cameron	Novartis Pharma AG
Chris	Cassidy	Glaxo Smith Kline
David	Dawson	Johnson & Johnson
Mark	Dito	Medtronic
Edward	Dzwill	Johnson & Johnson
Dawn	Fowler	Edwards Lifesciences
Carin	Griffiths	Johnson & Johnson
Tracey	Herres	Glaxo Smith Kline
Grant	Hodgkins	Alcon Labs
Teresa	Hodgson	Johnson & Johnson
Mark	Hoyle	Covidien
Georg	Keller	B. Braun
Anthony	Leavor	DePuy International
Brian	Lee	Schering Plough
Lloyd	Mager	Abbott Laboratories
Tim	Marsh	Pfizer
Robert	Mennow	Boston Scientific Corporation
Karen	Peterson-Doyle	Pall Life Sciences
Cynthia	Poetker	Abbott Laboratories
Dianne	Prince	Abbott Laboratories
Roger	Smart	Douglas Pharmaceuticals Ltd
Andrea	Squire	Pfizer
Rene	Stistrup Jensen	Boston Scientific Corporation
Robin	Turner	Medtronic
Mark	Walchak	Pfizer
Mike	Wallace	Abbott Laboratories
Markus	Weinert	B. Braun
Thomas	Werthwine	Johnson & Johnson

Hospital/Retail Pharmacy Participants:

Name		Company
Frederique	FREMONT	C.H.I Robert Ballanger
Arne	Hensten	University of Tromsø
Feargal	Mc Groarty	St. James's Hospital
Teresa	Merchak	Ministry Healthcare
Jan-Joost	van Walsum	UMCG
sophie	verdeaux	Centre Hospitalo-Universitaire de Nice
Erik	Zwarter	Erasmus MC
Judie	Finesilver	National Health Service, England

Wholesaler/Distributor Participants:

Dirk	Rodgers	Cardinal Health
Ron	Bone	McKesson
Ted	Ng	McKesson
Franco	Sagliocca	McKesson

Other Participants (Transportation, Logistics, Associations, Governmental etc.):

Name		Company
Rodrigo	Klein	Interfarma
Robert	Perry	US Association for Healthcare Resource and Materials Management (AHRMM)
Sue	Thompson	US National Council for Prescription Drug Programs
Luiz Emillio	Ferreira	Brazilian Instituto Brasileiro de Etica Concorrencial
John	Howells	US Healthcare Distributors Management Association (HDMA)
Huijun	Gao	Shanghai Institute for Food & Drug Safety
Ibrahim	NAYIR	Turkish Ministry of Health, G.D. of Pharmaceuticals and Pharmacies
Ilisa	Bernstein	US FDA
Jay	Crowley	US FDA
Connie	Jung	US FDA

8. GSMP Process:

For complete information regarding the GSMP (including access to the GSMP Manual), please refer to the website at: <http://www.gs1.org/services/gsmg/overview/>.

9. Sessions

The WG is responsible for scheduling meetings to accomplish their work. Sessions are defined as face-to-face or physical meetings and teleconferences. All GSMP Sessions include the necessary Anti-Trust cautions as defined by GS1 legal counsel. The Anti-Trust caution is located on the GS1 website at: http://www.gs1.org/services/gsmg/support/gs1_antitrust.html.

10. Face-to-Face Meetings

The Process Manager schedules face-to-face meetings with reasonable advance notice to allow for proper planning. Face-to-face meetings will cover 2 or 3 days per meeting and will be held in order to speed up the work as much as possible. Participants are expected to cover their own expenses related to travel, accommodation, and time for the physical meetings. Face-to-face meetings will be arranged in GS1 GO locations: **Brussels, Belgium** or **Princeton, NJ, USA**, at GS1 Global Healthcare conferences or may be hosted by participant companies or Member Organizations



11. Teleconferences

Traceability in Healthcare II **WG** teleconferences will occur every Tuesday using the Genesys system as follows:

Which Tuesday	GMT	CET	EST	Japan (Tokyo)	Australia (Sydney)	New Zealand (Auckland)
1 st Tuesday of Month:	10:00	11:00	05:00	18:00	20:00	22:00
2 nd Tuesday of Month:	12:00	13:00	07:00	20:00	22:00	Midnight
3 rd Tuesday of Month:	14:00	15:00	09:00	22:00	Midnight	02:00 Weds
4 th Tuesday of Month:	16:00	17:00	11:00	Midnight	02:00 Weds	04:00 Weds
5 th Tuesday of Month (If applicable) same as 1 st Tuesday:	10:00	11:00	05:00	18:00	20:00	22:00

The first / Kick off teleconference is scheduled for Tuesday 31st March 2009 (07:00-08:30 EST; 13:00-12:30 CET). Separate conference call invitations will be issued via email, these will contain the local dial in numbers – Meeting room is *332443*.

12. Agendas and Minutes

GSMP Community Room facilities will be used to support this WG. The Process Manager is responsible for preparing all agendas and minutes.

Agendas must include:

- Review of the agenda.
- Approval of previous meeting or call minutes.
- Discussion of all pending issues and action items.

Meeting minutes should record:

- The original agenda
- Members, participants, guests, and staff present
- Requests for notation
- Decisions, resolutions, and action items.



13. How to Join

You can join this WG through the **GS1 Community Room**.

If you are already a GS1 Community Room member:

1. Access the GS1 Community Room at: <http://community.gs1.org/members/>
2. Click on **All Groups**
3. Choose **HC Traceability in Healthcare** from the list. The group's home page will appear.
4. Click on **Join the Group** in the upper left of the group's home page

If you are NOT a GS1 Community Room member:

1. Apply for GS1 Community Room membership by using our Online Form at: http://community.gs1.org/kmembership_info/person_signup/
2. Once you receive your username and password, follow the directions above to join this WG.