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The global language of business

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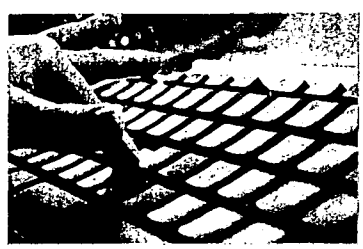

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HUG Standards Development Strategy

Version 1.1
13 Nov 06

Milestones

A1	26 Jul 06	Adopt existing GS1 Application Standards in Healthcare
A2	31 Dec 07	GSMP: Prioritized AIDC Application Standards
S1	31 Oct 06	GSMP: GTIN Allocation Rules for Healthcare
S2	31 Mar 07	GSMP: Healthcare Business Data AutoID Standard
S3	30 Jun 07	GSMP: Healthcare Product Serialization Standard
S4	30 Sep 07	GSMP: Healthcare Data Carrier/Scanning Standard

B1	28 Feb 07	HUG Business Case for Packaging/Marking AIDC

2006 A1 S1 2007 S2 B1 S3 S4 2008 A2

GS1 Standards Group

Packaging/ Direct Marking	GTIN Allocation; Business Case; AutoID Data; Carriers; Serialisation; AIDC Application Standards
Product Classification	Product Data Dictionary
Healthcare Data Synch	eCatalogue

GS1 ヘルスケアユーザーグループ(HUG)について

2007.3.23 訂正版
物流通システム開発センター

1. 経緯

1) 2005年5月、大手グローバルヘルスケア企業がボランタリーでGS1の中にヘルスケアユーザーグループを結成

ミッション: 患者の安全確保を目的としてヘルスケア業界で使用するための自動認識のグローバル標準を開発して普及させる

ヴィジョン: 各国の関係官庁や業界団体が流通標準化について検討する際に頼られる唯一の相談窓口となる

目 的 : ヘルスケア分野の流通標準の開発、eビジネスの新技術の業界への啓蒙、GS1に対する助言、GS1標準の普及促進

2) 開催動向

2005年9月第1回HUG会議開催、以後2006年9月まで4回開催。 年3回開催が基本。

	開催時期	開催場所	日本の参加企業
1	2005年 9月	ブリュッセル	オリンパスメディカル、テルモ
2	2005年11月	ブリンストン(米)	オリンパスメディカル、テルモ
3	2006年 3月	ローマ	
4	2006年 6月	ミネアポリス(米)	オリンパスメディカル
5	2006年 9月	パリ	オリンパスメディカル
6	2007年 2月	ベルリン	オリンパスメディカル
7	2007年 6月	オーランド(米)	

2. 現在の組織・活動

- **4つのワーキングチーム(略称 WT)が活動中**
  - ① オートIDデータWT……製品識別のためのビジネス要件、データ要件をまとめる
  - ② GTIN付番ルール WT ……商品識別コードGTINの付番ルール作成。原案が完了。
  - ③ シリアライゼーションWT……医療機器や人体埋め込み器具自体の識別マーキングの検討
  - ④ ビジネスケース WT ……利用事例の収集・アウトプット(ミシガン州立大学協力)

- 現在のメンバーは、約40社、64名。
  医薬品メーカー、医療機器メーカー、GS1各国組織が中心。 各会議開催ごとにメンバーの変動あり。

医薬品メーカー	15	ファイザー、ジョンソン&ジョンソン・ファーマ、メルク、バクスター、アストラゼネカ、サノフィ・アベンティス、ノバルティス、プリミール、セレシオ、ウェイス・バーマスケジュールユーテカル、GEODIS、セファロン、アムゲン、アンジオ・ダイナミックス、BVメッド、
医療機器メーカー	14	エースクラップ、ビー・ブラウン、スミス・メディカル、ボストン・サイエンティフック、クック、メドトロニック、タイコ・ヘルスケア、ボール・メディカル、アルコン・ラボラトリーズ、エドワーズ・ライフサイエンス、ホスピーラ、ジョンソン&ジョンソン、テルモ、オリンパス・メディカル、
IT ベンダー	3	IBM、SAP、オラクル
政府系機関	7	米国 FDA、英国 NHS、カナダ PHSC(パーソナル・ヘルス・セーフティ・コンサルタンツ)、ニュージーランド厚生省、ドイツ厚生省、フランス厚生省、スペイン州政府
卸業者	2	米マッケソン、仏クラディ・メッド、
病院	2	仏ポンピドー総合病院、ジュネーブ大学病院
運送	1	DHL
団体	1	欧州ジェネリック医薬品協会、
合計	40	

GS1 組織	15	本部、米、英、仏、独、伊、スイス、日、スペイン、オーストリア、オーストラリア、カナダ、ハンガリー、アイルランド、オランダ、

- 上記GS1の各国組織は希望すれば Non-voting メンバーとして参加可能である。
  役割: 上記ワーキングチームに参加して HUG の活動をサポート

3.HUG の活動と国内業界の GS1 標準化の動向比較

W T	活動概要	国内業界の対応動向
オート ID データ WT	現在、医薬品へのバーコードによる製品識別に必要なデータ項目と必要理由について、日米欧からアンケート調査し、記入内容を精査中。国際電話会議に流開センターが参加。5月にデータ要件をまとめる予定。	医療機器業界(別紙参照) 1999年 医療機器業界GS1 採用宣言 2000年 UCC/EAN-128 ガイドラインでGS1 データ項目標準化。 2005年日本医療器材工業会GS1 採用 2006年日本歯科商工協会GS1 採用 2006年日本医用機器工業会GS1 採用 (銅製用具への二次元シンボル採用) 医療用医薬品業界(別紙参照) 1989年 JANコードの利用開始 2006年9月厚労省GS1 標準によるバーコード表示実施要項を通知 2007年3月厚労省バーコード表示実施要項を一部改正
GTIN付番ルール WT	医療用医薬品、医療機器、大衆薬についての付番ルールの原案作成済。 4月開催の GSMP で検討予定	① 医療用医薬品、医療機器ともにGS1付番ルールに対応可能 ②大衆薬工業会での付番ルールの普及推進(流通SCM事業との連携必要)
シリアライゼーション WT	現在、医療機器や人体埋め込み器具自体の識別に必要なデータ項目と必要理由について、日米欧からアンケート調査し、記入内容を精査中。	日本からオリンパスメディカルシステムズ(株)が医療機器業界の代表として参加。
ビジネスケース WT	現行の医療業界でのGS1 標準による事例を収集、編集中。	HUG 会議で流開センターが進捗フォロー

GS1 HUG

GS1 HUG™ Global Healthcare User Group
Berlin Germany 30 January - 1 February 2007

30 January 2007

From 8:30 onwards: Registration

GS1 HUG™ Primer

9:00 – 11:30 Training Session on GS1 Standards – BarCodes, eCom, GDSN and EPCglobal, GS1 HUG™ Basics – Mission & Vision

BarCodes and eCom – *David Buckley, GS1 Global Office*

David Buckley is a 10 year veteran of GS1. In that time he has occupied various roles in the development and implementation support of GS1 standards. In his current role, Mr Buckley's main responsibilities are focused on assisting GS1 Member Organisations with tools that support the consistent implementation of standards with particular emphasis on the GTIN Allocation Rules and Helpdesk web systems. Mr Buckley also provides the secretariat to the ISO working group in the area of Bar Code data content

Upon completion of his degree in Economics from the University of Loughborough, Mr Buckley joined the graduate programme of the Xerox Corporation in his native of England. During this time he worked primarily on quality and product rationalisation. Xerox further supported his MBA studies which were awarded in 1994.

Within the HUG work programme, Mr Buckley has provided GS1 Staff support to the Work Team on GTIN Allocation Rules for Healthcare led by Mark Walchak (Pfizer) and Mark Hoyle (Tyco Healthcare) and the Bar Code Implementation in Healthcare Baseline survey.

GDSN – *Rolf Stark, Sinfos*

Rolf Stark holds a Diploma as Master of Business Administration at the University of Trier. After his studies, he was project manager for development and implementation of a computer aided sales information system for the Chamber of Commerce, Germany. In 1992 he joined Madakom, a joint venture of GS1 Germany (formerly Centrale für Coorganisation GmbH) as Project manager and GfK Panel Service, a world leading market research institute. Madakom provided scanner based P.O.S. data for market research purposes.
From 1997 to 2002 he was the Division Manager and Executive Board Member at GS1 Germany responsible for SINFOS, the standard based master data pool. Since 2002 Rolf is Chief Executive Officer of SINFOS GmbH, a joint venture of GS1 Germany and Pronet NDH AG, a leading supply chain management service provider.
Since 1997 Rolf Stark attends to the interests of the German consumer goods industry in miscellaneous national and international standardisation bodies of GS1-UCC, ECR Europe and Global Commerce Initiative (GCI).

GS1 HUG

EPCglobal – *Craig Alan Repec, GS1 Germany*

Craig Alan Repec is Project Manager in the RFID/EPC Solutions division of GS1 Germany. Over the past five years, he has been involved in a range of international standardization projects for both EDI and EPC, with responsibilities including the coordination of German efforts within GS1's Global Standards Management Process (GSMP) and communications for GS1 Europe's European EPC Project (EEP)

Craig studied German at the College of the Holy Cross in Worcester, Massachusetts, including a year abroad at the Humboldt-Universität in Berlin, Germany. Thereafter he was assigned an English language teaching assistantship at a commercial academy in Vienna, Austria, by the Fulbright Commission. Following completion of Keane Inc.'s Accelerated Software Development Program (ASDP), Craig worked as a Keane consultant on diverse application management engagements in Boston and Washington DC for over two years. He then served as project manager with an internet technology start-up in Bonn, Germany, before joining GS1 Germany in 2001.

The HUG – Mission and Vision – *Rich Hollander, Pfizer*

Rich Hollander is Senior Director of Packaging Services for Pfizer Inc.'s Global Manufacturing group. His responsibilities include package design and development activities supporting the Animal Health, Consumer Healthcare and Human Health businesses as well as the development and implementation of global packaging strategies. Rich received his Bachelor's Degree in Mathematics from Rutgers University in 1985 and his Masters Degree in Industrial Engineering from the Georgia Institute of Technology in 1987. He worked as a consultant with Andersen Consulting from 1988 until 1990 focusing in manufacturing information management systems. He joined Pfizer in 1990 as an Industrial Engineer and in 1992 became Manager of Package Engineering. Since then Rich's responsibilities have grown to include all areas of package design and development for Pfizer. Outside of Pfizer Rich has been an active leader on various committees, work groups and task groups aimed at addressing issues within pharmaceutical packaging. Rich currently co-chairs the GS1 Global Healthcare User Group and is the former chair of the Product Quality Research Institute's Packaging Work Group, USP Project Team on Packaging, Storage and Distribution, Institute of Packaging Professional's Drug and Pharmaceutical Packaging Committee and PhRMA's Packaging Work Group. He continues to be an active member on all of these work groups.

GS1 HUG

Work Teams

Auto ID Data - *Mark Walchak, Pfizer & Mark Hoyle, Tyco Healthcare (see HUG Work Team feedback session)*

Serialisation - *Stephen Hess, Merck – (see HUG Work Team feedback session)*

Regulatory – *Jackie Elkin, Medtronic*

Jackie has been working in the medical device sector for more than 18 years. Currently, Jackie holds the position of Regulatory Compliance Manager for Medtronic, Inc. Corporate Regulatory Compliance. Her responsibilities include the development and implementation of global policy and standards around Standard Product Identification for Medtronic products and services. In this role, she is also responsible for managing product identification applications and associated governance teams to ensure Medtronic distributed products are in compliance with established Corporate Quality and Regulatory Affairs Policy.

Jackie's responsibilities also include providing regulatory compliance leadership and consultation to project teams from various functional groups within the corporation in order to establish regulatory, quality and validation compliance for global business solutions and enterprise systems.

Prior to joining Medtronic, Jackie worked as a Sr. Paralegal in the Hospital Products Group of Pfizer, Inc. Her background includes managing product liability and patent litigation cases as Sr. Paralegal and then as a Litigation Support Manager.
Jackie has a Paralegal Degree and an IT Management Degree from Concordia University, St. Paul, Minnesota.

Support Team

Communication & Coordination – *Jim Willmott, Smiths Medical*

Jim Willmott is the Group Labelling Manager for Smiths Medical, a part of Smiths Group plc. His responsibilities include the development of, and ensuring compliance to, corporate identity guidelines for packaging, labelling and instructions for use, used by the manufacturing sites worldwide. This encompasses regulatory, legal and language requirements for all medical devices sold in all markets. In addition, Jim is also responsible for the labelling artwork creation, for key products lines sold in Japan, using primarily MAC computers and applications.

Jim joined Smiths Medical in June 2002, having previously worked for other leading medical device manufacturers, in both Regulatory Affairs and Marketing positions. He was based in Germany and Japan before returning to the UK to join Smiths Medical. He is also a member of several committees and task forces within trade associations and standards authorities (e.g. ABHI, Eucomed, BSI & CEN)

11:30 – 12:00 Registration and Lunch

12:00 - 13:00 Lunch

GS1 HUG

13:00 Opening and Introduction

Welcome by GS1 GO - *Miguel Lopera, GS1 Global Office, Belgium*

Miguel A. Lopera is President and Chief Executive Officer of GS1 (formerly known as EAN International) since April 2003. To add to his responsibilities, he was appointed Chief Executive Officer on 1st January 2004 of GS1 US (formerly known as the Uniform Code Council - UCC), the US based counterpart and joint owner with EAN International of the global EAN.UCC standards system.
Mr. Lopera, a Spanish national, brings to both organizations a wealth of division management, marketing and IT experience gained in every aspect of the FMCG business having spent 24 years with Procter and Gamble. Joining P&G as an IT analyst in 1979, he became IT Director of P&G Spain and later IT Director of P&G UK, Ireland and Scandinavia. In 1992, he changed career to Marketing, becoming Marketing Director of Laundry Detergents, Europe, in Brussels, Marketing Director of Fabric & Home care in Spain and later responsible for the Fabric & Home Care and Food & Beverages Divisions of P&G Iberia (Spain and Portugal) based in Madrid. His major expertise has been in the areas of new brands introduction and European pricing.

Mr. Lopera is an early developer, strong believer of Collaborative Commerce between Manufacturers and Retailers. He created a Collaboration Program between key retailers such as Mercadona, Carrefour, Auchan and P&G Spain back in 1984, based on multifunctional teams, something unique at that time.

Miguel is an Ingeniero Superior of Electronics and Telecommunications (E.T.S.I.T of Madrid) and MBA for the Instituto de Empresa (Madrid).

Welcome GS1 Germany - *Jörg Pretzel, GS1 Germany*

Jorg Pretzel became CEO of GS1 Germany (formerly CCG) in 2003 and Chairman of GS1 Europe in 2005. Prior to joining GS1 Germany, Jörg Pretzel had a managing position at Herlitz PBS AG and Uvex GmbH. Between 1981 and 1996, Jörg Pretzel served as CEO for Central Europe and Vice President of Sales at A.C. Nielsen. Jörg Pretzel graduated in Business Management at the University of Munster.

Greeting - *Jürgen Völlkopf, B.Braun*

Jürgen Völlkopf joined B.Braun in 1990 after studying business administration and mechanical engineering at Technical University Darmstadt, Germany. The first years he worked as project engineer on various topics such as, customer service reorganisation, master production scheduling, early e-commerce projects and also took part in a bar coding working group of EUCOMED.

In 1994 he moved over to controlling and started building up the B. Braun Group management reporting systems. In 1999 he became Senior Vice President Controlling and business administration.

Since 2002 he is the first globally responsible logistic manager of B.Braun as Senior Vice President Logistic and Supply Chain. He is responsible for all logistic operations of the B. Braun Group and coordinates the supply chain activities of all B. Braun Divisions. In dual roles he is responsible for the Supply Chain Management of the largest division, Hospital Care. In this position he's takes care of the global master scheduling, inventory, delivery performance and strategic purchasing of Hospital Care

GS1 HUG

Ministry of Health Germany - *Dr. Klaus Theo Schröder, State Secretary*

Professional career.
Dr. Schröder's studies were followed by research, investigating issues relating to the use and effects of modern technologies, structural, research and innovation policies at the Comprehensive University of Duisburg, the Vienna University of Economics and Business Administration, the University of Trier and the Fraunhofer-Institut für Systemtechnik und Innovationsforschung in Karlsruhe
Political career:
In November 1986 Dr. Schröder entered into (what was then) the Ministry for Labour, Health and Social Affairs of the region of Northrhine-Westphalia in Düsseldorf; various executive functions in the fields of, inter alia, labour market and structural change, children, youth, family affairs as well as basic and cross-cutting issues of social and health policy.
In December 1994 he became State Secretary at the Thuringian Ministry for Social Affairs and Health in Erfurt, a function in which he was successful in elaborating, inter alia, a new hospital plan and restructuring the Thuringian hospital landscape
In December 1999 he became State Secretary at the Berlin Senate Administration for Labour, Social Affairs and Women, where he took on responsibility particularly for health policy, the stabilisation of Berlin's health insurance funds and the reorganisation of the cities hospitals.
In December 2000 Dr Schröder became a top executive at the Rhön-Klinikum AG, Bad Neustadt an der Saale, in charge of the management regions of Baden-Wuerttemberg, Hesse, Northrhine-Westphalia, in January 2001, State Secretary at the Federal Ministry of Health, in October 2002, State Secretary at the Federal Ministry of Health and Social Security and in November 2005, State Secretary at the Federal Ministry of Health

GIRP (European Association of Pharmaceutical Full-Line Wholesaler) - Lothar Jenne, *Chairman Technical Committee*

In 1970 Lothar Jenne entered into the family business "Max Jenne Arzneimittel-Grosshandlung KG", a family-run medicine wholesale trade company based in Northern Germany, employing approx. 350 staff. In 1977 he became Managing Director of the subsidiary Max Jenne GmbH. In 1980 he became a general partner of the Max Jenne Arzneimittel-Grosshandlung KG
From 1990 – 2005 Lothar Jenne was vice-chairman of the WGA (Trade Association for Wholesale and Export Trades in Schleswig-Holstein), 1997 – 2006, chairman of the PHAGRO (Federal Association of the Pharmaceutical Wholesale Trade) and since 1998, chairman of the administrative board of IFA GmbH (Information Centre for Medicine) the nation-wide clearance centre for all national data on medicines and drugs, 2003 a member of the Executive Committee of GIRP - the European Association of Pharmaceutical Full-line Wholesalers, 2005 the chairman of the Technical Committee of GIRP, 2006 the chairman of the PHAGRO Rationalisation Committee and 2006 a member of the executive committee of the North German employers' association AGA

14:30 – 15:00 Coffee break

GS1 HUG

ADKA, Association of Hospital Pharmacists Germany - *Dr. Werner Kittlaus*

Dr. Hans Werner Kittlaus is chairman of the committee for drug packaging of the Bundesverbandes Deutscher Krankenhausapotheker (ADKA) *[German Association of Hospital Pharmacists]*.

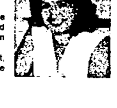
After graduating in pharmacy at the University of Munich he obtained his PhD at the Max-Planck-Institute for Biochemistry. He first worked at the Munich University hospital pharmacy before taking on the lead in the central pharmacy of the hospitals in the Munich region.

Dr. Kittlaus received the Lösch-Innovation-Prize for his developments in the field of safe cytostatics-containers and is regularly speaking on the topic of "Packaging and Identification of drugs as related to patient safety, prevention of medical errors and protection of patients and staff".

SPAIN – Projects of the Regional Healthcare Services Areas of Andalusia, Galicia and Catalonia – *Jesus Gavira. Sub Director Purchase and Logistics, Andalusia;*

Meritxell Serra Sanz, Purchase and Distribution Policy Manager and Carme Casanovas Garill, Purchase Assistant Manager, Catalonia

Meritxell Serra has a degree in Medicine and Surgery and in Economic Sciences. She has over 17 years experience in Financial Management in some of the 8 Hospitals of the Institut Català de la Salut. Moreover, she was Financial Manager of Bellvitge Hospital, as well as Financial Manager of the Research and Investigation Foundation of Bellvitge (IDIBELL) for 9 years.
Currently, Meritxell Serra is Purchase Manager of the Institut Català de la Salut and her responsibilities include investment, purchase for all Catalan Primary Healthcare and the 8 public hospitals of their Institution; reducing costs, cataloguing all products as well as product identification and providing all services required for Healthcare.
In addition, she is also a Member of the Designing Core Team, mainly in charge of the economic aspects of the SAP project.



Carme Casanovas has a degree in Medicine and Surgery. She has been working for 25 years in the Public Health System, specifically in the economic and medical area. She was Purchase Manager for nine years in the Traumatology and Rehabilitation Hospital in La Vall d'Hebron. At the same time, and from 1994, she became the Chief of the Outpatients Area in this hospital
In 1999 she was nominated Logistics Assistant Manager and Administrative Contractor in Bellvitge Hospital, being mainly responsible for the purchase and logistics management and budget's pursuit. During this period, she also took part in the Board of Directors, among other functions
Currently, she is Purchase Assistant Manager of the Institut Català de la Salut, coordinating hirings, purchases and logistics. Furthermore, she is a member of the team that is in charge of implementing the SAP project

Benjamin Rodriguez, Sub Director Economic Resources, Galicia

Benjamin Rodriguez has a degree in Industrial Engineering and is the Economic Resources Sub director of the Ourense Hospital Complex (a hospital with more than a thousand beds) and the Logistics Innovation Project Manager of SERGAS. Benjamin has been working with the Automatic Identification and EDI technologies and has participated in many conferences for Logistics in the Health Field. He has been awarded with the 10th National Prize for Health Administration and Management Innovation in the Supply Chain and is professor for the Public Management Foundation of Galicia Health Administration in the Purchase and Logistics in Health Area.
His previous jobs include, Technical Director of a water packer company, Supply Chain Chief Executive of the cars factory Citroen and Purchase Chief Executive of the Ourense Hospital Complex.

CHINA: The New Regulations for Medical Devices – *Zexia Huang, GS1 China*

Zexia Huang has worked at GS1 China (the Article Numbering Center of China) for 11 years since she graduated in 1995. She did research work on Supply Chain Management and has been involved in developing National Standards on numbering and bar coding, based on GS1 and ISO standards. She was responsible for International cooperation from 1998-2001 and, since 2002 as a Deputy Director of Member Services, she is responsible for designing and maintaining member service system as well as developing training courses and organising training programs for member companies and the staff of GS1 China.

Currently, Zexia is on loan from GS1 China and working and training at the GS1 Global Office in Brussels on Traceability, Healthcare and EPC. With a bachelor degree in International Enterprise Management, she received a Master education on Project Management before she moved to Brussels in January 2006.

Business Case for Global Standards in Healthcare - *Ed Dzwill, J&J Pharma and Dr. Hugh Lockhart, Michigan State University*

Ed Dzwill is Manager Package Technology for the Global Pharmaceutical Supply Group since March 2006. GPSG provides supply chain management to Johnson & Johnson's Pharmaceutical sales and marketing companies, Ortho-McNeil Pharmaceuticals Inc, PriCara, Ortho Women's Health and Urology, Janssen Ortho-McNeil Primary Care, Ortho-McNeil Neurologics, Alza, Tibotec, Ortho Neurogena, Vistakon Pharmaceuticals, and Ortho Biologics. His responsibilities include discovery and evaluation of new package design and development activities as well as involvement in global packaging initiatives in Mass Serialization, RFID, Anti-Counterfeiting, and Digital Printing.

Dr. Hugh Lockhart holds B.S. and M.S. degrees in Packaging, and a PhD in Forestry Products. He has taught packaging courses and conducted research at the School of Packaging since 1977. Prior to 1977, Hugh worked for seven years as Manager of Packaging Technical Services at Parke, Davis and Company in Detroit, Michigan.

Since 1977 Hugh has taught courses in Pharmaceutical and Medical Device Packaging and Packaging Laws and Regulations. He has conducted research in several areas important to medical packaging. Among them are dissolution shelf life of solid oral drugs, refrigerated (cold chain) shipment of drugs, torque behaviour of CT closure-closure systems, legibility of package labels, and tamper evidence of packages. He has also conducted research in medical device packaging related to the seal strength and seal integrity of sterile packages. In 2002 Hugh was the coordinator of the Drug Master File Workshop sponsored by the School of Packaging in Washington, D.C.

Hugh is a member of national research and testing committees, related to medical packaging. They include; ASTM Committees D-10 on Packaging and F-2 on Flexible Barrier Materials and the Packaging Working Group of the Product Quality Research Institute (PQRI), which is a national group of academic, government and industry experts in packaging of pharmaceuticals. Hugh served from 1995 to 2005 as a member of The USP Expert Committee on Packaging, Storage and Distribution.

16:00 Meeting closure

19:30 Networking Night

31 January 2007

08:00 – 08:30 Coffee

Unit Dose Requirements

Hospital Tilburg, Netherlands - *Albert W. Lenderink*

Albert Lenderink studied pharmacy at the University of Leiden from 1974 to 1982. He then worked at the Ziekenhuisapotheek Midden-Brabant as a hospital trainee pharmacist from 1982 to 1984, hospital pharmacist from 1984 – 1990 and then as the Director of pharmacy from 1990.

The Ziekenhuisapotheek Midden-Brabant is responsible for the drug distribution of the following institutions; Integraal Zorgcentrum De Vloet, Oisterwijk, St. Elisabeth Ziekenhuis, Tilburg, GGZ Midden-Brabant, Tilburg, Dongen & Waalwijk, Kraamhotel De Meiboom, Tilburg, Revalidatie Centrum Leypark, Tilburg, TweeSteden ziekenhuis, Tilburg, TweeSteden ziekenhuis, Waalwijk, Verpleeghuis St. Elisabeth, Goirle, Stichting De Runne, Goirle, Verpleeghuis de Voickaert, Dongen, Dr. Bernard Verbeeten Instituut, Tilburg, De ver vijzels, 's-Hertogenbosch and Bergland Kliniek, Tilburg.

Hospital Forlì, Italy - *Martina Minguzzi and Silena Sistu*

Martina Minguzzi is Director of the Inter-Health Board Project of Oncological Pharmacy and Radiopharmacy for Forlì Health Board and IRST (Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori), Meldola, also co-ordinating the same sector for the entire area of Romagna.

After having graduated in Pharmacy from the University of Bologna she obtained a PhD in Oncological Pharmacy from the University of Milan in 2002. She first worked as a Pharmacist in Santa Maria delle Croci Hospital in Ravenna and, up to 1999, chief of the Pharmacy Department of Ravenna Health Board. From 2002 to 2004, Ms Minguzzi was the Co-ordinator of the Pharmacy Programme of Forlì Health Board.

Silena Sistu is Head of the Information and Communications Technology Unit of Forlì Health and Social Services (Azienda USL di Forlì).

Ms Sistu holds a Degree in Electrical Engineering from the University of Bologna and a Post-degree course in Information Systems Analysis organized by the Region of Emilia Romagna. She previously worked as Head of the Data Processing Unit of the Urban Water Consortium for the provinces of Forlì and Ravenna (now Romagna Acque S.p.A.) and Programme analyst in the Information Systems Department of Rimini Borough Council.

Ms Sistu was co-author for the theses "Principles and innovative applications in hospital logistics' unitary drug dose" (2004) and "Computerized management of sensitive personal information in the public health sector" (2006), Bologna University.

University Hospital Geneva, Switzerland – Dr. *Pascal Bonnabry*

Since 2000, Dr Pascal Bonnabry is chief pharmacist of the Geneva University hospitals (Switzerland). He is head of the information systems resort of the Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA). Dr Bonnabry studied at the Geneva University and obtained his pharmacist diploma in 1992. He specialised in clinical pharmacology and obtained a PhD in 1996. Since 1996, he is active in hospital pharmacy.

He teaches hospital pharmacy at the Geneva-Lausanne school of pharmacy and has the function of « chargé de cours ». He organizes a three year post-graduate education in hospital pharmacy, in collaboration with the University and the Lausanne University hospital, since 1999. He has specialization titles in clinical pharmacology and hospital pharmacy.

Hospital Bruges, Belgium - *Frankie Meulemann*

Frankie Meulemann has over 30 years experience in the hospital pharmacy of Sint-Jan, Bruges and is responsible for automation. He is project leader pharmacy software (1996 – 2006) for Infohos-IHC – the Belgian standard for hospital pharmacy software (more than 70 hospitals). He is also responsible for the general product database, Infohos-IHC.
Frankie is supporting the use of bar codes at the VZA (Flemsch organisation of hospital pharmacists) and an active user of e-commerce in collaboration with EDI-Health – the association of Belgian healthcare suppliers.

16:20 – 16:00 Coffee break

Hospital Wiener Krankenanstaltenverbundes (KAV), Austria – *Dr. Wolfgang Gerold*

Dr. Gerold is leading the pharmacy division of the Directorate General of the Wiener Krankenanstaltenverbund, Vienna, since 1990 and is also responsible for medical economics and pharmacy since 2007. Having studied pharmacy at the University of Vienna, he obtained his PhD at the same university at Prof. Dr. Heinisch in 1986. He worked in hospital pharmacies and graduated additionally in Hospital Management.

Dr. Gerold is teaching at the University of Vienna and in the framework of the professional training of the Austrian Pharmaceutical Chamber and the Medical Chamber in Vienna. He was the founder and chief-editor of the trade magazine "Österreichische Krankenhauspharmazie" from 1987 – 1999 and member of the advisory board of the "European Hospital Pharmacy" until 2002. Dr. Gerold holds several positions at the Austrian Pharmaceutical Chamber and is author of the "Arzneimittel-Schnellerkennung" (a guide to quickly and safely identify drugs) since 1983.

RFID in Hospitals

University Hospital Jena, Germany - *Dr. Michael Hartmann*

Dr Michael Hartmann has served as the Head of the Pharmacy Department at the Hospital of the Friedrich-Schiller-University, Jena, Germany, since 1995. Prior to this appointment, he held positions including Senior Staff Member in the Pharmacy Department at the Hospital of the Barmherzigen Brüder, Paderborn, Germany, and Research Fellow at the Harvard Medical School, Mailman Research Center, Belmont, USA.

In addition to holding a degree in Pharmacy, Dr Hartmann has specialized in clinical and educational pharmacy and he has been awarded a Master Business and a Doctoral Degree. His areas of study and interest also include public health, economy for medical practice, and cost-effectiveness analysis for medical technologies and pharmaceuticals. He holds the venia legendi for Health Economics and is teaching Health Economics, Public Health and Comparison of Health Care Systems for medical student at the University of Jena.

Chelsea and Westminster Hospital London, UK - *India Hardy*

India Hardy is a pharmacist Project Managing within the UK's National Health Service. Responsibilities include the implementation of inpatient electronic prescribing and charting of medication using GE Healthcare's Lastword application. This project's pilot aims to incorporate the use of RFID by nursing staff for positive patient identification, at the patient's bedside, at the time of medication administration.
India studied a Bachelor of Pharmacy at the University of Sydney and holds an MRPharmS for practicing in the UK.

12:30 – 13:30 Lunch

HUG Cooperation Partner

Eucomed (The Voice of the Medical Technology Industry in Europe) - *Mike Kreuzer, Chairman ETF*

Michael Kreuzer is the Technical and Regulatory director of ABHI (Association of British Healthcare Industries). In addition, he is also the chairman of the Eucomed E-business and supply chain management task force (ETF) as well as the Association Secretaries Council, a role which brings him into close contact with the various National medical technology associations in Europe. The current focus of the Eucomed ETF group is bar coding and auto identification capture technologies.

e-Catalogue, Classification, GDSN

Comparatio Health (Purchasing Organisation of University Hospitals in Germany) – *Dr. Frank Brüggemann*

Frank Brüggemann has over 20 years experience in the healthcare industry. His complete hospital background reaches from his experience at the ward department and his work as a physician in surgery and orthopaedics as well as in IT and process optimization, consulting in various areas. Frank is currently working as the Managing Director of GSG and as a senior consultant for Comparatio Health GmbH. In addition to being a member of the GS1 global Healthcare User Group, Frank is working with the University of Applied Sciences Faculty of Business Management and Social Sciences Healthcare Computing and Quantitative Methods in Osnabrück, Germany. His main focus is the standardization and optimization of logistics processes in hospitals.

His knowledge in informatics and healthcare processes is an ideal prerequisite to work on global standards regarding product identification and communication for the healthcare industry.

14:30 – 15:00 Coffee break

Global Data Synchronisation Network (GDSN) – *Tom Werthwine, Johnson & Johnson Medical Devices*

Tom Werthwine has over 25 years experience in the medical device industry. His background includes regulatory affairs, research & development, and marketing.

Tom is currently with the Johnson & Johnson Global Supply Chain Group. In addition to being a member of the GS1 Global Healthcare User Group, Tom is an active member of the AIM Global Healthcare Action Group, the EPCglobal Healthcare and Life science Action Group, and the Health Industry Business Communications Council. Tom holds a B.A. from Penn State University.

Classification Systems in GS1 – *Zoltan Patkai, GS1 Global Office*

Zoltan Patkai has over twenty years experience in various fields of supply chain and information management with excellent references gained from Blue Chip companies such as Dow Chemical and Unilever, in a global market based in Belgium, UK and Hungary. He negotiated agreements, owned business processes, delivered solutions to complex problems ranging from strategy formulation to implementation helping to re-engineer processes and run companies to meet the new business requirements, cope with huge volume growth and changing customer needs.
Zoltan joined GS1 in July 2003 and is responsible for leading the development of Global Product Classification methodology.

19:00 Evening event

1 February 2007

09:30 – 9:60 *Coffee*

HUG Work Team Feedback Session

Auto-ID Data – *Mark Wdchak, Pfizer and Mark Hoyle, Tyco Healthcare*

Mark Wdchak is Senior Manager of Global Packaging Technology at Pfizer. His area of responsibilities includes areas of consumer health, human health and animal health. Mark is active in the bar coding, and anti-counterfeiting areas. Mark is also a member of the International Federation of Animal Health's Global Traceability Core Team.

Mark received his bachelors degree in Packaging Technology from Michigan State University in 1970, a Masters of Business Administration from Xavier University in 1976, and is currently completing course work for a Masters in Packaging Technology from Michigan State University.

Mark joined Pfizer in 2004 after having worked for 30 years in the healthcare and consumer goods area.

Mark Hoyle has a broad and varied experience across a number of industries but has concentrated within pharmaceutical and medical device manufacturing for the last 12 years. He is today focused with Tyco Healthcare as the leader for European Packaging.

Mark's growth in the industry follows an engineering path, especially in the area of new product and process introduction. In his present role he is responsible for global strategy development and implementation for product identification, complemented with a background in automation and controls.

Prior to joining Tyco Healthcare, at the beginning of 2005, Mark has worked as Process Development Group Manager for Ocular Sciences Inc., with key responsibilities for product launch of their daily disposable contact lens range. Prior to his six years with OSI he has worked as a Systems Validation Engineer for Glaxo, staying very involved with developing technologies and their introduction to the healthcare industry.

Serialization – *Stephen Hess, Merck*

Stephen Hess joined Merck in 1987 supporting the animal health packaging business. Since then he has worked in various Human health and vaccine packaging related positions including International and Domestic responsibilities. He is currently the Executive Director of packaging technology for Merck and Co., Inc.
Prior to joining Merck, Stephen worked at Purdue Pharma and Olin Chemical in packaging related functions. He graduated from Michigan State University with a BS in Packaging in 1980.

11:00 – 11:30 *Coffee break*

HUGLITs (HUG Local Interest Teams):

Switzerland – *Christian Hay, GS1 Switzerland*

Christian was born in Zurich, Switzerland in 1954 and is married with 2 children. Christian has a track record of over 15 years in Healthcare and played a leading role in the implementation of the EAN UCC System (now GS1 System) in narcotics control in Switzerland, logistics between pharmaceutical companies and wholesalers and aspects of the new billing rule for Health insurance providers (TARMED). He worked for over 3 years for GS1 Europe, Switzerland and France - to address the specific standardised identificaton needs of the healthcare sector. Traceability and product pedigree are the key issues for patient safety. He is further involved in several hospital projects with bar codes and RFID, as support to enhance accuracy and reduce risks. He coaches some of these hospitals in the development of new process management.

Chile – *Jose Luis San Juan, GS1 Chile*

Jose Luis San Juan has taken responsibility in GS1 Chile for the Identification Area, and from a few months ago he is involved in the preparation of work groups related to codification standards in different areas from the Chilean National market (Health [public and private], Retail, Export, etc.).
Jose has 8 years experience in SONDA S.A. (the largest IT company in South America), where he has designed and participated in the implementation and installation of technological solutions in more than 35 warehouses and more important centres of distribution in the country. From establishing client requirements, designing solutions, technical and economic proposals, he then provides detailed implementation.
Jose has previously worked in new technologies in 'Foundation Chile', through the sale and distribution of South American technological products of different types and origins. He was born in Spain and moved to Chile in 1994. He developed, for more than 10 years, substantial work in the School of Engineers of Mines of Madrid, through the investigation and development of technological products associated to the mining and other industries in general.

Australia-New Zealand – *Ulrike Kreysa, GS1 Global Office on behalf of Mark Fuller, GS1 Australia*

12:45 – 13:00 **Discussion – Summary – Next steps – Date of Next Conference**

13:00 **Closure of meeting**

13:00 – 14:00 *Lunch*

14:00 – 17:00 **Visit to the Warehouse of Phoenix – a German Wholesaler LIMITED TO 50 PARTICIPANTS (currently all spaces taken)**

GS1 Activities

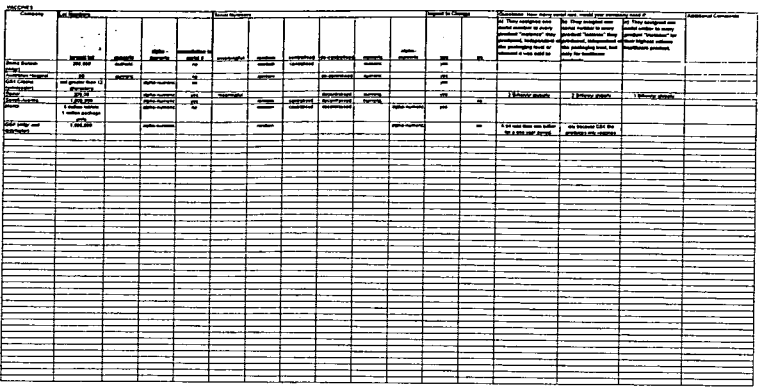
EPCglobal HLS BAG (Health Life Science Business Action Group) – *Michael Rose, J&J and Ron Bone, McKesson*

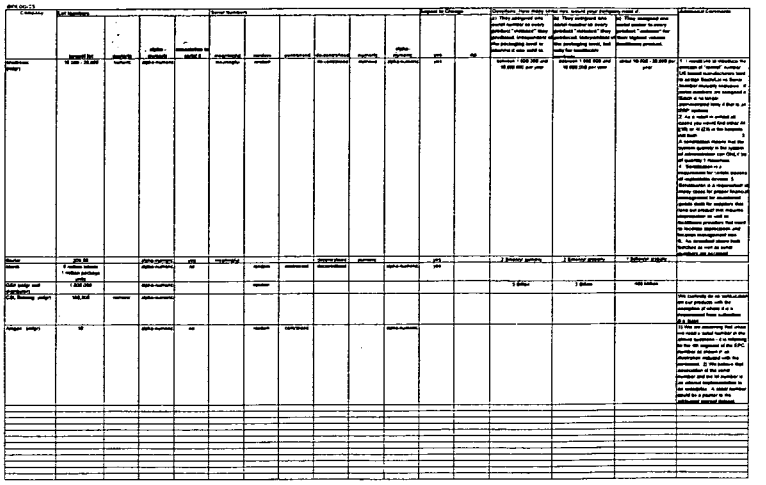
Mike Rose has worked for Johnson & Johnson for over 30 years.
Mike was appointed Vice President, RFID/EPC Global Value Chain with responsibility for Johnson & Johnson's RFID/EPC strategy. Mike's key responsibilities include, working with Johnson & Johnson's operating units and their customers to assess the impact of RFID on business processes, information and enabling technology, overseeing J&J's RFID Incubator Fund to stimulate innovation through RFID, and Collaborating with industry associations, regulatory agencies and external standard setting organizations to establish the future direction of RFID/EPC.
Mike is a member of EPCglobal's Board of Governors. Mike is a tri-chair of EPCglobal's Healthcare and LifeSciences Business Action Group, and is member of EPCglobal's Business Steering Committee.
Prior to his current assignment, Mike was most recently the Chief Information Officer for Ortho Biotech. In his career, Mike has held various positions of responsibility across Information Management and Discovery Research.
Mike graduated from La Salle University with a BA in Biology, and received an MSE in Computer Science from the University of Pennsylvania.

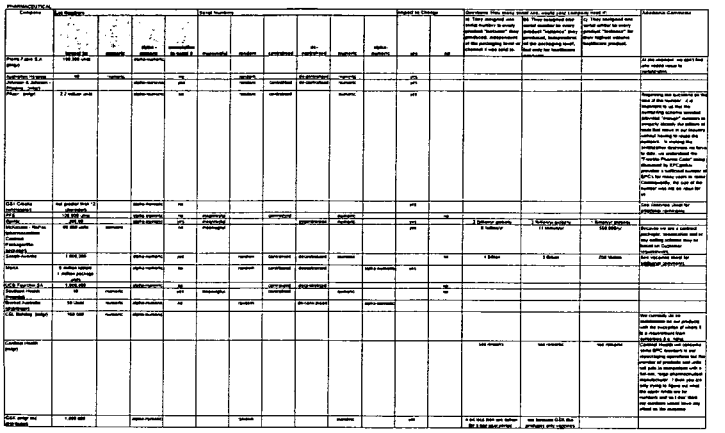
Ron Bone is Senior Vice-President of Distribution Support at McKesson Pharmaceutical, San Francisco. In his role he is responsible for RFID & CSOS, the SAP Buy Side Business Owner and Field Distribution Network Standardization. He has worked for 33 years with McKesson Corp., in areas of operations, sales and financial management.
Ron is a member of the EPCglobal - Business Steering Committee and Tri-Chair of the Healthcare and Life Sciences Business Action Group as well as a Member of Industry Relations Committee of the Healthcare Distribution Management Association (HDMA).

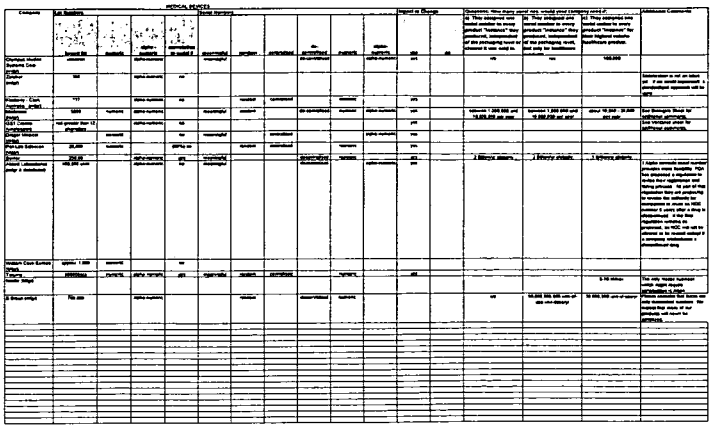
EHI (European Healthcare Initiative) – *Nicolas Florin, Chairman*

Nicolas Florin is CEO of GS1 Switzerland since 1st July 2006. Prior to his current role he worked for over 10 years for the Galenica Group, a diversified Group active throughout the healthcare market, from manufacturer to retailer. Nicolas first worked as financial controller of the Wholesale subsidiary Galexis and after that as Business Development Manager and later on as General Manager of the Alloga Group, a European Pre-wholesale company providing broad range of specialized logistics services to pharmaceutical manufacturers. In addition to his CEO role for GS1 Switzerland, Nicolas has become Chairman of EHI (European Healthcare Initative) as of 1st January 2007.









INSTRUMENTS

Company	Lot Numbers				Serial Numbers						Impact to Change		Questions: How many serial nos. would your company need if:			Additional Comments
	largest lot	numeric	alpha - numeric	association to serial #	meaningful	random	centralised	de-centralised	numeric	alpha-numeric	yes	no	a) They assigned one serial number to every product "instance" they produced, independent of the packaging level or channel it was sold to.	b) They assigned one serial number to every product "instance" they produced, independent of the packaging level, but only for healthcare products	c) They assigned one serial number to every product "instance" for their highest volume healthcare product.	
B Braun - Aesculap (mfgr)	150 - 200	numeric		yes	meaningful		centralised			alpha-numeric	yes					
Landanger SA (mfgr)	250,000 instruments / year	numeric		no	meaningful		centralised		numeric		yes					We all need a same structure code for future customer needs.
Boston Scientific (mfgr)	10,000		alpha - numeric	yes		random	centralised	de-centralised		alpha-numeric	yes					

IMPLANTS

Company	Lot Numbers				Serial Numbers						Impact to Change		Questions: How many serial nos. would your company need if:			Additional Comments
	largest lot	numeric	alpha - numeric	association to serial #	meaningful	random	centralised	de-centralised	numeric	alpha-numeric	yes	no	a) They assigned one serial number to every product "instance" they produced, independent of the packaging level or channel it was sold to.	b) They assigned one serial number to every product "instance" they produced, independent of the packaging level, but only for healthcare products	c) They assigned one serial number to every product "instance" for their highest volume healthcare product.	
St Jude Medical (mfgr)	4 digits		alpha-numeric	yes	meaningful	random	centralised	de-centralised		alpha-numeric	yes					
B Braun - Aesculap	500	numeric		no		random	centralised	de-centralised		alpha-numeric		no				
Boston Scientific	10,000		alpha - numeric	yes		random	centralised	de-centralised		alpha-numeric	yes					
Stryker Europe (mfgr)	10		alpha-numeric	no	meaningful			de-centralised		alpha-numeric	yes		many millions each year	many millions each year	no idea	

HUG AIDC DATA WORK GROUP | Updated 7 March 2007 | to incorporate Japanese, Australian and Volker Ze
Business Requirements Template | Created January 12, 2007
COMBINED MASTER LIST

Number	Role	NEED Business Requirement (WHAT?)	BECAUSE Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
[illegible]		should serialize logistic units	to improve logistic efficiency and inventory management			Jose Javier Sanchez #4	
[illegible]		needs a global and unique way of defining the unit of measure for product identification EU US Team proposes we put this requirement in the parking lot as the specifics of measurements required and why they are required are not provided however HUG shoul		two reqts - one is what is the unit of measure (kilo, pounds) also a reqts for variable measure (nominal, actual)	Closed by EU-US Team	pharma #18	Identification
		Regulatory requirements for traceability	to conform to regulatory requirements	this is not a valid req		medical devices #19	Regulatory
		must meet regulatory requirements regarding the product's remaining shelf life before shipping	to avoid the patient in need getting expired product			pharma #5	Dating
		We need to identify the software or firmware version of a medical device to ascertain the data requirements of managing the current state of electro / mechanical build	Complexity of Devices can mean that changes which affect form, fit or function are not immediately apparent i.e. a software or firmware alteration may add or delete certain functionality, this needs to be recognised. This may cross the configuration mana			medical devices #13	Attribute
[illegible]	Hospital	data that can be captured by automatic data capturing in high quality automatic identification carriers that meet GS1 minimums for conformance (quality) (e.g., bar width, minimum ISO parameter grades, symbology placement, etc.) EU-US Team proposes to move this to parking lot as it is in the scope of carrier phase	To avoid misread, multiple scans and failure	Mandatory	Closed by EU-US Team	VA #2, HS #1, #2	
[illegible]	Hospital	needs facilitation of calculation of doses when dispensing (e.g. liquids). NEED TO UNDERSTAND IF FACILITATION OF CALCULATION OF DOSES ARE WITHIN SCOPE FOR AIDC EU Team Proposal: Move to parking lot as this is a database issue or a visual indicator (color	Regularly mistakes happen during doses calculation and delivering at point of care	Mandatory	Closed by EU-US Team	VA #9, HS#11 #23, #41	
[illegible]	Hospital	needs special instruction with regards to contraindication for products. NEED TO UNDERSTAND IF SPECIAL INSTRUCTIONS ARE WITHIN SCOPE FOR AIDC EU Team Proposal: Move to parking lot as this is a database issue	To avoid mistakes in treatment - patient safety! Staff needs to know what NOT to do!	Mandatory	Closed by EU-US Team	VA #10	
[illegible]	Hospital	does not need serial numbers on pharmaceutical products. CONTRADICTS #2 above EU Team recommends moving to parking lot as #2 covers serial #s even if they are not used by all and because serial numbers can be used in combination with lot numbers for future	No need for this data - more suitable for implants, pumps, instruments etc.	Mandatory	Closed by EU-US Team	VA #11	
[illegible]		(At receipt) data capture must happen as a vaccine is received into stock for inventory and costings	For automated dispensing and stock control			biologicals #1	Identification

Number	Role	Business Requirement (WHAT?)	Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
[illegible]		(At receipt) the person receiving the instrument must be able to identify if the instrument at unit level (Serial No) is the instrument ordered and is either a new instrument or a repaired instrument	For inventory and instrument management purpose			surgical instruments #3	Attribute
[illegible]	Hospital	(sterilisation) need to identify the appropriate sterilization process(es) for the trade item EU-US Team proposes we move to parking lot as this is a database issue.	to associate the container (and the included tray & instruments) to the sterilisation cycle (process). To be able to validate all the peel packs and containers included in a sterilisation cycle. To associate the implants at general unit level to the ster	Mandatory	Closed by EU-US Team	surgical instruments #22 and #23, implants #22 and medical devices #12	Attribute
[illegible]	Hospital	(sterilisation) Reusable instruments at unit level (Serial No) must be linked to their sterilization process. EU-US Team proposes we move to parking lot as this is a database issue	To assure proper sterilization and life cycle of the instrument. And to reduce the transmission of disease. PROPOSED: to link the reusable instrument to their sterilization process and to assure proper sterilization and life cycle of the instrument. Al	Mandatory	Closed by EU-US Team	surgical instruments #21, HS #2, #3, #20, #40, #45, #54, #57, #80, #85, #100, #114	Attribute
[illegible]	Hospital	Cleaning process has to be identified. PROPOSED by US Team: must be able to identify an instrument with a serial number at the unit level before and/or after the cleaning process. Volker's Comment: Move to parking lot OK	To associate the instruments and implants at unit level (Serial No) to the cleaning cycle for traceability purposes	Mandatory	Closed	surgical instruments #16, implants #9	Attribute
ES parking lot	Hospital	Assembling process has to be identified. PROPOSED: must be able to identify implants at the unit level (serial number) in the assembling process EU & US Team proposes checking with Volker on the purpose of the requirement. US Team proposes to place on parking lot if Volker confirms that the requirement is for a process similar to sterilization and cleaning. US Team would propose that if assembly is similar to kitting see the kiting requirements above. Volker's Comment: Move to parking lot. Identification of 'Assembling Process' is similar to #52 (Steril. Proc.) and #67 (Cleaning Proc.)	To associate the implants at general unit level at the assembling station for completing purposes (rebuilding, functional tests for corruption, inventory, sterilization). US team suggests removal of "corruption"	Mandatory	Closed	implants #21 HS #33	Identification
[illegible]	Hospital	In the hospital a unique product identifyer		Mandatory	Closed	Pharma	
[illegible]	Hospitals	need to have shipping/storage information. PROPOSED: Move to parking lot as it is not embedded in the automatic identification. Must be covered in the database and it is already mandatory to be on the packaging using regulatory marketing symbols for thing	One other type of data that might be helpful, is any shipping/storage information - such as protect from heat, or protect from light. If this were incorporated into the product information, it would be easier to identify those items requiring special hand	Mandatory	Closed by EU-US Team	HS #43	
[illegible]	wholesale	an additional (not alternative) product identifier for regulatory assigned "national codes that identifies the issuing agency as well as the product	To be completed.	Optional	Closed by EU-US Team + Australians 3/8/07		US Team proposes to treat the requirements similar to #14 (ie establish a team)
[illegible]	Retailer	Must have the ability to filter out specific level of packaging from others depending on the level of identification	For efficiency in logistics	closed		Walmart 3/8/07	
[illegible]	Retailer	When appropriate, associated data (what all serialised units were on what pallet) should be kept with the ability to share	Expedites receiving process and may be used to identify potential problems should situations occur while product is shipping	closed		Walmart 3/8/07	

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Business Requirements Template | Created January 12, 2007
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Number	Role	NEED Business Requirement (WHAT?)	BECAUSE Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
[illegible]		must identify trays as a loan tray to be returned	So the hospital can assure accounting of loan trays			surgical instruments #4	Marketing
[illegible]		must identify trays as a loan tray for long term use in a hospital	So the hospital can assure accounting of loan trays			surgical instruments #5	Marketing
[illegible]		data on primary/secondary package must match manufacturing batch records EU-US Team Proposal: Delete this as it is out of scope not within work stream boundaries (point of finished goods to end-of-treatment)	to ensure consistency between physical products and batch records	considerable discussion - need at all levels of packaging see batch/lot expiration date, product identifier match	Closed by EU-US Team	pharma #3 & medical devices #3	Manufacturing
		ideally, human readable information should not be on the label more than once and each field in text must have a way for a human to know what it is (e.g., LOT#, BIN, what the date means YYMM, etc.) Replaced with 13a and 13b	to allow for package size constraints and opportunity to introduce inaccuracy	date format between what is in bar code and human factors considerations - vs/d reqts	Closed by EU-US Team	pharma #2 & medical devices #2	Manufacturing
[illegible]	Manufacturers, Wholesalers, Repackers	Uniqueness – Pharmaceutical item identification at the lowest level of packaging approved by the manufacturer/regulator for transport and logistics from the manufacturers releasing site MUST remain unique for 11 years	To ensure no possibility that two objects will ever inadvertently share the same identifier	Forever - means forever	Open	HLS Pharma #2	
[illegible]	Manufacturers, Repackers	Global – Pharmaceutical item identification at the lowest level of packaging approved by the manufacturer/regulator for transport and logistics from the manufacturers MUST have the same meaning and MUST NOT imply a geographic location of information about the object EU-US Team proposes we delete the requirement as the GTIN and Serial # standard shall not require anyone to encode location point of manufacturer, etc. information, but not restrict internal schemes.	A manufacturer may have dedicated facilities for producing/packaging a given product line. In these instances knowledge of the site reveals the product, negating the anonymity desired	Optional	Closed	HLS Pharma #16	e.g. Manager number does not indicate site of manufacture
[illegible]	Hospitals and other Customers	must be informed of any changes as governed and defined in the GTIN allocation rules for Healthcare	To ensure that manufacturer and customer systems are aligned enabling faster and accurate ordering, issue resolution			medical devices #18	Marketing
[illegible]	Distributor	in a distribution centre the identification of products must be linked to a product file	to be able to locate the product in the warehouse. To allow an			distributor #4	Identification
[illegible]		in a distribution centre data capture should happen at purchasing	to assure conformity of product informations on product file			distributor #5	Procurement
		in a distribution centre the identification of	to assure accuracy of information			distributor	Regulatory
JJ deleted combined with 58		Hospitals need a global unique number for identifying products. And, in a hospital data capture must happen as pharmaceuticals are received into stock, at the time of dispensing and at the time of administration	a)The unique identification of a product will increase patient safety and automation will reduce errors while capturing the data and save time. b) For automated dispensing and stock control	mandatory	open	pharma #15	Identification
[illegible]		data capture must be possible at	Cost allocation when processed			surgical	Marketing
[illegible]	Hospital	data capture must happen at the time of dispensing	for accuracy and traceability	Mandatory	Closed	vaccines #2 biologicals #2 Japan #2	Regulatory
[illegible]	Hospital	needs an identification of products by batch/lot	to track medications and for effective recalls	Mandatory	Closed	VA #3	
[illegible]	Hospital	(Expiry date) needs expiry date	To alert staff if products are expired (note: this rationale was added to #49 & #50)	Mandatory	Closed	VA #5	
[illegible]	Hospital	(Expiry date) needs expiry date in a standard format	to enable proper software development	Mandatory	Closed	VA #6, HS #4	

Number	Role	Business Requirement (WHAT?)	Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
	Hospital	(Expiry date) Expiry date must match (country-specific) import requirements	To avoid delay in getting the product to the patient in need	Mandatory	Closed	medical devices #5	Dating
[illegible]	Hospital	needs only to have prefixes for the data in the barcode on the package. If multiple bar codes are on a package. PROPOSED: needs a way to identify the correct barcode if multiple bar codes are on a package EU Team Proposal: replace this with 54a and 54b	To enable proper and correct scanning	Mandatory	Closed by EU-US Team	VA #12	
[illegible]	Hospital	the identification of brand, batch & expiry etc must be linked to a patient file. PROPOSED: must identify brand, batch and expiry of vaccines and biologicals to link the trade item to a patient file EU Team Proposal: Out of scope because lacking automat	this is a government regulation. We need to identify the government regulation(s) that apply. This was not provided from the sub team	Mandatory	Closed by EU-US Team	vaccines #4 biologicals #4, HS #2 #32	Regulatory
[illegible]	Hospital	Replace with 56a and b In the hospital to autoID the information of "sets" would be key to all products that bundle different product with different data elements within a set. PROPOSED: to autoID the information of "sets" would be key to all products th	Some sets include products with a variety of products with different data elements. Some of these products have a serial number, some of them have a lot and some have not	Optional	Closed by EU-US Team	pharma #24	Attribute
[illegible]	Hospital	(At receipt) data capture must happen as a vaccine is received into stock for inventory and costings EU-US Team proposes we delete and replace with 57.	For automated dispensing and stock control	Mandatory	Closed by EU-US Team	vaccines #1 Japan #1, HS#9	Identification
[illegible]	Hospital	(At receipt): the person receiving the new implant must be able to identify that actual implant (Item No) by data capture of the information on its package EU-US Team proposes we delete and replace with 57.	To link the ID of the implant to an inventory, receipt process, validation of the correct delivery	Mandatory	Closed by EU-US Team	implants #2 HS #1, #2, #3, #10, #19, #25, #32	Identification
[illegible]	Hospital	Instruments (Serial No) have to be identified at unit level PROPOSED: EU-US Team proposes to delete and include in 64a	For vigilance purposes, this including maintenance tracking	Mandatory	Closed by EU-US Team	surgical instruments #29, HS #2, #3, #20, #38, #40, #45, #54, #57, #80, #85, #100, #114, #43	Regulatory
[illegible]	Hospital	Instruments (linked to one patient) have to be identified before the cleaning process. PROPOSED by US Team: must link instruments identified with a serial number at the unit level with one patient before entering the cleaning process	A different cleaning (disinfection) process is necessary for instruments which have been used with a potentially infected patient (CJD disease). Volker's Comment: BIT covered by #64a is OK. Please add the rational to #64a, too !	Mandatory	Closed	surgical instruments #15	Attribute
[illegible]	Hospital	Instrument at unit level (Serial No) has to be identified before and/or after the cleaning process. PROPOSED by US Team: must be able to identify an instrument with a serial number at the unit level before and/or after the cleaning process	To manage incoming instruments into the CSSD (before / after = depending on local rules, if the instruments are pre-cleaned at OR, then instruments at unit level (Serial No) can be read before cleaning at CSSD)	Mandatory	Closed	surgical instruments #17	Attribute
[illegible]		in kind of patient contact we need to associate a loaned implant	provide a history of a unique loan implant			implants #20	Marketing
[illegible]		A tray must be able to be identified as a loan tray if it is a loan tray to be returned	To ensure accounting of loan trays			surgical instruments #4	Marketing
[illegible]		A tray must be able to be identified as a loan tray if it is a loan tray for long term use in the hospital	To assure accounting of loan tray			surgical instruments #5	Marketing
		Trade level(s) of packaging - minimum transaction information enabling electronic transaction activity, accurately and uniformly	Business functionality and methodology - needs to be expanded			medical devices #16	Marketing
[illegible]	Hospital	Peel packs, tray & container have to be identified. PROPOSED by US Team: must be able to identify peel packs, tray and container	To manage the journey of goods in the CSSD (planning purposes, informing users about scheduled availability, etc.) Volker's Comment: Incorporated into #58a is OK. Please add the rational to #58a, too !	Mandatory	Closed	surgical instruments #13	Identification

Number	Role	Business Requirement (WHAT?)	Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
[illegible]	Hospital	Instruments have to be identified at unit level (Serial No) PROPOSED by US Team: Has to be able to identify an instrument with a serial number at the unit level. CAN #34 and #75 be combined by combining the rationales? Volker's Comment: YES, can be combined	Limit instruments crossing between trays	Mandatory	Closed	surgical instruments #19 HS #2, #3, #20, #40, #45, #54, #57, #80, #85, #100, #114	Identification ?
[illegible]	Hospital	Instruments have to be identified at unit level (Serial No). PROPOSED: must be able to identify instruments in sets at the unit level (Serial number) EU Team Proposes to delete and replace with 58c developed by the US Team	Must be able to scan the item to determine which set it belongs to	Mandatory	Closed by EU-US Team	surgical instruments #8, HS #2, #3, #20, #40, #45, #54, #57, #80, #85, #100, #114	Identification
[illegible]		Instruments have to be identified at unit level (Serial No)	Definition of the ownership of an instrument to another house			surgical instruments #7	Identification
[illegible]		Tray at unit level (Serial No) has to be identified by entering the CSSD	To manage incoming trays and define the delivery time. To enable locate a tray and recall for any reason			surgical instruments #14	Identification
[illegible]	Hospital	In a hospital data capture at unit level (Serial No) must happen as an instrument/peel pack/tray is being prepared. PROPOSED: must be able to capture data at the unit level (Serial NO) as an instrument/peel pack/tray is being prepared EU Team proposes 1	To assure that traceability of the instrument/peel pack/tray can be established or maintained	Mandatory	Closed by EU-US Team	surgical instruments #20, HS #2, #3, #20, #40, #45, #54, #57, #80, #85, #100, #114	Identification
[illegible]	Hospital	In a hospital peel packs/trays' availability is checked before the operation. PROPOSED: must be able to check the availability of peel packs/trays before an operation EU team proposal: Instruments, peel packs and trays must be identified as trade units	To assure that all the necessary instruments/peel packs/trays are in inventory and not out of date (available for use)	Mandatory	Closed by the EU-US Team [illegible]	surgical instruments #25	Identification
[illegible]	Hospital	In a hospital the completeness of the available peel packs/trays is verifyed before the operation. PROPOSED: must be able to verify the completeness of the available peel packs/trays before an operation EU team proposal: Instruments, peel packs and tr	To assure that all the necessary instruments/peel packs/trays are there and accounted for	Mandatory	Closed by the EU-US Team	surgical instruments #26	Identification
[illegible]	Hospital	In a hospital the completeness of the available instruments/peel packs/trays is verifyed after the operation. PROPOSED: must be able to verify the completeness of available instruments/peel packs/trays after the operation EU and US team proposes we de	Also to account for all instruments/peel packs/trays and to assure that nothing was left in a patient	Mandatory	Closed by the EU-US Team	surgical instruments #27	Identification
[illegible]	Hospital	Hospitals need a global unique number for identifying products. And, in a hospital data capture must happen as pharmaceuticals are received into stock, at the time of dispensing and at the time of administration. PROPOSE: Deleting and combining with #39	a)The unique identification of a product will increase patient safety and automation will reduce errors while capturing the data and save time. b) For automated dispensing and stock control	Mandatory	Closed by the EU Team + US Team & Australians 3/08/07	pharma #15, HS #9, #11, #18, #25, #32, #45	Identification
[illegible]	Hospital	correct implant on hand for the optimal procedure at that right time in term of size and dimension. PROPOSE: DELETE as it appears to be a duplicate of #32 EU & US Team agrees to delete	minimized time for implementation, best clinical outcome, optimized patient safty	Mandatory	Closed by the EU-US Team	implants #23, HS #10, #20	Identification
[illegible]	Hospital	Implants have to be identified generally. PROPOSED: Delete and add rebuilding and sterilization to #35 EU & US Team agrees to delete and moved the two words to #3	information which is required to secure the right usage have to be available, e.g. information for rebuilding, sterilization, assembling	Mandatory	Closed by the EU-US Team	implants #6, HS #18, #20, #32, #33	Attribute
[illegible]	Hospital	Instruments (Item No) have to be identified. PROPOSED: must be able to identify the item number of instruments EU & US Team proposes to delete and add the words "functional tests for corruption, inventory," to #5	When verifying the instruments functions, having access to functionality tests descriptions. For instruments made of multiple parts, instructions to "rebuild" the instrument. When handling the instrument, finding right cleaning, sterilisation, etc. instr	Mandatory	Closed by the EU US Team	surgical instruments #11, HS #33, #38	Attribute

Number	Role	Business Requirement (WHAT?)	Rationale (WHY?)	Mandatory/Optional	Status	Source	WT remarks
[illegible]	Hospital	Instruments have to be identified at unit level (Serial No). PROPOSED: Delete and add rationale to #64 EU & US team agrees to delete and has moved rationale to 64a while removing reference to the solution (SN)	Special tracking of high value and intensive maintenance instruments	Mandatory	Closed by the EU-US Team	surgical instruments #12, HS #2, #3, #20, #40, #45, #54, #57, #80, #85, #100, #114	Attribute / Regulatory
[illegible]	Hospital	All instruments at unit level (Serial No) must be identifiable (not only the new ones, but also the existing ones). CAN THIS BE COMBINED WITH #54? EU & US Team proposes we delete after adding the text to the rationale of 64a as follows: F enable functio	To initiate or maintain the life cycle record of the instrument. To enable efficient lifespan management e.g. instruments not scrapped before, not used beyond recommended lifespan. Identify instruments needs per period to enable efficient product manageme	Mandatory	Closed by EU-US Team	surgical instruments #9, HS #2, #3, #20, #40, #45, #54, #57, #80, #85, #100, #114	Attribute
[illegible]	Hospital	a way to identify what is coming into the hospital and what is in the box EU & US Team proposes we delete after adding the word traceability to the rationale for #3	as the starting place for traceability	Mandatory	Closed by EU-US Team	Added in Berlin	Regulatory for France
[illegible]	hospitals	the expiry date will also be relevant to any medical devices and supplies, and particularly those that come in contact with the patient. PROPOSE: Delete and add and relevant medical devices and supplies, and particularly those that come in contact with t		Mandatory	Closed by EU-US Team	AHA email #1 bullet point	
[illegible]	Hospital (AHA is the American Hospital Assoc not a manufacturer)	I would advocate adding labeling on pharmaceuticals at the unit-dose level. This means that manufacturers would deliver products packaged at the unit dose level with an auto ID tag on it (bar-code or RFID). The data would be similar to what is discussed		Mandatory	Closed by EU-US Team	AHA email #2 bullet point	
[illegible]	hospital pharmacist (EAHP is the European Hospital Assoc not a manufacturer)	must produce single dose-packed drugs and include a barcode on each single dose EU Team Propose: Replace with 104a and 104b	To improve the efficiency of safer procedures and allow a final control just before the administration of drugs to patients. This will significantly increase the patient's safety. This will also improve the traceability up to the patient level	Mandatory	Closed by EU-US Team	EAHP brief presentation of Single Dose recommendations 04/01/07	
[illegible]	hospital pharmacist (EAHP is the European Hospital Assoc not a manufacturer)	must produce single dose-packed ampoules and vials with a barcode on each single dose on a label (not engraved on the glass) EU Team Propose: Replace with 104a and 104b		Mandatory	Closed by EU-US Team	EAHP brief presentation of Single Dose recommendations 04/01/07	
[illegible]	hospital pharmacist (EAHP is the European Hospital Assoc not a manufacturer)	the primary packaging must precisely describe the content of the drug EU Team Propose: Replace with 104a	to describe the content of the drug up to final control at bedside and to enable easy and safe use of the drug and to provide protection against environmental influences such as light, moisture, pressure and microbial contamination during transport, handl	Mandatory	Closed by EU-US Team	EAHP brief presentation of Single Dose recommendations 04/01/07	
[illegible]	hospital pharmacist (EAHP is the European Hospital Assoc not a manufacturer)	for ampoules and vials, the label must precisely describe the content of the drug with additional information regarding the total amount and volume (x mg + y ml) and the concentration of the solution (z mg/ml) EU Team Propose: remove as it is covered by	to describe the content of the drug and additional information up to final control at bedside and to enable easy and safe use of the drug and to provide protection against environmental influences such as light, moisture, pressure and microbial contaminat	Mandatory	Closed by EU US Team	EAHP brief presentation of Single Dose recommendations 04/01/07	
[illegible]	Retailer	Product information (GTIN) should also convey the unit quantity (pallet, case, inner pack, unit)	Used to expedite handling			Walmart 3/8/07	

Term	Definition
Adverse events	Any event that happens along the pharmaceutical supply chain which is not desired or is a non-standard process.
AHA	American Hospital Association
Approved Healthcare Trade Item	Trade item identification at all level of packaging approved by the manufacturer/regulator for transport from the manufacturers releasing site to the end-user.
Authentication	
Chain of custody	
Cold Chain	
Container	Hard pack for trays
Control Number	Control Number (as defined by FDA) means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, form which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished dev Control Numbers are used during the entire product lifecycle from manufacturing through distribution for purposes of identification, traceability and to facilitate corrective actions both internally and in the field (recall).
	Control Numbers are used during the entire product lifecycle from manufacturing through distribution for purposes of identification, traceability and to facilitate corrective actions both internally and in the field (recall).
COHH	Control of substances hazardous to health
Device Traceability	Trace = Quickly identify the technical source (e.g. which packaging line, time and date of packaging or release, etc.) and also identify the affected sublot (= time range) within packaging in order to find out about the "neighboring" instances (serial numbers)
Device Tracking	Track = Locate the "neighboring" instances within the supply chain to quickly withdraw them from the supply chain if necessary
EAHP	
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPR	Electronic Patient Record
GIRP	
IFU	Instructions for use
Instrument	the item itself (means item No)
Kit (also see Set)	Combination of different regulated products.
Loan	Focus area : Processes regarding products which are loaned from supplier side
Macro	Focus area : Ordering, delivery, goods receipt, stock/asset management
Mandatory	Means that minimum one user described this as mandatory (could be a legal regulation). As a consequence this may not be considered as mandatory by all users.
Micro	Focus area : CSSD processes, operating theatre processes
Optional	Means that minimum one user described this as "nice to have", to optimise patient safety, process managements, quality, etc.
Pedigree	Record of the movement and change of control for an entity
Peel pack	one or a few instruments packed in a soft packs
Reagent	Substance used for test reference or calibration of equipment; solutions for invitro diagostics
Recommended for process management	Not directly linked to patient safety, but necessary for appropriate process management
Re-processable	scaple, hammer, endoscopes
Repair	Focus area : External repair processes
Reprocessed Single-Use Device	A reprocessed single use device is an original device that has previously been used on a patient and has been sjujected to additional processing and manufacturing for the purpose of an additional single use on a patient.
Re-usable	wheel chair, cane
Set (also see Kit)	Combination of different regulated products.
Single-Use Device (SUD)	A device that is intended for one use or on a single patient during a single procedure.
Sterialization Event	
Trace	Quickly identify the technical source (e.g. which packaging line, time and date of packaging or release, etc.) and also identify the affected sublot (= time range) within packaging in order to find out about the "neighboring" instances (serial numbers)
Track	Locate the "neighboring" instances within the supply chain to quickly withdraw them from the supply chain if necessary
Tracked Device	It seems that there is not a single definition of tracked devices - rather it is defined both by what it means to be a tracked device and what devices are currently required to be tracked. More specifically, from FDA's standpoint, a tracked device is one
Tray	could be packed in a soft or container way (equivalent : basket, corb)
Unit level	The single implant (means lot number controlled)
vCJD	variant Creutzfeldt-Jakob disease
Vigilence	the person in charge of the product in the country or region has the ability to monitor performance or record complaints to determine if adverse affects are due to the product and to make decisions related to this study

http://www.fda.gov/cdrh/comp/guidance/169.html

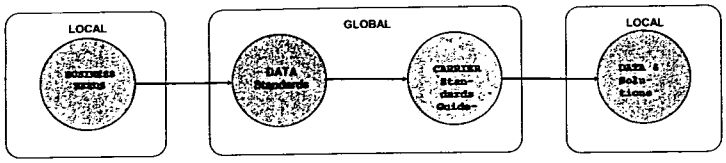
AS OF 21 March 2007

	closed	parking	delete		closed	parking	delete		closed	parking	delete		closed	parking	delete
1	X			34	X			64a	X			100	X		
2	X			35			X	65			X	101	X		
3	X			36	X			66			X	102		X	
4		X		37		X		67		X		103			X
5	X			38	X			68	X			104			X
6	X			39	X			69			X	104a	X		
7	X			40			X	70			X	104b	X		
8	X			41	X			71			X	105			X
9			X	42			X	72			X	106			X
10			X	43			X	73				107			X
11			X	44	X			74			X	108			X
12	X			45			X	75			X	109		X	X
13			X	46			X	76				110	X		
13a	X			47	X			77				111	X		
13b	X			48			X	78				112			X
13c	X			49	X			79				112A	X		
14		X		50	X			80			X	112B		X	
15	X			51		X		81			X	113		X	
16	X			52		X		82				114			
17	X			53		X		83			X	115			
18	X			54			X	84			X				
19	X			54a	X			85		X					
20		X		54b	X			86							
21		X		55			X	87							
22		X		56			X	88			X				
23				56a	X			89			X				
24				56b	X			90			X				
25			X	56c	X			91		X					
26			X	57	X			92	X						
27			X	58			X	93			X				
28	X			59			X	94			X				
29			X	60		X		95			X				
30			X	61		X		96			X				
31			X	62		X		97			X				
32	X			63		X		98			X				
33	X			64			X	99	X						

GS1 Healthcare Roadmaps

Part 1 Data Standards
Part 2. Carrier Standards & Guidlelines
Part 3. Data
Part 4 Enabled Solutions

Conceptual Overview



Part 1. Data Standards

		From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
AIDC	Auto ID Data	4Q 06	1Q 07	0.75 FTE		GS1 MOs Scott Gray Tom Heist Ulrike Kreysa	Mark Hoyle (Tyco Healthcare) Mark Walchak (Pfizer)	Define data required for automatic identification, i.e. GTIN, serial number, lot number, expiration date
	Serialization	4Q 06	2Q 07	0.75 FTE		GS1 MOs Scott Gray Tom Heist Ulrike Kreysa	Stephen Hess (Merck) Massimiliano Molinari (Johnson & Johnson)	Define serialization schema for healthcare products, with product traceability for patient safety as highest priority (how and where to use mass serialization for traceability)
	Carriers	3Q 07	3Q07	2 x 0.2 FTE	All Stakeholders asked to participate	BarCode EPCGlobal MOs	TBD	Identify the data carriers for healthcare product packaging and direct marking. Establish standards for carrier printing/marking/encoding, scanning/verifying/decoding and quality (where and when to use which barcode type like EAN-13, GS1-128, RSS, Data Matrix or RFID tags)

		From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
	AIDC Application Standard	2Q 07	4Q07	0.25 FTE	2 x 0.2 FTE	GS1 (Business Units and MOs)	TBD	Construct packaging/direct marking AIDC application standard(s) specific to appropriate product group or sub-industry requirements, with patient safety as the highest priority
TRACK & TRACE	Track & Trace Standard	1Q 06	1Q 08	0.5 FTE			John Howells (HDMA) Chuck Schramek (EPCglobal) HLS Co-Lead	Create the business requirements essential to delivering [a data carrier dependent] track and trace Forward and reverse logistics
	e-pedigree (USA)	1Q 06	4Q 06			Traceability EPCGlobal	Dirk Rodgers (Cardinal Health) Eli Perlman	Create a pedigree document specification and usage guidelines that provide a platform for the pharmaceutical supply chain to comply with the various state and federal pedigree laws

		From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
E	*e-pedigree (Global)* *after the discussion with EPCglobal team members it seems that we should not work on a global e-pedigree solution but on a global track and trace solution*	*2Q 07*	*4Q 07*	*0.5 FTE*	*US team member to assist Global effort*	*e-Com* *Traceability*	*TBD*	*Create a pedigree document specification and usage guidelines that provide a platform for the healthcare supply chain to comply with a range of possible pedigree laws*
	Authentication	1Q 08	3Q 08	0.5 FTE	All Stakeholders	Traceability MOs	TBD	Standard for authentication of individual items, cases or pallets using a GS1 data structure.
GS1 KEY	GLN	1Q 08	2Q 08	0.5 FTE	All Stakeholders	BarCode e-Com MOs	TBD	Definition of GLN usage in Healthcare Evaluate global GLN registry
	Patients & Staff	1Q 08	2Q 08	0.2 FTE	Participation by Hospitals and National Insurers	TBD	TBD	Assessment of GSRN, GLN or other possibilities for Personal ID. Decision: GLN or GSRN
	GIAI/GRAI Asset Standard	3Q08	4Q 08	0.2 FTE	Hospitals and Instrument Mftg.	BarCode EPCGlobal MOs	TBD	Fixed Asset and Returnable Asset Standards. Standards for usage off assets identifiers in healthcare.

		From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
DATA	e-Com Standard	1Q 09	4Q 09	1 FTE	All participants in Supply Chain	e-Com MOs	TBD	e-Com messages for healthcare to be used in supply chain processes
	EPC-IS Standard	1Q 08	2Q 09	1 FTE		Traceability EPC Global Network	Craig Asher (IBM) Richard Swan (3CI)	
	Data Sharing/Ownership Standard	1Q 08	2Q 09	0.5 FTE	All participants in Supply Chain	Traceability EPC Global	T&T, DE JRG	

Notes:
1. All Standards to go through GSMP after the "TO" due date, approximate time for GSMP is 6 months
2. Each Quarter is 3 months: 1Q - 4Q = 12 months
3. For further information on each deliverable please refer to: *Appendix B. Detailed Description of Deliverables*

Part 2. Carrier Standards & Guidelines

	From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
2D Data Matrix RSS/RSS Composite EAN/UPC, GS1-128		2Q 08					Final Approval of Application Standard in Healthcare
RFID							
UHF/HF Decision	2Q 06	3Q 07					EPCGlobal to support both. 100% UHF case/pallet. 80/20 HF/UHF at the item level
Item Level Tagging Standard	1Q 06	3Q 07	0.5 FTE	ILT JRG	EPCglobal	Clive Hohberger (Zebra Technologies), Tom Pizzuto (Wyeth), Vivian Underwood (Andersen Merchandisers)	Define a comprehensive set of item-level requirements. Examine the interoperability of data carriers
Tag Data Standard w/User Memory	1Q05	4Q 07	0.5 FTE	TD JRG	EPCglobal	Barba Hickman (Intermec) Rick Schuessler (Symbol Tech.)	Create the Use Cases and Business Requirements for User Memory on RFID tags

	From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
Privacy Standard	1Q 06	2Q 07	1.0 FTE	PPSC	EPCglobal	Elizabeth Board (EPCglobal)	
Tag Disposal/ Environmental	1Q07	1Q 08					
New Silicon for HF Gen 2	4Q 07	3Q 09	0.5 FTE	HF AIWG	EPCglobal	Clive Hohberger (Zebra Technologies) Alastair McArthur (TagSys)	Item Level
HF Gen 2 Scale Up	4Q 09	1Q 10	0.5 FTE	HF AIWG	EPCglobal	Clive Hohberger (Zebra Technologies) Alastair McArthur (TagSys	Item Level
Decommissioning	1Q 07	3Q 07	0.5 FTE	All Stakeholders	Traceability EPCGlobal	TBD	Create the business requirements essential to rendering an RFID tag partially or totally inaccessible to ensure consumer and patient privacy

Notes: 1. RFID Standards follow EPC process and EPC Standards Development Process.

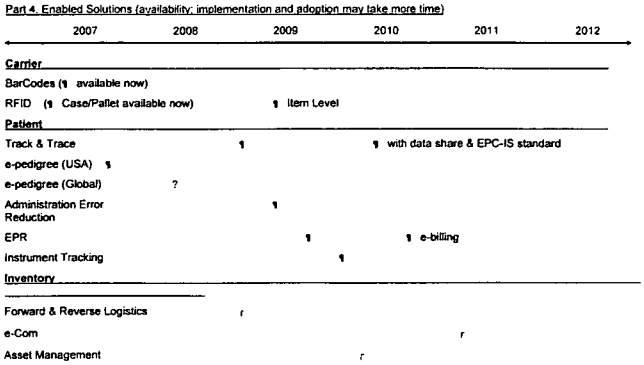
3. Data

	From	To	GS1 Resource	User Resource	GS1 Participation	User Leaders	Deliverable
Product Data Dictionary	1Q 07	3Q 07	0.5 FTE	All Stakeholders	GDSN MOs	TBD	Definition of necessary product data/attributes for healthcare products
e-Catalogue/Classification	1Q 07	3Q 07	0.5 FTE	All Stakeholders	GDSN MOs	TBD	Global model for healthcare catalogues including global classification for all healthcare products.
e-messaging							
Data Exchange Joint Requirements Group	3Q 06	1Q 07	1.0 FTE	All Stakeholders	EPCglobal	Craig Asher (IBM) Ron Moser (Walmart) John Howells (HDMA)	Framework and Standard for exchanging data among trading partners within the EPCglobal community

Notes:

1. Data Standards to follow GDSN procedures for GSMP

Part 4. Enabled Solutions (availability; implementation and adoption may take more time)



Note: Please refer to *Appendix A. Solution Requirements*

Appendix A. Solution Requirements

1. e-Pedigree (counterfeit, diversion)
   - Auto ID Data
   - Serialization
   - e-Pedigree Messaging Standard
   - for RFID, e-Pedigree RFID technical requirements necessary
   - carriers
2. e-Prescription (Administration Error Reduction)
   - Auto ID Data
   - Carrier Standards at the unit dose/unit of use level
   - Patient ID
   - Carriers
   - Electronic Prescribing software (non GS1 GHI solutions)
3. EPR (Patient safety, efficient records management)
   - Auto ID Data
   - Carrier Standards at the unit dose/unit of use level
   - Patient ID
   - Service Staff ID
   - Carriers
   - *(Instrument ID Solution)*
   - e-Com for e-billing
   - procedure codes (non GS1 Standard)
4. Instrument ID (Patient safety, instrument management)
   - Auto ID Data
   - Serialization
   - GIAI/GRAI
   - Carriers
5. Track and Trace (inventory control, counterfeit, diversion)
   - Auto ID Data
   - Track & Trace Standards for Healthcare
   - Data Sharing/Ownership Standard
   - EPC/IS or Network Standard
   - Carriers
6. e-Commerce (supply chain efficiency, inventory control)
   - GDSN
   - GLN
   - e-Com Standard
7. Asset ID (Asset management tools)
   - GIAI/GRAI
   - Carriers
   - option: serialization

Appendix B. Detailed Description of Deliverables

- Auto ID Data – Define data required for automatic identification, given business requirements and the GS1 mission, with patient safety as highest priority (which data are needed to support business objectives for patient safety – GTIN, serial number, lot number, expiration date)
- Serialisation – Define serialisation schema for healthcare products, with product traceability for patient safety as highest priority (how and where to use mass serialisation for traceability)
- Carriers – Identify the data carriers for healthcare product packaging and direct marking. Establish standards for carrier printing/marking/encoding, scanning/verifying/decoding and quality (where and when to use which barcode type like EAN-13, GS1-128, RSS, Data Matrix or RFID tags)
- AIDC Application Standards: Construct packaging/direct marking AIDC application standard(s) specific to appropriate product group or sub-industry requirements, with patient safety as the highest priority. Content to include:
  - ✓ Impacted product scope by product group or sub-industry
  - ✓ Appropriate portions of relevant standards, including prior HUG driven standards
  - ✓ Relevant location, packaging level, AIDC technologies
  - ✓ Practical timeframe for adoption
  - ✓ Expected stakeholder support and business impacts

> Minimise the number of different healthcare application standards and associated required AIDC technologies while maintaining practicality and appropriate differentiation.
>
> Product groups may be formed through relevant commonality
  - Examples: stakeholders, supply chain channels, business/financial models, appropriate AIDC technologies, dosage form, single/multiple use

> Sub-industries may be derived from regulatory or industry accepted product classification
  - Examples: device/pharmaceutical, implants, OTC/Rx

HUG AIDC DATA WORK GROUP — Updated 15 March 2007

Business Requirements Template — Created January 12, 2007

COMBINED MASTER LIST

Number	Role	NEED: Business Requirement (WHAT?)	BECAUSE: Response (WHY?)	Mandatory/Optional	Status	Source	WT category	HS Comments
[illegible]	Manufacturer	must correctly identify product/package	to avoid mix-up and to assure that the right primary package goes into the right secondary package. And, for clear identification in supply chain processes	Mandatory	Closed	pharma #1, medical devices #1 & surgical instruments #1	Manufacturing	
[illegible]	Manufacturer	must use serialization for pharmaceutical products	In Spain it is a Federal Ministry government requirement and the recommendation of EFPIA for patient safety as anticounterfeiting measure (serialization is the most natural solution), support traceability including providing for efficient product recall, and will facilitate legitimate reimbursement (avoid fraud)	Mandatory	Closed	Jose Javier Sanchez #3		
[illegible]	Manufacturer	must identify, with a unique identifier for data capture, all levels of packaging, from dose unit up to the highest level of packaging	to know which product and level of packaging is. To ensure patient safety, traceability, improve logistic efficiency and inventory management	Mandatory	Closed	Jose Javier Sanchez #1 & #2		
[illegible]	Manufacturer	must be able to pick the right product for the right patient (case and item level) when shipping directly to patient	to protect patient against receiving the wrong product (e.g., no dispensing by pharmacist)	Mandatory	Closed	medical devices #8 & pharma #8	Identification	
[illegible]	Manufacturer	must be able to identify the product in hand	to identify the product if: a) product information is unreadable to user (language or missing text) b) medical device is partially compromised c) function of medical device is unclear to user	Mandatory	Closed	pharma #4 & medical devices #4	Identification	
7	Manufacturer	must identify instruments, trays, and containers (e.g., kit, set of medical instruments) at the unit level	to secure the completeness of the tray included in the container during the assembling process	Mandatory	Closed	surgical instruments #19	Manufacturing	
[illegible]	Manufacturer	must identify Class IIB and Class III reusable instruments	to comply with France and Austria government regulations for traceability	Mandatory	Closed	surgical instruments #10	Regulatory	
1[illegible]	Manufacturer	data captured in a carrier must be consistent with human -readable information	to ensure interchangeability of information source	Mandatory	Closed	pharma #2 & medical devices #2	Manufacturing	
1[illegible]	Manufacturer	human-readable information associated with auto-ID data carrier need not be on the label more than once	to allow for package size constraints and opportunity to eliminate inaccuracy		Closed	pharma #2 & medical devices #2	Manufacturing	
1[illegible]	Manufacturer	each field associated with the auto-ID carriers in text must have a way for a human to know what it is (e.g., (01),(10),(17) or alternatively LOT# Expiry, what the date means YYMM, etc.)	increase data accuracy	Mandatory	Closed	pharma #2 & medical devices #2	Manufacturing	The requirement does not imply that everything in a bar code must be printed in the human readable form.
1[illegible]	Manufacturer	identify the bar code's human readable information fields that are required need to appear next to each other and as close as possible to the bar code, but need not be adjacent to bar code where space constraints exist	for efficiency (human factors) during migration to auto-ID and in redundancy for technology failure		Closed	EU-US team	Manufacturing	The requirement does not imply that everything in a bar code must be printed in the human readable form.
1[illegible]	Manufacturer	needs a Control Number (date) for managing recalls	for speed and consistency of response	Mandatory	Closed	medical devices #9	Regulatory	
1[illegible]	Manufacturer	needs to know the expiration in time (not just MMDD) for products with a short life cycle	to ensure an expired product is not given to the patient.	Mandatory	Closed	therapeutic nutritional #1	Dating	
17	Manufacturer	must be able to identify the item number within the lot and where it was produced within the lot (e.g., time - production packaging information)	to respond to an inquiry from an end-user or a regulatory body (trigger recall, complaint, interval, etc.)	Mandatory	Closed	pharma #9	Regulatory	
1[illegible]	Manufacturer	must be able to identify tracking information for a product. (also see glossary for tracking)	to respond to an inquiry from an end-user or a regulatory body (trigger recall, complaint, interval, etc.)		Closed	medical device #8 & pharma #8	Regulatory	
1[illegible]	Manufacturer	must be able to identify tracing information for a product. (also see glossary for tracing)	to respond to an inquiry from an end user or a regulatory body (trigger recall, complaint, interest, etc.)		Closed	medical device #8s & pharma #8	Regulatory	
2[illegible]	Manufacturer	must be able to prove a product and/or product package is authentic. EU Team proposes approval of the requirement and deletion of the yellow comment box after adding the blue wordings. US TEAM needs a definition of authentic, authentication and chain of custody	to ensure patients get authentic product (via e.g., point-of-administration, point-of-dispense authentication, track and trace)	Needs more discussion on what authenticate (e.g., product is and package is and chain of custody is) - HLS needs to be supplied - add definition for chain of custody	Closed by EU Team	medical devices #7 & pharma #7	Authentication	
7	Manufacturers, Wholesalers, Repackers	Uniqueness – item (lowest item level whose pack has been sealed for distribution robustness and integrity by the manufacturer or item created by licensed kit builder who then acts as the brand owner) level identifier MUST refer to no more than one object. EU-US Team: we need HLS to provide the specific regulations and where within those regulations these suggestions are made. HLS confirm the red wording and to develop wording for scenario where distributor is breaking down a product below what the manufacturer verifies for integrity	Federal and State regulations are suggesting serialization as the means to ensure product pedigree requirements are met	Optional	Open	HLS Pharma #1	Regulatory	
[illegible]a	Manufacturers, Wholesalers, Repackers	Pharmaceutical, Biologics and Therapeutic Nutritional item identification at the lowest level of packaging approved by the manufacturer/regulator for transport and logistics from the manufacturers releasing site MUST remain unique for 11 years from their expiry date. (Still need HLS input for packaging before scenario)	To ensure no possibility that two objects (pharmaceutical, biologic and therapeutic nutritional products) will ever inadvertently share the same identifier		Open	HLS Pharma #2		FDA has proposed a regulation to revise their registration and listing process. As part of that regulation they are proposing to revoke the authority for companies to reuse an NDC number 5 years after a drug is discontinued. If the final regulation remains as proposed, an NDC will not be allowed to be reused except if a company reintroduces a discontinued drug.
2[illegible]b	Manufacturers, Wholesalers, Repackers	Blood and blood derivative products item identification at the lowest level of packaging approved by the manufacturer/regulator for transport and logistics from the manufacturers releasing site MUST remain unique for 30 years.	To ensure no possibility that two objects (blood products) will ever inadvertently share the same identifier		Closed	HLS Pharma #2		
25c	Manufacturers, Wholesalers, Repackers	Medical Devices, Instruments, Implants item identification at the lowest level of packaging approved by the manufacturer/regulator for transport and logistics from the manufacturers releasing site MUST remain unique for forever.	To ensure no possibility that two objects (medical devices) will ever inadvertently share the same identifier		Closed	HLS Pharma #2		
2[illegible]	All Supply Chain Stakeholders	Inter-operability – GS1 Application Identifiers (e.g., GTIN, Serial Number, SSCC) MUST be readable via various carriers – e.g. Bar code and RFID	Co-existence of bar code and RFID technologies requires the seamless integration at a data level (AIs) of the two technologies	Optional	Closed	HLS Pharma #24		
3[illegible]	Distributor	in a distribution centre or warehouse operators in goods in, picking, returns & dispatch departments must be able to identify all approved healthcare trade items by automatic data capture	to record the flow of incoming and outgoing goods. And, to allow a control of order conformity to suppliers and order conformity shipped to hospital, pharmacist, CP's NHS	Mandatory	Closed	distributor #5 Japan #5	Procurement	
[illegible]	Distributor	at the receipt at a distribution centre must identify products by automatic data capture on the package, the outer and the shipper	to link a product ID to database information about the location in the warehouse, where and how the product should be stored (e.g., in ambient area, fridge area or secure area like narcotics). Also an industry guideline in Japan	Mandatory	Closed	distributor #1	Identification	
[illegible]	Distributor	for receipt of healthcare trade items identification must include a batch/lot number and expiry date on the unit of sale	to allow the release of the stock per batch number & rules of FEFO (first expiry, first out) or FIFO (first in, first out). To assure traceability as requested by regulatory bodies. (Already started for animal health)	Mandatory	Closed	distributor #2	Dating/Identification	
[illegible]	Hospital	must have a unique product identification down to the unit of use	for inventory control, correct dispensing, purchasing	Mandatory	Closed	VA #1		
[illegible]	Hospital	must identify the brand owner responsible for the specific device, identify the specific device and the device's lot or serial numbers for adverse event reporting	A consistent approach to be adopted thus delivering maximum benefit of the data represented - uniform data set	Mandatory	Closed	medical devices #9 HS #4, #11	Regulatory	The respondent #4 insists on interoperability, consistency of data, the possibility to use same data format in various environments (part of interoperability within and between hospital)
[illegible]	Hospital	data capture must capture the identification of products and lot/batch number and time of dispensing and administration	for accuracy and traceability	Mandatory	Closed	vaccines #3 biologicals #3 also incorporated #42 and #43	Regulatory	
[illegible]	Hospital	data capture must happen in the operation room after the operation to identify at the unit level the unique identification of all the peel pack/tray instruments used in the operation	To provide traceability of the instruments/peel packs/trays used (or present in the OR because even if not used they stay close to an infectional area) in an operation and to link the use to the patient files. Identify patients involved after an incident	Mandatory	Closed	surgical instruments #28	Identification	
[illegible]	Hospital	must have a consistent data format (e.g. dates) throughout the supply chain	Software can not handle different formats and recognise that the same product is behind it	Mandatory	Closed	VA #4, HS #4, #20, #102, #32		see comment at BR #38
47	Hospital	must have an expiry date in human readable and automatic identification on all packaging of product that requires it	a) We must not use expired product. b) expiry date helps to control the inventory. (note: b) might be combined with another requirement regarding inventory management	Mandatory	Closed	pharma #19 HS #2 AHA email #1 bullet point (to include medical device)	Dating	many similar responses from the hospital side
4[illegible]	Hospital	only needs month and year for the expiry date for standard products delivered by manufacturers	This would be enough information for the handling of standard pharmaceutical products and to alert staff if products are expired.	Mandatory	Closed	VA #7		
[illegible]	Hospital	Must have date and time to hours and minutes in the expiry date for special products produced in the pharmacy like parenteral nutrition or cytostatics	These products have very limited stability and to alert staff if products are expired	Mandatory	Closed	VA #8		
[illegible]	Hospital	must identify what data authority (e.g., GS1, other) governs the definition for the fields in the bar code or RF tag	To enable proper and correct scanning	Mandatory	Closed	VA #12		
[illegible]	Hospital	must identify one data field in the bar code or RF tag from other data fields	To enable proper and correct scanning	Mandatory	Closed	VA #12		
[illegible]	Hospital	must automatically identify regulated sets, peel packs, trays, loaned trays and containers as a product which then describes within the database record all the components of the set, peel packs, trays, loaned trays and containers	Hospitals may need to know what is in a set because a component might have an adverse effect on a patient and a manufacturer must know which lots would be affected by a recall of a component and hospitals may need to track what components have been used on a patient who then develops (i.e., vCJD)	Mandatory	Closed	pharma #24	Attribute	
[illegible]a	Hospital	within a set, all components that require (e.g., regulatory, functional reason) individual identification must have this identification. This automatic identification must only be on the individual level as opposed to individually identified on the outer set packaging	See 56a plus: To identify components when they become separated from the kit. To ensure the same trade item at the component level is not identified with a different GTIN when included in sets. To ensure the correct (set as opposed to component GTIN bar code) is scanned on the set package	Mandatory	Closed	pharma #24	Attribute	Use of the word regulated is intended to differentiate from an ancillary component, accessory, or unregulated item in the kit (e.g., device to break the seal on a tube of ointment)
[illegible]c	Hospital	within a set, all components that require (e.g., regulatory, functional reason) individual identification must have the identification of the set, kit, peel packs/ trays and containers from which it came	Must be able to scan the item to determine which set it belongs to		Closed		The identification to which tray/container a component belongs is only realized by a database. The individual items don't carry information of the trays physically	
57	Hospital	Must be able to identify actual trade items within the hospital	To link the trade item ID to an inventory management, receipt process, validation of the correct delivery, automated dispensing	Mandatory	Closed by EU-US Team + Australasia 3/8/07	surgical instruments #2 HS #25 #32	Identification	
[illegible]	Hospital	must identify re-processable medical devices at the unit level on the product. (ID number must survive the life cycle)	A. to track through the sterilization, desinfection or cleaning cycle. B. To monitor life cycle C. To track maintenance D. To limit instruments crossing between trays E. Special tracking of high value and intensive maintenance instruments F. Enable functional testing and disposal G. Instrument inventory management/forecasting H. to locate a device, instrument, asset	Mandatory	Closed	US Team		
[illegible]	Hospital	must be able to trace at the unit level implants in a human being	fulfillment of law in land for vigilance purposes and recalls	Mandatory	Closed	implants #17 HS #18, #32	Regulatory	
7[illegible]	Hospital	Proposed during 8March call: Single use devices which are reprocessed (must be associated with the/re-identified by the reprocessor. [illegible] PROPOSED: must be able to identify [illegible] which have been reprocessed. Australasia Comment: Requirement 73 - the HUG - Australasia asked for clarification around the meaning of the term re-processing, as they were concerned about [illegible] "single use item". For example, does re-processing mean the packaging for a [illegible] joint replacement was opened, the [illegible] too small, so this implant was [illegible] and re-packaged for use with [illegible]? The feedback from this group [illegible] this requirement could be [illegible] further	Associate commercial identity of reprocessor with specific device. (Removed: Re-establish shelf life.) Need definition of single use devices and reprocessing - Leighton to provide definition	Mandatory	Closed by the US Team	medical devices #21	Identification	
7[illegible]	Hospital	The GS1 system should differentiate different strenghts and package sizes	Some suppliers use the same product number for products with the same basic function and differenciate these only with additional information outside the product number. This could lead to dispensing errors To differenciate different configurations of the same product (different strenggths and/or package sizes)	Optional	Closed	pharma #21 HS #9, #11, #20, #25 #32	Identification	
7[illegible] Delete Covered by [illegible]	Hospital	For a number of products the serial number is required for invoicing and [illegible]/patient file. THIS IS VERY VAGUE. CAN WE DELETE AND ADD THE RATIONALE TO # 57 (depending of agreement of #57) #31 (instruments) and #78 & #79 (trays)	the serial number is used in the documentation of a patient record to ensure the tracking mechanism it is needed for implants (recording for patient file and assurance) and for [illegible]	Mandatory	Closed by the US Team	pharma #22 HS #18, #45	Identification	
7[illegible] Deleted [illegible]	Hospital	A tray must be able to be identified at unit level (Serial No) as a loan tray if it is a loan tray. PROPOSAL: must be able to identify a loaned tray at the unit level (serial number) if it is a loan tray. Voltier's Comment: OK, can be deleted	To link the tray ID to the patient file, this means that the ID data set of the tray must be harmonised with the trays belonging to the hospital so that the patient file includes an appropriate link to the history of the tray	Mandatory	Closed by the US Team	surgical instruments #30	Identification	
7[illegible] Delete [illegible]	Hospital	A tray must be able to be identified (Serial No) as a loan tray if it is a loan tray for long term use at this hospital. PROPOSED: must be able to identify a tray at the unit level (serial number) if it is a loan tray for long term use in the hospital. Voltier's Comment: OK, can be deleted	To link the tray ID to the patient file	Mandatory	Closed by the US Team	surgical instruments #31	Identification	
[illegible]	Hospital	correct implant on hand for the optimal procedure at that right time in kind of size and dimension. PROPOSED: must be able to identify that the implant on hand is the correct implant size and dimension for the correct procedure. EU Team agrees with proposed text above. US Team recommends: Identify the implant at the time of procedure.	minimized time for implementation, best clinical outcome, optimized patient safety. Proposed: change rationale to "to assure the correct implant for the correct procedure.	Mandatory	Closed by the EU Team	implants #23 HS #10, #20	Identification	
[illegible]	Hospital Manufacturer Sub contractor	Sterilization events: containers used to hold trays during sterilization events and the trays themselves must be identified	The container identification is associated to the trays which are in turn associated to the surgical instruments in the event of a failure in the sterilization process (sterilization event number) or recall	Mandatory	Closed	surgical instruments #24	Identification	
[illegible]	Hospital	In a hospital peel packs/trays' availability is checked before the operation. PROPOSED: must be able to check the availability of peel packs/trays before an operation. EU team proposal: Instruments, peel packs and trays must be identified as trade items with expiry dates. US firmly believes that this is covered above and can be deleted. Voltier's Comment: The availability check before an operation has to be done on tray and peel pack level, not on single instrument level.	To assure that all the necessary instruments/peel packs/trays are in inventory and not out of date (available for use)	Mandatory	Closed by the EU Team	surgical instruments #25	Identification	
9[illegible]	Hospital	In the hospital, we must be able to track and trace products	To support vigilance, possible recall and association of product use with the EPR	Mandatory	Closed	pharma #23 HS #9, #18 #32, #45	Identification	
[illegible]	Manufacturer	need to identify the date of production to the month	meet regulatory demand (human readable only)	Mandatory	Closed	Added in Berlin		
10[illegible]	Hospitals	need to automatically capture in a barcode the quantity (count) of "inner box"(a grouping of unit of use) for biologicals contained in a bigger shipper box	It is the unit of trade (order/receiving) and need to be recognized throughout the supply chain as required by Japan's industry guideline	Mandatory	Closed	Japan #5	Regulatory for Japan, this is associated with AI(11) and AI(30) being used in conjunction by Japan, this is not per GS1 system	
10[illegible]	Hospitals	need to capture the batch number when using reagents	batches of reagents may vary and quality control issues require tracking of batches including for calibration between diagnostic equipment & reagent	Mandatory	Closed	HS #38		
10[illegible]a	Hospital	I would advocate adding identification on pharmaceuticals at the unit-dose level. This means that manufacturers would identify products packaged at the unit dose level with a unique product identifier	To improve the efficiency of safer procedures and allow a final control just before the administration of drugs to patients. This will significantly increase the patient's safety.	Mandatory	Closed	EU Team rework of 104-108		
10[illegible]b	Hospital	I would advocate adding identification on pharmaceuticals at the unit-dose level. This means that manufacturers would identify products packaged at the unit dose level with a unique product identifier, lot, expiry date.	Lot and expiration date must be added to product identification to enable the traceability up to the patient level	Mandatory	Closed	EU Team rework of 104-108		

NOTE: ANY ADDITIONAL UK Department of Health Business Requirements will be added here.
UK Department of Health has no additional business requirements per response 3/7/07

Number	Role	Business Requirement	Response			Source
110	Retailer	must have identification of products and their individual instances	product identification is required to support current business systems and processes such as instance identification will facilitate recall which will lead to increased patient safety	closed		Walmart 3/8/07
111	Retailer	The minimum data set possible in a barcode or RFID tag to support business requirements such as recall, authentication, track and trace.	Unnecessary data may limit the number of products that can be marked with AIDC technology.	closed		Walmart 3/8/07
112 A	Retailer	Product information at each level of packaging must be unique to lead to quantity information in the master data	you need to be able to identify the level of packing being recalled if there is a recall.	closed		Walmart 3/8/07
11[illegible]	Retailer	data capture should happen as automatically as possible	Auto data capture insures consistent, less error prone processes			Walmart 3/8/07
11[illegible]	Retailer	If product information is distributed from multiple locations, i.e. distributors, must be able to allocate and trace serial numbers to distributor and manufacturer	Necessary in maintaining unique serial information on a product. Also may be helpful in identifying problems/trends arising from the distributor onward in the supply chain.			Walmart 3/8/07

GS1 Healthcare Governance Charter
- draft -

Version	Date	Changes	Responsible
1 0	18 09 2006	Final version for LT Meeting in Paris	Ulrike Kreysa
1 1	25 09 2006	Feedback from LT discussion in Paris incorporated	Ulrike Kreysa
1 2	06 10 2006	Final document for LT vote with changes after comments from Mark, Peter and Jim	Ulrike Kreysa
1.3	11 10 2006	Inserted background about status of non-for-profit for GS1 and fees are used to cover HUG activities according to work plan Voted on and approved by HUG Leadership Team	Ulrike Kreysa
1.4	27.02.2007	Changed title to GS1 Healthcare for clarification purposes, made modifications as requested at January 2007 Meeting only Changed "industry, to "sector, Feedback from HLS co-Chairs pending Changes in red	George Smeon

1.0 Mission

To lead the healthcare sector to the effective utilization and contribute to the development of global standards with the primary focus on automatic identification to improve patient safety.

2.0 Vision

To become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) seeking input and direction for global standards in the healthcare sector.

3.0 Accountability

To the GS1 Management Board

4.0 Membership

4 1 Voting Membership Criteria

HUG Voting Members must be a member company of a GS1 member organization. Members can be manufacturers, wholesalers/distributors, GPO's, hospitals and pharmacies, logistics provider, doctors and nurses.
Voting members of the HUG contribute to the HUG activities and basic operational costs with an annual fee.
The HUG membership fee is Euro 3 500 per year. Conference fees will be different for voting HUG members and non-voting HUG members.
GS1 is a not for profit global standard organization. The GS1 global Healthcare User Group (GS1 HUG™) is a GS1 facilitated healthcare members group. GS1 HUG activities are self funded. These fees are collected and dispersed on a revenue neutral basis. The funds collected are to cover the costs of the meetings and activities of the GS1 HUG and other appropriate costs including a surplus account to cover anticipated costs. The fees and activities are determined by the Leadership Team annually and are adjusted based on the forecast activity.

Voting members have voting rights in the development of global standards and password-protected access to all documents. They can be candidates for the Leadership Team and the Co-Chair positions.

If a member misses three or more physical meetings/conferences, membership is considered inactive, that means that the voting rights are waived until the Leadership Team reinstates them.

4.2 Voting Criteria

More than one individual can represent voting member companies, however, each member company has only one (1) vote, even if they have multiple divisions.

Plenary decisions of the HUG, for example ratifying guidelines and Work Team results, will be taken by simple majority of the members that are entitled to vote, a quorum of 50% is necessary. Voting will be done by e-ballot.
GS1 supports and manages the decision process but has no voting privileges.

4 3 Non-voting Membership Criteria

Organizations with a keen interest in standards development and patient safety may support the GS1 global Healthcare User Group (GS1 HUG™) by participating in the Work Teams. Non voting members are eligible to become members of HUG Work Teams, attend HUG events, and have

limited access to documentation and work results. Associations, regulatory bodies and educational institutes can be non-voting members with no voting privileges.

The Leadership Team decides when non-GS1 members can participate at conferences/meetings, non members cannot vote.

4 4 Healthcare Provider

Organizations and / or individuals who deliver healthcare to the patient are considered healthcare providers. Healthcare providers are encouraged to use the GS1 system and participate in the HUG as voting members.

4 5 Technology and Solution Providers

Technology and Solution Providers can participate in HUG Work Teams, only by invitation through the respective Work Team leaders, to provide technical input. Upon invitation of the Leadership Team, they can participate in HUG conferences/meetings as observers, without voting privileges.

5.0 Organizational Leadership

5 1 Leadership Team

The Leadership Team shall comprise of a minimum of seven (7) full members and a maximum of twelve (12) full members. Membership should be geographically balanced. Qualifications to serve as a Leadership Team member include subject matter expertise in the GS1 System and associated technologies. GS1 Member Organization representatives (maximum 3 – adequate to market activities) may also serve as additional non-voting Leadership Team members.

Roles and Responsibilities

The Leadership Team shall

- elect two Co-Chairs through nomination and consensus
- develop and maintain the overall HUG strategy
- manage, finance, conference/meeting planning, public relations, membership and policy
- ensure geographic and supply chain stakeholder balance
- formulate individual positions of the HUG in response to regulatory, customer, and local standards initiatives
- represent HUG membership to external groups and organizations with interests in standards and patient safety - GS1 representatives shall be engaged
- create Work Teams to respond to, or drive, specific initiatives
- ensure that Work Teams are adequately resourced
- appoint Work Team leaders, review progress of the Work Teams on a regular basis and ensure that there is alignment between the Work Teams

- ensure participation in the Global Standard Management Process (GSMP) by representing the HUG in GSMP and by using GSMP and EPCglobal as appropriate for any standards to be developed

Leadership Team members must be able to act as their organisations representative in key-decisions.

The Leadership Team shall hold regular scheduled teleconferences to monitor progress, discuss issues and meet in person in conjunction with the HUG conferences. Further face-to-face meetings can be organised if necessary.

Limits of Authority

Decision-making is achieved through consensus, which is defined as approval without sustained opposition – a quorum of 50% is necessary.

Leadership Team Selection Process

A candidate to the Leadership Team must be engaged in GS1 Standards development efforts and should be able to promote the implementation of the developed global standards and best practices in their organizations and should therefore be able to provide linkage between their business and the GS1 HUG™. An election committee, consisting of HUG Co-Chairs and the GS1 Global Office, shall nominate candidates. Candidate confirmation is obtained by e-ballot of the membership.

Term Limits

Leadership Team members serve a one-year term which is renewable.

5 2 Co Chair

The Leadership Team shall elect two Co-Chairs. The Co-Chairs should provide adequate representation from all healthcare sectors and an attempt should be made to keep a geographical balance.

Roles and Responsibilities

Co-Chairs shall

- convene and preside at HUG conferences and meetings
- approve agendas proposed by the GS1 Group Manager Healthcare
- facilitate the consensus process
- disseminate and monitor communications with membership
- assign duties as necessary to advance the work of the HUG
- report to the GS1 Management Board

Term Limits

Co Chairs serve a term of 2 years with the possibility to be re-elected for another two years. Co-chair terms are staggered to ensure continuity. Co-Chairs must be able to act as a representative of their organisation in key decisions for the duration of their term. GS1 staff cannot serve as Co-chairs.

Limits of Authority

Decision-making is achieved through consensus with the Leadership Team, which is defined as approval without sustained opposition.

5 3 Work Team Participation

The HUG develops proposals for global standards through Work Teams.

Work Teams focus on specific business issues.

The working language is English.

HUG membership will review and approve, by majority vote, the results of the Work Teams before they enter the Global Standard Management Process (GSMP). The Work Teams champion the proposed standards through the GSMP.

5 4 Work Team Leaders

Work Teams are ideally co-chaired.

Leaders of the Work Teams are responsible for the progress of the team according to the scope and deliverables. They are also responsible for all administration of their team and will be supported in that task by staff from GS1.

5 5 Group Manager Healthcare

Roles and Responsibilities

- Facilitation of the HUG's decisions
- General Communication
- Reporting to GS1 Global Office (GO) Management
- Ensuring that HUG Leadership Team has sufficient support from GS1 staff
- Driving GS1 alignment with HUG goals and objectives

Term Limits

Group Manager Healthcare maintains the position as long as he / she remains in post.

6.0 Conferences and conferences procedures

There will be three conferences per year, the HUG Leadership Team determines time and place, but they should take place in different geographical regions. The agenda of the conferences are drafted by the Group Manager Healthcare and approved by the Leadership Team.

6 1 Conference fees

There are fees applicable for conferences, HUG voting members pay a reduced fee
Speakers participate free of charge at the conferences, as well as regulatory bodies, GS1 staff and GS1 Member organisations.
The Leadership Team decides if the HUG will reimburse the travel costs for a speaker – there will be no remuneration for speakers.

6.2 Anti Trust Statement

The GS1 Anti-Trust Statement must be brought to the attention of all participants at the beginning of each conference/meeting and teleconference.

6.3 Quorum

Leadership Team and Work Team decisions are not binding when a quorum is lacking at the time of the decision. GS1 GO shall maintain rosters of HUG, Leadership Team and Work Team membership. A quorum is defined as more than half of the registered roster.

6.4 Minutes

Where a quorum is present, minutes shall be taken and posted on the working area of the GS1 HUG™ website. The recording of minutes is a voluntary, rotating function of the members present.

7.0 Document Development Process

7.1 Document Types

Specific Responses regarding public policy

One or more Leadership Team members draft specific responses with subject matter support from the GS1 GO. The Leadership Team then reviews the proposed response. Substantive and editorial changes are suggested and approved by consensus. Review can be via a physical meeting, e-mail, teleconference or Webex, lead by the Work Team "Public Policy". The HUG will submit the response to the regulatory authorities either via the local GS1 Member Organisation or through the Group Manager Healthcare.

Position Papers

Any member of the HUG or a GS1 Member Organization can draft a position paper. Once drafted, the paper can be submitted to the HUG Leadership Team for adoption. Substantive and editorial changes are suggested and approved by consensus. Review and adoption can be via a physical meeting, e-mail, teleconference or Webex. Once the Leadership Team and originator reach agreement the position paper can be posted on and distributed via HUG website.

Press Releases

A press release is a succinct and timely announcement. Agreements among industry/sector groups, regulatory bodies, key customers and companies' adoption of GS1 Standards, or a change in GS1 HUG Leadership are possible press release topics. As topics are presented to the GS1 HUG™ Leadership Team, they shall reach a consensus before forwarding to GS1 GO Marketing to draft and publish.

8.0 Communications

Communication with associations and regulatory bodies is done through the Group Manager Healthcare at GS1 GO in alignment with the Leadership Team and according to the mission and work plan of the HUG.

GS1 provides the neutral platform for discussions between the healthcare industry and regulatory bodies.

The Support Team 'Communication and Coordination' is responsible for all marketing activities of the HUG, in alignment with the GS1 branding guidelines and the GS1 GO Marketing Team. GS1 GO maintains the HUG website (www.gs1.org/hug).
Communication, with regard to HUG global marketing activities, shall be the responsibility of the Leadership Team, in alignment with the GS1 branding guidelines and the GS1 GO Marketing Team. GS1 GO shall maintain the HUG website (www.gs1.org/hug).

For presentations to third parties GS1 HUG™ standard presentation templates shall be used.

Annex:

How to Use This Document – Document Conventions

MUST: This word, or the terms "REQUIRED" or "SHALL", means that the definition is an absolute requirement.
MUST NOT: This phrase, or the phrase "SHALL NOT", means that the definition is an absolute prohibition.
SHOULD: This word, or the adjective "RECOMMENDED", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
SHOULD NOT: This phrase, or the phrase "NOT RECOMMENDED", means that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
MAY: This word, or the adjective "OPTIONAL", means that an item is truly optional.

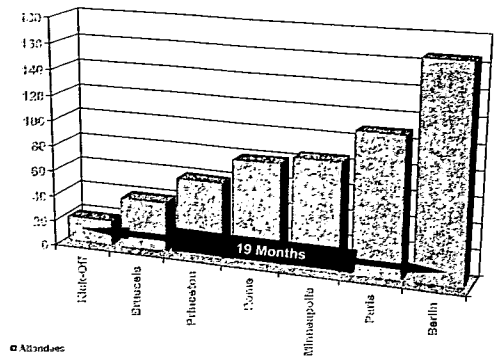
About the Global Healthcare User Group – GS1 HUG™

Ulrike Kreyer
GS1 Forum – 15 February 2007

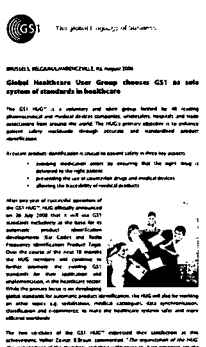
The global language of business

www.gs1.org

HUG Conference Attendees:



GS1 has embraced the healthcare sector AND the healthcare sector has embraced GS1



Global Healthcare User Group Chooses GS1 as Sole System of Standards in Healthcare

GS1 Switzerland
GS1 Chile
GS1 Australia
GS1 New Zealand
GS1 Canada
GS1 Germany
GS1 Serbia & Montenegro
GS1 Bosnia-Herzegovina
GS1 Macedonia

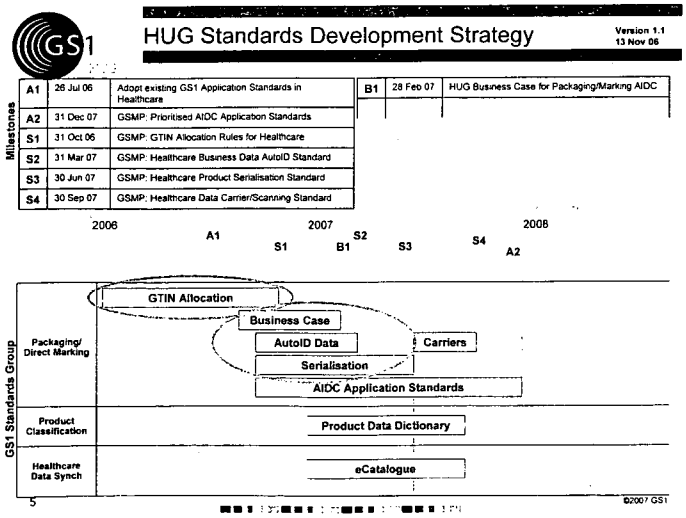
And more to follow soon.....

HUG Standards Development Strategy

Version 1.1
13 Nov 06

Milestones

A1	26 Jul 06	Adopt existing GS1 Application Standards in Healthcare
A2	31 Dec 07	GSMP: Prioritised AIDC Application Standards
S1	31 Oct 06	GSMP: GTIN Allocation Rules for Healthcare
S2	31 Mar 07	GSMP: Healthcare Business Data AutoID Standard
S3	30 Jun 07	GSMP: Healthcare Product Serialisation Standard
S4	30 Sep 07	GSMP: Healthcare Data Carrier/Scanning Standard
B1	28 Feb 07	HUG Business Case for Packaging/Marking AIDC



Dedicated to improving patient safety

- Prevention of medical errors
- Product authentication
- Tracking and tracing
- Increased supply chain efficiency

EPCglobal HLS Update

State of Pedigree and EPC/RFID Standards

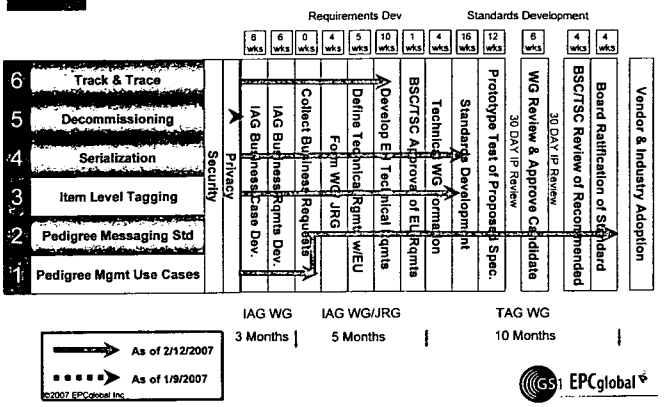
Global GS1 Forum 2007
Brussels, Belgium

February 15, 2007
Chuck Schramek
EPCglobal HLS Facilitator

EPCglobal

Standards Update

Current Status



EPCglobal

Standards Update

6 Track & Trace
5 Decommissioning
4 Serialization
3 Item Level Tagging
2 Pedigree Messaging Std
1 Pedigree Mgmt Use Cases

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete (Certification Requirements due 12/20/2006).
- Prototype event was successful.
- Passed Technical Review
- Intellectual Property Review period satisfied
- **Ratified standard – 01/2007**

EPCglobal

Standards Update

6 Track & Trace
5 Decommissioning
4 Serialization
3 Item Level Tagging
2 Pedigree Messaging Std
1 Pedigree Mgmt Use Cases

Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG -- starting with Serialization.

EPCglobal

Standards Update

6 Track & Trace
5 Decommissioning
4 Serialization
3 Item Level Tagging
2 Pedigree Messaging Std
1 Pedigree Mgmt Use Cases

Define requirements and/or guidelines for decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Work Group to be chartered & initiated February 2007; anticipating 6 month effort
- US Drug Enforcement Agency interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry

EPCglobal

Standards Update

6 Track & Trace
5 Decommissioning
4 Serialization
3 Item Level Tagging
2 Pedigree Messaging Std
1 Pedigree Mgmt Use Cases

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Common vocabularies and location identifiers drafted
- Additional use cases to be addressed:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed
- Pedigree-on-Demand concepts being Investigated
  - IBM/VeriSign – Solution Provider Perspective
  - Cardinal Health – Supply Chain End-User Perspective
- Integrate with GS1 Traceability efforts

EPCglobal

研究成果の刊行に関する一覧表

著書

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秋山昌範	医療現場におけるIT化の現状と展望～バーコードとリアルタイム情報処理による医療プロセス管理	首藤紘一	ジャピックジャーナルNo.3	日本医薬情報センター	東京	2005	67-77

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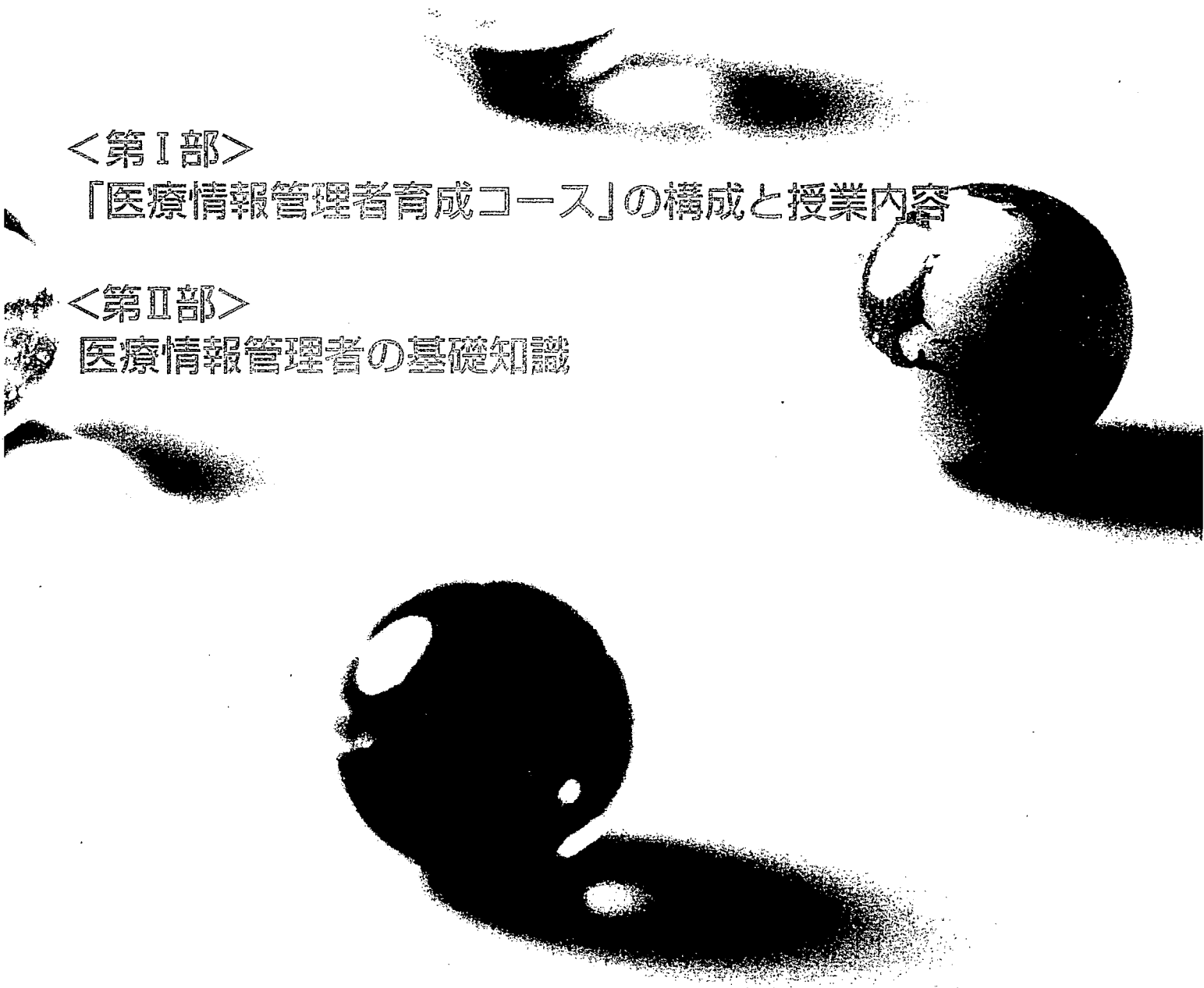
医療情報管理者

講座

テキスト

【第1版】



＜第Ⅰ部＞
「医療情報管理者育成コース」の構成と授業内容

＜第Ⅱ部＞
医療情報管理者の基礎知識

平成16年度
「医療情報管理者育成のためのモデルプログラム開発事業」
モデルシステム開発委員会

<第7章>
リスクマネジメントのための情報技術

■この章の学習の目標

医療事故を防ぐためには，人間系の運用管理も重要だが，IT（情報技術）を上手く組み合わせることが重要である。この章では，ヒューマンエラーの発生原因，防止方策としてのITの利用を学習する。

【学習のポイント】

1. 米国医学院の報告と国民の意識変化
2. 業務フローとITの活用
3. リアルタイム処理の重要性と実施データの活用

■学習のポイント

ポイント1　米国医学院の報告と国民の意識変化

医療の高度化，専門分化が進む中で，質の高い医療従事者の養成や，質の高い医療提供の環境整備を図っていくとともに，患者・国民の適切な選択によって良質な医療が提供されるよう，情報の積極的な提供を図る必要がある。同時に，医療の質の確保ということでは，近年続発している医療事故について，患者の安全を守るという観点から，行政や医療機関がともに総合的に取り組むことが求められる。

医療過誤の対策として，厚生労働省も医療安全対策会議を設置し，医療安全対策に重点を置いてきた。特に注射事例は約3,500事例と全体の3割を占めており，その多くは与薬業務に関する事例であったと報告されている。従って，医療過誤対策の中心は，与薬業務におくべきと考えられている。

米国には，情報システムを利用した医療過誤対策を行っている病院もある。そして，その後システムの改良を行い，10年前に比較して医療過誤は86%減少したと報告されている。前述したようにわが国における川村班報告においても，与薬業務が医療過誤の最多であった。さらに，BWHによると，コンピュータ化されたオーダリングシステムにより医療過誤防止の可能性があるとされている。旧厚生省は平成12年8月8日の医療審議会総会に，医療安全対策の推進方策に関する検討議題を提示した。その内容は，前述した医療のリスクマネジメントシステム構築に関する研究班報告によると，医療過誤対策の中心は，与薬業務におくべきと考えられており，注射や服薬時における誤薬投与対策が最も重要と考えられる。

1）国民意識の変化

今日の社会では工業化，情報化が進み，遺伝子工学や医療技術の高度化により社会も変化してきた。特に，環境権，知る権利，プライバシーの権利などの「新しい人権」が登場した。また，個人の