

5. When you identify serial numbers are the numbers meaningful (containing intelligence) or random? meaningful

6. Was number size/capacity a criterion for choosing meaningful or random numbers? _ yes

7. Is the allocation of your serial numbers centralized or decentralized? __ centralized __ decentralized __ both

If both, please explain.

8. Was number size/capacity a criterion for choosing centralized or decentralized allocation of numbers.

_____yes _____no
11. Would there be an impact on you if you had to change your number structure?

_____yes ____no
12. If your answer to 9 was yes, please explain the impact.

13



Ówęsinomianie

✓ Manufacture

✓ Distributor

✓Wholesaler √Hospital

✓Vaccines ✓Biologics

√Therapeutic Nutritional

✓Pharmaceutical ✓ Medical Devices

✓ Instruments

✓ Implants ✓Animal Health

✓Dental

14







Alpha Numeric - 100%

Numeric - 0%

Meaningful - 25%

Random - 75%

Centralized - 33%

De-Centralized - 66%

Both - 100%



Next steps

Receive Q and A feedback and access Please submit by Feb 10

Complete the business requirements case sub team So far:

Vaccines

Biologicals

Medical Devices

Therapeutic Nutritional

Pharma - started via HLS, sub team kick off now.





17



Understand and rationalize the business requirements

1st pass - Is the business requirement within scope?

yes - move on

 $no-highlight \ for \ move \ to \ parking \ lot$

2nd pass - Is the business requirement clearly written?

ves - move on

no - highlight for rework

3rd pass - Is the rationale correctly stated?

yes - move on

no - highlight for rework

Make plan for rework of highlighted business requirements.





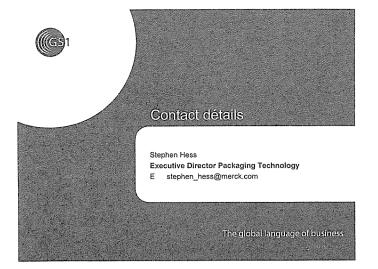
Work Team Meetings Thursday 8:30 AM NYC time

Next Call is Wednesday Feb 7 5:30 PM NYC time 1 out of 4 calls to engage our colleagues in Asia Pacific

Phone: 877-864-7187(US) +1-720-348-446(international) pass code * 1527657 *

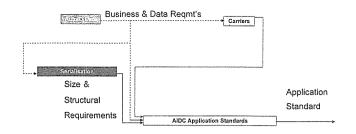








AIDC Data & Serialisation Work Teams Deliverables







21

Senalisation Work Team Work Team Leaders



Stephen Hess

Packaging Technology

Executive Director of

Merck



Pierre Stoquart

Director Packaging & Logistics, Technical Services

Glaxo Smith Kline

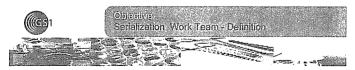


Auto-ID Application Standards Team's Objective

Construct packaging/direct marking AIDC application standard(s) specific to appropriate product group or sub-industry requirements, with patient safety as the highest priority and minimise the number of different healthcare application standards and associated required AIDC technologies while maintaining practicality and appropriate differentiation.

...and create a healthcare application standard to meet our business requirements





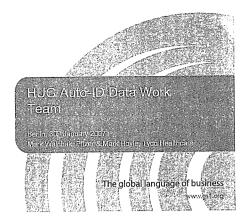
Mass Serialization is the process of generating and applying codes to identify uniquely each individual instance of a given product entity. (For example each individual pack of a pharmaceutical product defined at SKU level). The codes may be sequential or randomized. The codes may be represented in a number of ways e.g. in human readable form (alpha-numeric) or machine readable e.g. barcode or RFID.

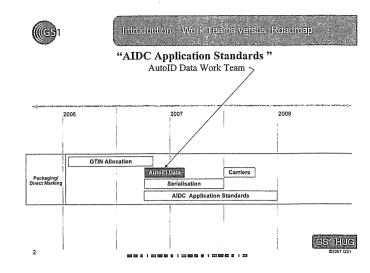
A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: Microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.

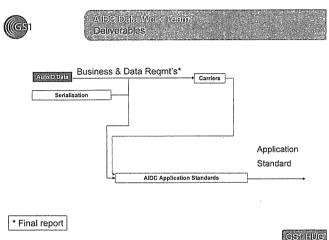


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	raffects on ca								8-13				
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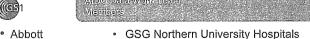












Johnson & Johnson

· NHS Chelsea & Westminster

Merck Germany

- Abbott Aexxdis
- Aesculap
- Baxter
- · Behring
- B. Braun
- **Boston Scientific**
- Celesio
- FDA Pfizer
- Novartis
- Procter & Gamble

Medtronic

- · Sanofi-Aventis
- · St. Jude
- · Tyco Healthcare





And GS1 Organizations from:

Australia

Pfizer

- Austria
- Canada
- China
- France
- Hong Kong Hungary
- Italy

- Japan
- New Zealand
- Spain
- Switzerland
- UK
- · USA







AIDC Data Work Team Froect Plan



key
--- physical meetings
task scheduled
task complete

18 1 海霉素素:液糊或量:液酶或量:溶





"Because there are no Global Application
Standards for the Automatic Identification of data
related to Healthcare, this team will identify the
Business Requirements and Data Requirements to
be used for the development of a global standard
for the automatic identification of vaccines,
biological, pharmaceuticals, therapeutic nutritional
products, medical devices, instruments and
implants with the goal of improving patient safety."

CS/ HUC C2007 GS1

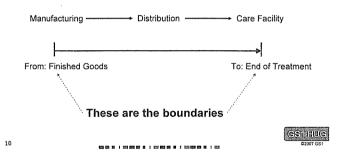


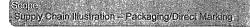
AIDC Data Work Team's Scope

- The starting point on the supply chain will be at the manufacturer and the point of finished goods, because marking only starts at the point of finishing. Upstream from this point will be out of scope.
- Food services will not be included but therapeutic nutritional products will be included. Note: Therapeutic nutrition is defined as "Therapeutic Nutrition business means enteral and parenteral nutrition of products and services to treat patients who require feeding on that specific route because of a specific disease or to prevent a potential disease."
- Adverse events related to data capture shall be considered within scope and used as an input to preparing the deliverable.
- Animal healthcare will not be in scope at this time, but input will be considered..
- · Equipment used to transport patients is out of scope.
- · A facility's assets used by a patient such as tables, lights, etc. is out of scope.

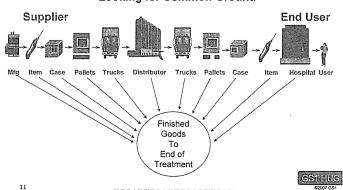








Looking for Common Ground





AIDC Data Work Team Business Requirements

For this task the work team has:

- 1. Gathered Business Requirements
- 2. Compiled and Condensed
- 3. Agree upon Content (team consensus)

Next Steps:

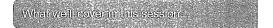
The approved business requirements will be used to establish the DATA requirements.











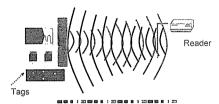
- 1. Fundamentals of RFID
- 2. EPCglobal Standards
- 3. EPCglobal Network "Internet of Things"
- 4. EPCglobal Organization

GS (HUG



Radio Erequeincy (dentification (REID)

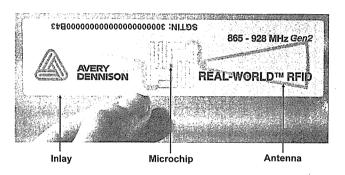
- · Non-contact data transmission by means of radio waves
- Read ranges of up to several meters
- · High storage capacity
- · Re-writeable data
- · No line-of-site contact necessary
- Simultaneous identification of multiple items







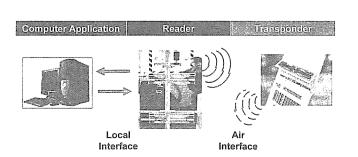
fransponder Layout



GIS1LIHUUG

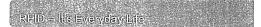


. Components of ลุก เฟลีID System















... but up to now, only in closed systems



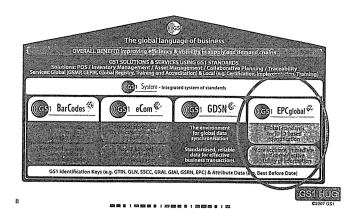


What we'll cover in this session.

- EPC: A pillar of the GS1 System



- 1. Fundamentals of RFID
- 2. EPCglobal Standards
- 3. EPCglobal Network "Internet of Things"
- 4. EPCglobal Organization





Electronic Product Code (EPC)

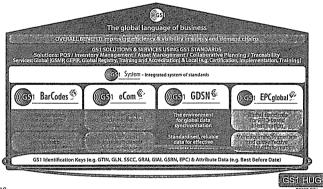
- · Identification of individual objects
- · On the basis of RFID (transponder as data carrier)
- · Globally unique and collision-free
- · Access key to additional information stored in databases





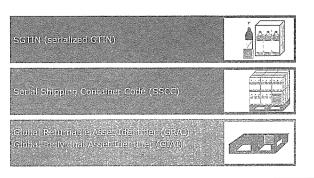


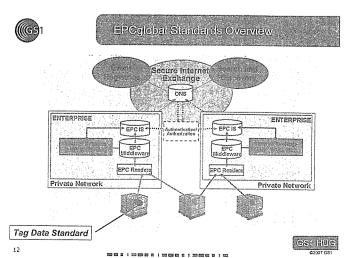
ERC one of the Identification Keys on which the GS1 System is built





IEPC at Itemi, čase and paliel level



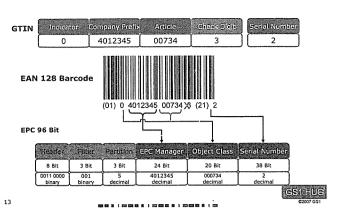




Tag Data Standard

15

Compatibility GTIN - EPC SGTIN





EPCglobal Tag Data Standard

Binary - on-tag representation

Tag's Uniform Resource Identifier (URI) -

in software when all tag info needs to be represented urn:epc:tag:sgtin-96.3.0614141.100743.2

Pure Identity URI - just the EPC

urn:epc:id:sgtin:0614141.100743.2

@\$11 HU@

EVELL SECURE Internst So train and Exchange Discovery

CNS

ENTERPRISE

EPC IS

Authorization

EPC Readers

Private Network

GEN 2 AIP



EPOglobal Air Interface Protocol

Specifies...

- · physical transfer of data between transponder and reader
- Commands which the reader can execute in its communication with transponders
- · Anti-collision procedures for simultaneous reads

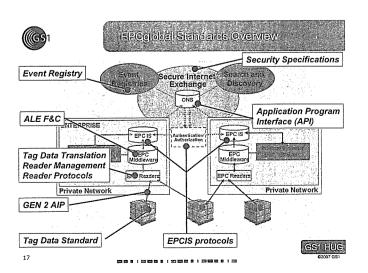
Features include...

- EPC Air Interface

 ISO 18000-6 Part C
- Frequency: UHF
- High read & write speeds (50-200 tags/second)
- KILL Function

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EPCglobal Standards Overview

Tag Data Standard	How to encode EPC tags information based on various numbering system standards?
G2 Air Interface Protocol	How does a reader communicate with tags?
Reader Protocol	How does middleware communicate with a reader?
Reader Management	How to manage a multiple EPC reader environment?
Tag Data Translation	How a reader converts tag data standards to an Internet compatible format?
Filter and Collection ALE	How to count the number of EPC's from multiple readers based on specific criteria?
ONS Application Layer Interface	Where to find more information about an EPC?
EPC IS Protocols	How to store and retrieve information about an EPC?
Security Specification	How to keep EPC information secure?
Network Architecture	How to find where is an EPC and where it has been?





What we'll cover in this session

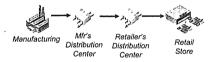
- 1. Fundamentals of RFID
- 2. EPCglobal Standards
- 3. EPCglobal Network "Internet of Things"
- 4. EPCglobal Organization





EPC Information Services (EPCIS)

- Which EPC numbers have been read?
- When have the EPC numbers been read?
- Where have the EPC numbers been read?
- Why have the EPC numbers been read?



EPCIS events are the basis for improving business processes





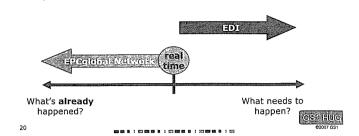
Traditional EDI vs. EPCglobal Network

EDI (EANCOM or X12): process-centric

· Request for action or a series of actions to generate an event or service

EPCglobal Network: event-driven

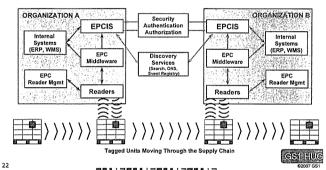
Automatic logging of movement and events in real time, as they are occur





The EPCglobal Neiwork

Supply Chain Visibility Event Related Information





23

21

Supply Chain Visibility

The power of event-related information...

- · Improved consumer availability
- Demand driven supply chain
- Reduced inventory
- · Increased productivity
- · Reduced claims and resolution costs
- Reduced shrinkage
- · Improved promotional effectiveness
- · Reduced counterfeit
- · Improved ability to track and trace

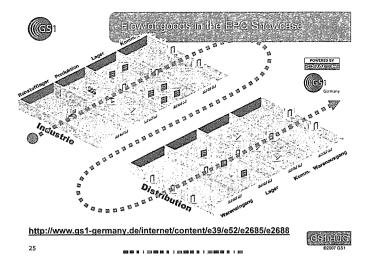


Supply Chain Visibility

- · If you can't see it, you can't measure it
- If you can't measure it, you can't control it
- If you can't control it, it's probably costing you too much money
- And you probably don't even know how much











- 1. Fundamentals of RFID
- 2. EPCglobal Standards
- 3. EPCglobal Network "Internet of Things"
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EPCGlobal Organization

- · Founded in 2003 by von GS1 und GS1 US
- Specifications based on the work of the Auto-ID Center at MIT
- · User-driven and user-sponsored
- GS1 Member Organizations (MOs) are the exclusive representatives of EPCglobal at national level



From Auto-ID Centre to EPColobei



Partnership between 100 global firms, including founders:

- Uniform Code Council (GS1 US)
 EAN International (GS1)
- · Procter and Gamble
- Gillette

EPCglobal 4

- Global:
- Standards Development
- Adoption
- Brand management and marketing
 Policies (Privacy, Intellectual Property)

- Local:

 101 countries worldwide

 Member communication

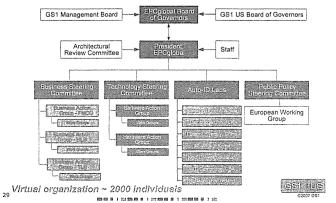
 Member Support



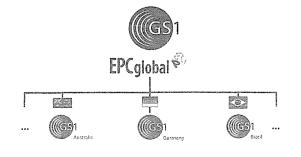
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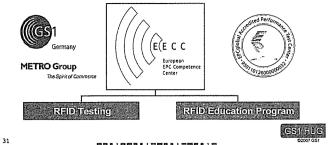
GS/f. Member Organizations (MOs) – Representatives of EPOglobal at national level





European EPC Competence Genter (EECC)

- Accredited as EPCglobal Test Center in September 2005
- Focus on European regulations and processes
- Goal: support the rollout of RFID and EPC in Europe



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EECC's Service Portfolio

RFID Testing

- Applied Tag Performance (ATP)

 Transponder Placement
- Read Range (860 960 MHz)
- Orientation Sensitivity (360°)

"Real Life" Dynamic Testing

· In live production environment

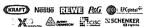
Custom RFID Testing

· Individually tailored

RFID Education Program

- · Technical principles and functions
- · EPCglobal & ISO Standards
- · RFID regulations
- EPCIS, EANCOM® interim solution
- · Applying transponders
- · System and application design
- · User reports from EPC pilots

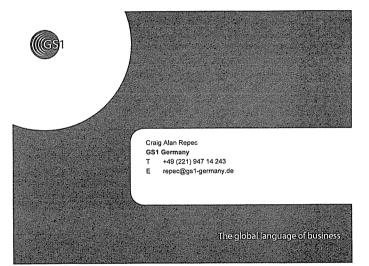
Instructors from standardization (GS1), users (industry/retail/logistics) and technology manufacturers and providers



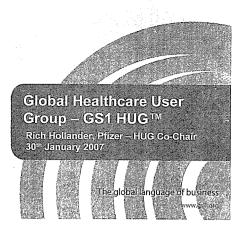
Further info: epc@eecc.info













GS1 Global Healthcare User Group:
Mission and Vision

Our Mission Lead the healthcare industry to the effective utilization and development of global standards, with the primary focus on automatic identification to improve patient safety.

Our Vision To be the single source for regulatory agencies and trade organizations (manufacturers, wholesalers, distributors, hospitals and pharmacies) to seek input and direction for global standards in the healthcare industry.





GS1 Global Healthcare User Group: Stepped plan



Primary focus

Develop global standards for automatic product identification, using Bar Codes and RFID.

Future projects

Medical catalogue
Data synchronization
Classification
E-commerce
And more ...





GS1 Global Healthcare User Group; Areas of focus

Prevention of Medical Errors



Encoding of the unit dose or unit of use package to enable automated verification to ensure right dose, for the right patient at the right time. Encoding of the unit of use package to enable automated verification to ensure the right device for the right natient.

Product Authentication

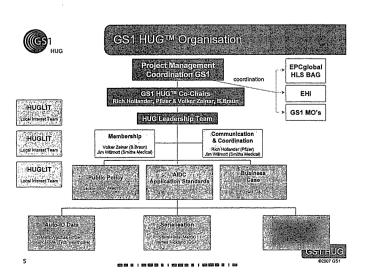
Utilizing a GS1 data structure, enable authentication of individual packages, cases or pallets.

Tracking and Tracing

Utilizing a GS1 data structure, work with supply chain trading partners to enable an electronic pedigree for individual packages such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

Increase Total Supply Chain Efficiency Through greater visibility, accuracy and velocity.





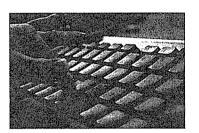
The GS1 HUG™:

What is our roadmap for the next two years?





GS1 website



www.gs1.org





HUG Standards Development Strategy

Version 1.1

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
	A2 S1 S2 S3	A2 31 Dec 07 S1 31 Oct 06 S2 31 Mar 07 S3 30 Jun 07

		2006	A1	S1	2007 B1	S2 S	3		S4 A2	2008	
Standards Group	Packaging/ Direct Marking	GTIN Allo	cation	Business Autol	D Data Serialisat	ion pplication		Carriers andards			The state of the s
	Product Classification				Produ	ct Data D	ictic	nary			
GS1	Healthcare Data Synch		A CONTRACTOR OF THE PARTY OF TH		normalista de la composición del composición de la composición de	eCatalog	ue	- No. He was			HUG

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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 関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

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

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

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・・・・・ 製品機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・・・・ 商品線別コード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線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・アウトブット(ミンガン州立大学協力)

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。

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、パクスター、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・パーマスケジュール ューテカル、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 ペンダー	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	仏ポンピド一総合病院、ジュネーブ大学病院
運送	1	DHI

団体	1	欧州ジェネリック医薬品協会、
숙왕	40	
EI RI		

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

WT	活動概要	国内業界の対応動向
オートID データ WT	現在、医薬品へのパ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、日米飲 からアンケート調査し、記入内容を精査中。国際 電話会議に流閉センターが参加。5月にデータ要 件をまとめる予定。	医療機器業界(別新参照) 1999年 医療機器業界(別新参照) 1999年 医療機器業界(SI 採用宣言 2000年 UCC/EAN-128 ガイドライン でGSIデータ項目標準化。 2005 年日本医療器材工業会GS1採用 2006 年日本医用機器工業会GS1採用 2006 年日本医用機器工業会GS1採用 (鋼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 標準によるパーコード表示実施要項を通知 2007 年3 月厚労省パーコード表示実施 要項条一部改正
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鎖別 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



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 HUGTM Basics - Mission & Vision

BarCodes and eCom - David Buckley, GS1 Global Office

And Buckley is a 10 year veteran of GS1. In that time he has occupied vanous roles ne development and implementation support of GS1 standards. In his current role, provided the control of the control

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 nationalisation. Xerox further supported his IMEA studies which were awarded in 1920.

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

GDSN - Rolf Stark, Sinfos

Rolf Stark holds a Diploma as Master of Business Administration at the University of Titler. After Installation, he was project manager for development and implamentation Germany, in 1929 be joined Madakhan, a joint venture of GSI Germany (Installation Centrals for Coorganisation Gribit) as Project manager and GR Panel Service, a world leading market research installation, Madakon provided scarper based PLO S. From 1937 to 2002 he was the Division Manager and Executive Board Member at 303 Germany responsible for SINTOS, the standard based master data pool. Since 2002 Rolf is Chief Executive Officer of SINTOS Gribbli, a joint venture of GSI 1000 for the Chief Executive Officer of SINTOS Gribbli, a joint venture of GSI provider.

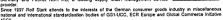


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Work Teams

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

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

Regulatory - Jackie Elkin, Medironic



Jackin'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 Medironic, Jackie worked as a Sr. Paralegal in the Hospital Products Group of Pfizer, Inc. Her beokground includes managing product fability and patent litigation cases as Sr. Paralegal and then as a Li

Support Team

Communication & Coordination - Jim Willmott, Smiths Medical

Jim Wilmost is the Circup Labelino Manager for Smiths Medical, a part of Smiths Group pile. His responsibilities include the dievelopment of, and ensuring compliance to corporate licently guidenies for peakagin, labeling and instructions for text, used by the manufacturing sites workside. This encompasses regulatory, legal and language requirements for all medical devices sold in all markets in addition, his is also responsible for the labeling amends creation, for key products lines sold in Japan, using princially MAC complexes and applications.



Jim joined Smiths Medical in June 2002, having previously worked for other leading medical device manufactures, in both Regulatory Affairs and Marketing positions. He was based in Germany and Japan before tethning to the UK by join Smith Medical He is also a member of several committees and task forces within trade associations and st (og ARHI, Eucomah, Bill & GER).

11:30 - 12:00 Registration and Lunch

12:00 - 13:00

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

Systemeto-link und knowalconforchung in Kartenuber (Professio careers)

Froblestic careers

Froblestic car

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

Cramman returnace Committee

In 1970 Labal Josen exhered into the family business. Max Jenna AzzeinstellGresshandung KD, a family no medicine wholesale trade company based in
Rotherm Germany, employing approx, 250 staff in 1977. The became Managing
Director of the subsidiary Max Jenne GmbH. In 1980 he became a general partner of
the Max Jenne Azzeinstell-Grosshandung KD.
From 1992 – 2005 Lother Jenne was vice-chairmen of the WCA (Trade Association for
From 1992 – 2005 Lother Jenne was vice-chairmen of the WCA (Trade Association for
From 1992 – 2005 Lother Jenne was vice-chairmen of the WCA (Trade Association of
From 1992 – 2005 Lother Jenne was vice-chairmen of the WCA (Trade Association of
From 1992 – 2005 Lother Jenne was vice-chairmen of the WCA (Trade Association of
From 1992 – 2005 Lother Jenne was vice-chairmen of the WCA (Trade Association of Parking Modelland) and the Committee of CRIP - The European
dings, 2003 a member of the Executive Committee of GRIP - The European
Association of Pharmacoulcular Mucha Wholesslers, 2005 the chairman of the
Technical Committee of GRIP, 2006 the chairman of the PM-GRID Association AGA
member of the exactive Committee of the Hort German englineyer association AGA



14:30 - 15:00 Coffee break



EPCglobal - Craig Alan Repec, GS1 Germany

Craig Alan Repoc 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).

Cooling studied German, all the Cellogie of the 1440 Cross in Worcester, Croiling studied German, all the Cellogie of the 1440 Cross in Worcester, Massachusetts, including a year abroad at the Humbold-Universität in Berin, Germany, Thereafter he was assigned an English Inaques teaching assistantiship at a commercial academy in Vienna, Austria, by the Futhright Commission of Coloring completion of Kerme Inc. 3. Accelerated Coheme Development Personn (ASDP), Christ worked as a Kezne consultant or diverse application management engagements in Section and Washington CG or over they are also avoid as project manager with an internet technology start-up in Bonn, Germany, before polining CSSI Germany is 2001.



The HUG - Mission and Vision - Rich Hollander, Pfizer

HUG – Mission and vision – rocur rotusnose, return Hollander is Comic Director of Packaging Genérace for Pfazer Inc.'s Clobal rifetioring group. He responsibiles include package design and development infectioning group. He responsibiles and contain package design and development and result of the supporting the Anniant Health. Consumer Healthcare and Human Health sease as well as the development and implementation of global packaging gelges. Rich received he Bacherior Degree in Malamentae from Fluggers and the Pfazer in Hamman of the Pfazer in 1909 as an Industrial Engineer and in 1902 became Manager of again Engineering. Since then Rho's terponsibilities have grown in clobed as in the Pfazer in 1909 as an Industrial Engineer and in 1902 became Manager of again Engineering. Since then Rho's terponsibilities have grown in clobed as it will be produced to the Pfazer in 1909 as an Industrial Engineer and in 1902 became Manager of again Engineering control to the Pfazer of Capity and the Pfazer of the Pf



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13:00 Opening and Introduction

Welcome by GS1 GO - Miquel Lopera, GS1 Global Office, Belgium

Miguel A. Logor in President and Cheb. Becautive Officer of GB1 (formety) known as EAN Internationally since Acid 2003. To add to his responsibilities, he was appointed Cheb Executive Officer on test Jausary 2004 of GB1 US (formerly known as the Uniform Code Council - UCC), the US based counterpart and pint owner with EAN International of the global EAN LOCK standards system to both crepations as warder of Cheb. Mr. Lopors, a Spanish national, brings to both crepations as warder of the Mind Mr. Lopors, a Spanish national, brings to both crepations as warder of the Mind Mr. Lopors, a Spanish national, brings to both crepations as warder of the Mind Mr. Lopors, a Spanish national, brings to both crepations as warder of the Mind Mr. Lopors, as Spanish national, brings to both crepations as warder of the Mind In 1979, he became IT Overtor of P.E.G. Span and later IT Director of P.E.G. UK, Island and Scandarius, in 1982, he changed career to Marketing, becoming Marketing Director of Laundry Detergents, Europe, in Brussels, Marketing Director of Fabric & Hermac care in Spanish and later responsible for the Fabric & Home Care and Fabrica Bereages Divisions of P.E.S. Deters (Span and Portugal) based in Makidot. His major repotress has been the dears of new faractis includitions and European pricing.



Mr. Lopera is an early developer, strong believer of Collaborative Commerce between Manufacturers Retailers. He created a Collaboration Program between key retailers such as Mercadona, Carrefour, Au-and PAG Spich back in 1984, based on multifunctional beams, comething 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 - Jürg 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, Jorg Pretzel had a managing position at Heltit PB1 KG and thex CmbH. Between 1981 and 1993, Jorg Pretzel served as CEO for Central Europe and Vice President of Sales at A.C. Nielson, Jorg Pretzel graduated in Dissieres Management at the University of Manates.



Greeting - Jürgen Völikopf, B.Braun

Jürgen Völkopf Johned B. Braun in 1990 after etudying business administration and mechanical engineering all Technical University Darmatoxt, Germany. The first years he worked as project engineer or various topics acut as, customer service a reorganization, master production scheduling, early e-commerce projects and also stock part in a ber cedity working group of EUCOMED.

Since 2002 he is the first globally responsible logistic manager of 8 Braun as Genior Vice President Logistic and Supply Chain, He is responsible for all logistic operations of the 8. Braun Force and coordinates the supply chain activities of all 8. Braun Force and Continues in dual rules responsible for the Supply Chain Management of the largest division, Hospital Gare. In this position feet are of the global master scheduling, inventory, divinery performance and stategies purchasing of Hespital the supplies of the

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

Hans Werner Kittlaus is chairman of the committee for drug packaging of the undesverbandes Deutscher Krankenhausspotheker (ADKA) [German Association (Hospital Pharmacists].

Dr. Kititaus received the Lösch-Innovation-Prize for his developments in the field of safe cytostatics-containers and is reputarly speaking on the topic of 'Packaging and Identification of drups 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

Mericel Serra has a degree in Medicine and Dargery and in Economic Sciences. She has over 17 years experience in Financial Management is some of the 8 hepstas of the instant Catala de is Saukt Moreover, the was Financial Manager of BeNigel Hospital, as well as Financial Manager of the Research and investigation Foundation of BeNigel (IDBELL) for 9 years of the Research and revestigation Foundation of BeNigel (IDBELL) for 9 years with Catalah de is Saukt and her responsibilities include forwatment, prombase for all Catalah Pinancial Catalah (IDBEL) for 9 years of the Saukt and Pinancial Catalah (IDBEL) for 9 years of the Saukt and Pinancial Catalah (IDBEL) for 9 years of the Saukt and Pinancial Catalah (IDBEL) for 9 years of the Saukt and Pinancial Catalah (IDBEL) for 9 years of the Saukt and Pinancial Catalah (IDBEL) for 9 years of the Saukt and providing all services required for Healing-Catalah (IDBEL) for 9 years of 10 years



Carme Casanoras has a degree in Medicine and Surgery. She has been working for 29 years in the Public Health System, specifically in the economic and medical area. She was Publicate Manager for nine years in the Traumatology and Rehabilisation Hospital in La Vel d'Hebron. At the same time, and from 1934, she became the Chef of the Outselfort Alexan this hospital became the Chef of the Outselfort Alexander Manager and Administrative Contractor in Behörge Hospital During this period, and elementation of the System Alexander of the Purchase and logistics management and budgets growth. During this period, she also took part in the Board of Directors, among other functions.

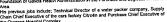
Corrodity, the 18 Purchase Astatistical Manager of the Institut Castal de la Salvit, coordinating Natings, portionase and logistics. Furthermore, she is a member of the team that is in charge of interpretating the SGP project.





Benjamin Rodriguez, Sub Director Economic Resources, Galicia

Benjamin Rodriguez has a degree in Industrial Engineering and is the Economic Resources Sub-diseased or the Oursels-Hospital Complex (a bespall when a Boussand besides) and the Logistic Inventible Marie and SERGAS. Benjamin has been working with the Alexander Administration and EDI technologies on than participated with any administration and EDI technologies on than participated with the Administration and EDI technologies on the participation of the Health Field. He has the Administration and Languegement Innovation in the Supply Chain and is professor for the Public Foundation of Seldan Health Administration and Management Innovation in the Supply Chain and is professor for the Public Foundation of Seldan Health Administration in the Muthors and Logistics in Health Individual Confessor (a Management Innovation in the Supply Chain and is professor for the Public Foundation of Seldan Health Administration in the Public and Individual Confessor (a Management Innovation in the Supply Chain and is professor for the Public Foundation of Seldan Health Administration in the Public and Individual Confessor (a Management Innovation In the Supply Chain and is professor for the Public Foundation (a Seldan Health Administration in the Public Administration and Management Innovation (a Management Innovation Internation Internat





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

Centification and Services as well as the Centification and the Centification and Ce

Currently, Zesia in on loan from GS1 China and working and training at the GS1 Global Office in Brussels on Traceability, Healthware and BPC. With a bachelor degree in International Enterprise Management, the received a Master education on Project Management before all moved to Brussels in January 2006



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31 January 2007

18:00 - 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 Ziekenhüsspotheek Midden-Brabant as a hospital trained pharmacist from 1982 to 1984, hospital pharmacist from 1984 — 1990 and then as the Director of pharmacy from 1990.

The Ziekenhulsspotheek Midden-Brabant is responsible for the drug distribution to believing listitutions; Integraal Zorgosmbum De Voet, Clastwell, S. E. Elsabet Ziekenbus, Tibung, Oog et Washel, Vinamund De Meboom, Tibung, Dereiddie Cerlium, Leyen Leyen Washel, Vinamund De Meboom, Tibung, Revididie Cerlium, Leyen Leyen, Leyen Leyen, Control Control



Hospital Forli, Italy - Martina Minguzzi and Silena Sistu

Martina Minguzzi is Director of the Inter-Health Board Project of Oncologics Pharmacy and Radiopharmacy for Forii Health Board and IRST (Istatus Scientific Romagnolo per lo Studio e la Cura del Tumori), Meldola, also co-ordinating the sam sector for the entire area of Romagna.

sector for the entire area of Romagna.

After having paraulated in Pharmacy from the University of Bologna she obtained a PIDI in Onzological Pharmacy from the University of Milan in 2002. She first worked as a Pharmaculi I Sama Maria dele Crod Hospital in Rivenna and, up to 1999, chief of the Pharmacy Department of Ravenna Health Board. From 2002 to 2004, Manguzzi was the Co-ordinator of the Pharmacy Programme of Forti Health Board.



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

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 University of the Characteristic Characteristics Character

Ms. Sistu was co-author for the theses "Principles and innovative applications hospital logistics: unitary drug dose" (2004) and "Computerized management



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RFID in Hospitals

University Hospital Jena, Germany - Dr. Michael Hartmann

Un Michael Hafmann has served as the Head of the Pharmacy Department at the Hospital of the Friedrich-Schlier-University, Jens, Germany, since 1959, Prior to Wai suppositionent, he hed positions including Series Staff Member In the Pharmacy Copartment at the Hospital of the Barrier-Bigles Broder, Padeborn, Germany, and Research Fellow at the Harvard Medical School, Malman Research Center, Bellmont, USA.

in administration of the common of the commo



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 inpotent electronic prescribing and tharting of medication using GE Healthcare's Lathword application. This projects pilot arms to incorporate the use of RPID by nameling staff for positive administration, at the patients' bedside, at the time of medication administration may be provided the project of the

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

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

Michael Infection of ABHI (Association, Bridsh Healthcen) enfourthers), and addition, he is set on the chairman of the Eucomed I business and supply chair management task force (EIT) as well as the Association Scientifiers Council, a role which brings him into close contact with the various National medical ischnology associations in Europe. The current focus of the Eucome EIT group is but occording and use fernification capture setuminogles.





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

Ed Dovel is Manager Packages Technology for the Global Pharmecunical Some Group since Marco 2006, GPGG provides supply chain management to Johnson Johnson's Pharmaceutical sales and marketing companies. Ortho-Mich Pharmaceutical sales and marketing companies. Ortho-Mich Pharmaceutical inc. PriCare, Ortho-Mich Michael Phrany Care, Ortho-Michael Heurologica, Alza, Tactore, Ortho Medica Violation Pharmaceuticals, and Ortho Biologica. Alza Tactore, Ortho Medica Violation Pharmaceuticals, and Ortho Biologica. Alza Tactore, Ortho Medical asi Irrodvennett in global packaging influences in Mass Serialization, RFID, An Counterfelling, and Digital Pricing.



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

Since 1977 Hugh has taught courses in Pharmaceutical and Medical Device Packaging and Packaging Laws and Regulations. He has conducted research several areas important to medical packaging, Annog have me dissolution shell file of solid craft drugs, refrigerated code chain) shipment of drugs, lorque behaviour of condiment-course systems, legibility of package labels, and lamper evidence or packages. He has also conducted research in medical device packaging related to the self-stringing has deed integrity of states packages. In 2017 highly was the coordinate self-stringing has deed incidingly of states packages, in 2017 highly was the coordinate self-stringing has deed indigingly of states.



Hugh is a member of national research and testing committees, related to medical packaging. They includ ASTM Committees D-10 on Packaging and F-2 on Flexible Barrier Materials and the Packaging Working Grouof the Product Quality Research Institute (PQRII), which is a national group of academic, government arindustry-experts in packaging or pharmacouncids. Hugh served from 1935 to 2005 as a member of The US

18:00 Meeting closure

19:30 Networking Night

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University Hospital Geneva, Switzerland - Dr. Pascal Bonnabry

Since 2000, Dr Pascal Bonnabry is chief pharmacist of the Geneva University hospital (Switzerland). He is head of the information systems resort of the Swiss Society Public Health Administration and Hospital Pharmacists (GSAAA). Dr Bonnabry studies at the General University and obtained his pharmacist (diplarma in 1921. He specialist in clinical pharmacology and obtained a PhD in 1996. Since 1996, he is active hospital pharmacy.

le teaches hospital pharmacy at the Geneva-Lausanne school of pharmacy and has ne function of a chargé de cours. He organizes a three year post-graduate ducation in hospital pharmacy, in collaboration with the University and the Lausanne inversity hospital, since 1999. He has specialization titles in canical pharmacology and herstal observance.



Hospital Bruges, Belgium - Frankie Meulemann

Frankle Meutemann has over 30 years experience in the hospital pharmacy of Sint-Jan, Bruges and is responsible for autemation. He is project leader pharmacy software (1956 - 2006) for intohospital – the Begleis antandard for hospital pharmacy software (more than 70 hospitals). He is also responsible for the general product database, inhospital.

Frankle is supporting the use of bar codes at the VZA (Flemisch organisation of hospital pharmacists) and an active user of e-commerce in collaboration with EDI Months in the association of Deletina bookhears appointed.



10:30 - 11:00 Coffee break

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

Dr. Genold is leading the pharmacy division of the Directorals General of the Wiener Krankenanshidernecturd. Wenna, since 1909 and is also responsible for medical economics and pharmacy since 2007. Having studied pharmacy at the University of Vienna, he obtained his PRD at the same university at Prof. Dr. Heinisch in 1826. He worked in hespital pharmacies and graduated additionally in Hospital Management.

worken in respect immunities and graduated and plant and in the Tamework of the professional training at the University of Vienna and in the Tamework of the professional training of the Austran Pharmaceutical Chamber and the Medical Chamber in Vienna, I ew sus the toucker and chief-elfect of the trade mapping of "Distercibishing Krankenhauspharmazie" from 1987 – 1999 and member of the advisory board of the "European Hospital Pharmacy" until 2022, ID. Genoth disseveral positions at the Austrian Pharmaceutical Chamber and it author of the Arzeninties-Chamberkennung" (a) guide to quickly and adrip Viennity drugs) the Arzeninties-Chamberkennung (a) guide to quickly and adrip Viennity drugs) the



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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 industy. His complete hospital background reaches from his experience at the ward department on this work as a hydracin in surgery and orthopades is well as in if and process and its work as a hydracin in surgery and orthopades is well as in if and an process of the proce

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 Heathbrane User Group, Tom is an active member of the AGI Global Heathbrane User Group, Tom is an active member of the AGI Global Heathbrane Action Group, in PEO/Global Heathbrane and Use science Action Group, in 9th elevant Industry Business Communications Courtel. Tom holds a BA. Am Pero Dissel University Global Services Communications Courtel.



Classification Systems in GS1 - Zoltan Patkai, GS1 Global Office

Zottan Pathai has over twenty years experience in various fields of exppty chain and information management will recollent references gained fixed properties of the propertie



19:30

Evening event



1 February 2007

08:30 - 9:00

HUG Work Team Feedback Session

Auto-ID Data - Mark Walchak, Pfizer and Mark Hoyle, Tyco Healthcare

Mark Walchak is Serior Manager of Global Packaging Technology at Pitzer. His area of responsibilities includes areas of consumer health, human health and animal health. Mark is active in the bar coding, and anti-counterfeting areas. Mark is also a member of the International Federation of Animal Health's Global Traceal/Sity Core

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



Prior to joining Tyroo Heathcare, at the beginning of 2005, Mark has worked as Process Development Group Manager for Ocular Sciences Inc., with key repossibilities for product launch of their deally disposable contact lens range, Prior to has worked as a Systems Voldation Engineer for Glaxo, staying very involved with der neit introduction to the bethicase involved.

Serialization - Stephen Hess Merck

Stephen Hers joined Mercia is 1937 seposting the animal health packaging business. Since them be has worked in various brunesh health and vaccine packaging related positions including international and Onnests: responsibles. He is currently because Director of packaging technology for Merck and Co., Inc. Prior to joining Merck, Stephen worked of Incube Phoras and Olin Chemical in packaging related functions. He graduated from Michigan State University with a BS in Packaging in 1930.



11:00 - 11:30 Coffee break

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HUGLITs (HUG Local Interest Teams):

Switzerland - Christian Hay, GS1 Switzerland

Christian was born in Zuich, Switzerland in 1954 and is married with 2 children. Christian has a trust record of over 10 years in Healthcare and played a leading role in the highest record of over 10 years in Healthcare and played a leading role in the highest particular countries. The second record is selected in Switzerland, legislics between pharmacutical companies and whotestates and aspects of the new billing rule for Health insurance providers (TARMED). He worked for over 3 years for GST Europe, Switzerland and France (TARMED), He worked for over 3 years for GST Europe, Switzerland and France 1 address the septice standardised in effection of the healthcare sector. Tracecability and produce pedigine are the key issues for patient safely, the is surport to enhance securing and reduce yield. High Dare codes and FRID, as support enhance securing and reduce yield. He cauches some of these hospitals in the development of new process management.



Chile - Jose Luis San Juan, GS1 Chile

Childe — Jose Luss San Julian, GST Childs

Colon Luis San Julian has taken responsibility in GST Chile for the Identification Area, and form a few months apo he is involved in the preparation of work groups related to codications standards in different areas from the Children Associan damket (Investigation Codicional Children). Retail. Export, etc.) Los Los Lorgest IT company in Double Anderdors in different states from the Children in the Investmentation and market and the Codicional Children Codicional Children Childr

Australia-New Zealand - Ulrike Kreyse, GS1 Global Office on behalf of Mark Fuller, GS1 Australia



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

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)

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GS1 Activities

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

Mice Rose has successful for Johnson & Johnson for over 30 years.
Mike was appointed Vice President, RFIDEPC Global Value Chain with responsibility for Johnson & Johnson & RIDIDEPC Global Value Chain with responsibility for Johnson & Johnson & RIDIDEPC Global Value Chain with responsibility with the property of the Chain of the

rcn. raduated from La Salle University with a BA in Biology, and received an MSE in Computer Science from versity of Pennsylvania.

Ron Bone is Senior Vice-President of Distribution Support at McKesson Pharmacoutical, San Francisco. In his role he is responsible for RFID & CSOS, the SAP Bys Side Distriess Downer and Find Distribution Heavest Standardization. He has worked for 33 years with McKesson Corp., in areas of operations, sales and financial management. Ren is a member of the EPCIglobal—Usenies Siltering Committee and Ti-Chair of the Healthcare and Life Sciences Business Action Group as well as a Member of Indistry Riskinon Commistee of the Healthcare Distribution Management Association (FIDMA).



EHI (European Healthcare Initiative) - Nicolas Florin, Chairman

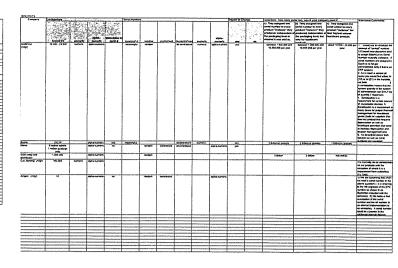
Nosa Fiori is CEO of GSI Switzerland since 1st July 2006. Prior is in current role he words for over 10 years for the Galeriac Group, a devestiled Group active stroughout the healthcare maintainer to relative. However, a devestiled Group active stroughout the healthcare maintainer to relative. Nicroba first worked throughout the healthcare maintainer to relative. Nicroba first worked throughout the healthcare for the Along Group, a European Pre-wholesate company providing broad range of specialized logistics services to pharmacedical manufacturers; in addition to his CEO date for Switzerland, Nicolula has become Chairman of EH (European Healthcare Infeather) and it 1 "Shanappy and the CEO an



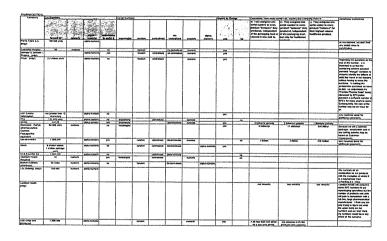
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Alugaritani.		needs a global and unique way of defining the					
		and of measure for product identification		two rects - one	Closed	proma.	Hertfichio
300		EU US Team proposes we put this requirement		is what is the	by EU.	#18	
		En no 1980 babase we bri ave tedwewes		ui of measure	U\$		
100		in the parking left as the specifics of		(Riffs, pounds) -	Team	1	
		measurements required and why they are resulted are not provided. Nowewer MING should		ateo a rects for			
		required are not provided, however HIVG shoul		vertebble	i		
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		shipping.					
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83.3		varsion of a medical device to ascertain the date	that changes which effect form, fo		1	devices	
354		requirements of managing the current state of	or function are not immediately		1	#13	
3352		electrs / mechanical build.	apparent, i.e. a software or				
1000			fernware afteration may add or				
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1,000,000	Hospital	data that can be captured by automatic data	To avoid misread, multiple scars	Mandatory		VA #2 HS	
1	1	capturing in high quality	and talkes		DY EU.	61, FZ	
	1	automatic-identification centers that meet GS1	<b>\$</b>		us		
2.5		minimums for conformance (quality) (e.g., bur	l		Team		
2000	ł	width, minimum ECO parameter grades.	i		ſ		
200	1	symboling placement, etc.)	1		f		1
332743	f	EU-US Yearn proposes to move the to parking	ł		Ī		
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12.70	Lecebech	needs facilitation of percutation of dealer when	Repliedy mistakes happen	Mandelory	Closed		į.
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	1	SCOPE FOR ADC	I	l	i	ĺ	ı
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34543	Hospital	needs special instruction with regards to	To most mostakes in treatment .	Mandatory		VA #10	
1000	1	contraindication for products. NEED TO	patient safety! Staff reads to		by EU-		ı
m 160	1	UNDERSTAND IF SPECIAL INSTRUCTIONS	know what NOT to go!	1	U3		1
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	Į.	EU Team Proposal: Move to perking lot as	i	ı	1	1	i
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Carron	Hospital	does not need sensi numbers on	No need for five data - more	Mandatory	Closes	VA #11	
	1	phomespacel products CONTRADICTS #2	suitable for implants, pumps,	, ,	by CU-		i
2840	1	shove	instruments sic.	ı	BY CU-		l
	1	EU Team recommends moving to parking for	1	ı	Team	1	I
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		NIED					
29.7		Mico Complete Control	RECAUSE		244	Name of the last	
	200000000000000000000000000000000000000	must specify trays as a loan tray to be returned.	So the hospital can ensure		105478	Surprised.	Madelina
12/12/04		, , ,	accounting of loan trays			Instrument	
t District		must spendly trays as a loan tray for long term	So the hospital can assure			s #4 surpcel	Marketing
200		use in a hospital	ecoxurting of lean trays			instrument 1 05	
Feb.es		date on premary his considery pechage must	to ensure consistency between	considerable	Closed	pharms #3	Handacture
1980		match manufacturing batch records EU-US Team Proposal: Dolete this as it is out	physical products and beach records	discussion - need of all	by EU.	& medical devices #3	
		of scope not within work arream browncartes		Serveda cal	Yearn		
		(point of Enished goods to end-of-treatment).		packaging see beich/fol		ĺ	
				espiration data, product	1		
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D CONTRACT		ideally, human-readable information about not	to allow for parkens size	Cate Town M	Chand	phone 6	Manufacturi
		be on the label more than once and each field in text must have a way for a human to know what	constraints and eccentually to	between what	by EU.	& medical	i
		4 is (e.g., LOTE, S.N. what the date means	ntroduce mecounicy	is in the code and butten	US Team	devices #2	
		YYSM4, etc.) Replaced with 13e and 13b		factors		ļ	
1		1		considerations - soft mote		İ	
	Wholesales	Uniqueness - Pharmace, Goal Item identification at the lovest level of peckaging	To armure no possibility that two objects will ever inachesterity	Forever - means forever	Open	HE,S	
65 But 177	Repachers	approved by the manufacture/regulator for	share the same identifier.	means sayer.	l	FTMTMA #2	
19d 32e		interport and logistics from the manufacturers releasing the MUST remain unique for 11 years					
7 199044	Harufactures		A manufacturer may be a	Optional	Closed		e q Manage
erioleta d		the lovest level of packaging approved by the	dedicated tackties for	-	-	Phenne	nanew see
		manufacturestrigulator for transport and logistics from the manufacturers MUST have the	producing/packaging a given product line. In these instances			#16	not indicate alte of
		same meaning and MUST NOT imply a	knowledge of the site remain the				menufacture
4.55		prographic location of information about the object	product, negating the anonymity desired			1	
		EU-US Team proposes we delete the				ĺ	
		requirement on the GTM and Serial if standard shell not require anyone to encode location.				l	
100		point of manufacturer, etc. information, but not matrix internal actions is			İ		
Patricipal.	Hospitals and	must be informed of any changes as governed	To ensure that manufacturer and			medical	Hartetop
	other Cartomery	and defined in the GTM ellocation rules for Healthcare.	curtomer systems are aligned enabling faster and accurate			devices \$18	
T delita:			entering, issue resolution				
14 CO. 15 CO.	CHARGON	in a distribution centre the identification of products must be linked to a product file	to be able to social the product in the warehouse. To allow an			garituter 84	Mentification
12.005es		in a distribution cantra data capture should	to essure conformity of product		-	destusor	Propuremen
Print 23		in a destitution centre the identification of	erformations on product file to assure accounty of information		_	destrutor	Pregulatory
55 Goleted tembined		Hospitals reed a global urrous number for	a)The unique identification of a	mendatory		Section .	tentification
nith \$9		identifying products. And, in a hospital data capture must happen as phermaceuticate are	product will increase patient selety and automation will reduce		i		ł
i		received into stock, at the time of dispensing and at the time of administration,	errors while capturing the data	İ	ı		l
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No. Section		data capture must be possible at	Cost aflocation when processed			Purpokali	Marketing
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Risk History	Hospital	(Berriel Ne) PROPOSED must be atte to disn'ly orbitamen a sate at the and level (Senal number) EU Team Proposes to defects and replace with Sec developed by the US Team	Must be able to scan the from to delermine which set it belongs to		Classed by EU- US Team	Naturnard 1 80 Hz 12, 62, 120, 840, 140, 854, 160, 854, 161, 8100, 1114	Identification
andered Andread		Instruments have to be identified at unit level (Serial No)	Defention of the ownership of an instrument to another house.			ratument s 67	tentification
r Suer		by entering the CSSD	To manage incoming trays and define the delivery time. To analitie locate a tray and receil for any reason.			Purposal Institutions o \$14	Identification
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et deser		in a hospital peer packularaya' avallatakiy is checked betane the operation. PROPOSED must be albe to check the availability of peer packularaya betane an operation. EU learn proposat <u>fortemments</u> , peel packs, and prior think be identified as trade form.	To assure that all the necessary mathuments/peol pocks/keys are to inventory and not out of data (mailable for use).	Mandatory		surgical sratument s #25	<b>Identification</b>
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1		Hospitals need a global unique number for interfring products. And, in he haspital date capture must happen as phenoscencicals were reclaimed into stock, at the fine of depending and at the time of administration. PROPOSE Delicing and combining with \$350.	a) The unique identification of a product will increase patient softly and sutton sion will reduce errors while capturing the data errors while capturing the data conditions the bij for adomated depending and stock control and the control productions of a control of the control and productions of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of a production of production of pro	Handatory	by the EU	preme #15 143 #9, #11, #18, #25, #32, #43	<b>Dimitrication</b>
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		Implants have to be identified generally PROPOSED. Oriete and add including and sterilisation to RIS. EU & US Team agrees to delete and moved the lives worte to RIS.	information which is required to secure the right usage have to be available; a g. information for rebuilding, stendardon, assembling	Vandelory	EU-US Took	implants 80 HS 8 18, 820, 822, 833	ANEUL
	risected	Instancent (see No) have to be identified PROPOSED must be able to shortly the non- number of instancent. EVA US Temporary to delete and soft the words "functional leafs for corruption, inventory, to 80.	When verifying the instanted functions, helving access to functionally tests descriptions. For instruments made of multiple perts, instructions to "technif" the testiment, When handling the instrument, finding right cleaning, secritication, etc. instr.	Mandatory	EU-US	surpicel instrument a #11 H3 #33, #38	Atrèus

		level (Social No) is the instrument ordered and is either a new instrument or a received	our selboureur brobone		l	ratureers s #3	ı
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Zeamer.	Managed	(sterilization) need to identify the ecurporists				L	
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100	1	EU-US Team proposes we move to parting	the included tray & instruments)		なりをひ		l
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67,70000-05	Hospital	Clearing process has to be identified	To exposible the instruments and	Mandaton	~	PUTPICAL	Attribute
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ALC: UNKNOWN	ı	identify on instrument with a serial number at	to the riesmina male for		ì	s #15.	
A-022054	1	the unit level before and/or after the cleaning	Proposition or services	I	į	englants.	
bequireza-	1	process. Volker's Convent. Move to	The same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the sa	I	1	enghants 22	
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es parking	Hospital	Assembling process has to be identified	To execute the implants of	Mandagory		emplants	Derefiçation
lat		PROPOSED must be able to idently instants	peneral unit level at the	Marcasy	Cesses	671 HS	Dersification
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	i	on the purpose of the requirement. US Taxon	tests for corruption, inventory,	l		ı	
	1	proposes to place on parking lot if Viginer	sterilisation) US team suggests	!		1	
	!	confirms to place on parting bit it types	removal of "corruption"	1		l .	
	1	construct that the requirement is for a process		1		l .	
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	1	Kiting see the billing requirements above					i
	1	Volker's Comment; Move to parking lot.		l			
		Volker's Comment; Move to parking lot. Identification of 'Assembling Process' is					
		Yother's Comment: Move to parking lot. Identification of 'Assembling Process' is similar to \$62 (Zteril Proc.) and \$67 (Creaning)					
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70374	Hospital	Velker's Comment, Move to parking lot. Identification of "Assembling Process" is similar to 862 (Sterik Proc.) and 867 (Creating bone. In the hospital a unique product indentities		Mandipory		Phema	
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	Hospital	(Expliny date) Expliny date must must high (country- specific) import requirements	To avoid delay in getting the product to the patient in need	Mandatory		devices #5	Daking
EL BAND	Hospital	needs only to have profuse for the data in the barcode on the package, if multiple bar codes are on a package PROPOSID: needs a way to stockly the correct barcode if multiple bar codes are on a package.  EU Team Proposal: replace this with Sila and	To enable proper and correct scanning	Mandatory	Closed by EU- US Team	VA #12	
el tidas	Hospias Hospias	The identification of brand, betch & equity etc. must be trived by a patient the PROPOSED: must blendly brand, batch and explay of vaccious and biologicals to link the trade from to a patient file. CU Team Proposat: Out of scope because Soldon authories!	this is a government regulation. We need to identify the government regulation(s) that apply. This was not provided from the sub tours.	Mendelory	ty EU- US Team	d4 tikogicada 84 HS 82,832	Regulatory
Towns.		In the trooptial to autoOD the information of feetal would be key to all products that burstle otherwise products with officient data elements within a set. PROPOSED: to autoiD the information of feetal would be key to all products in.	Some sets include products with a sensity of products with different data elements. Some of these products have a sensi number, some of them have a lot and some have not		by EU- US Tean	<b>274</b>	Attrouve
		(All receipt) data capture must happen as a vectine is received into atook for inventory and coolings. EU-US Team proposes we delete and reptace with 57.	For automated dispensing and slock control	Mandatory		VECCURES ST Jepan ST HSSS	identification
Name of	1 Scoupedar	[At receipt] the person receiving the new implies must be able to identify that actual implies (term highly that actual contains on the package EU-415 Team proposes we delete and replace with any in the proposes we delete and replace with \$2.	To sek the ID of the implant to an imentary, receipt process, residation of the correct delinery	,	by EU- US Team	#1,62, #3, #10, #18, #25, #32	identification
SEC.	·	at unit level PROPOSES: EU-US Team proposes to delete and include in E4a	For viplance purposes, this including maintenance tracking	Mandatory	US Yearn	7001/17000 5 627 HS #2 #3, #40, #45, #54, #57, #60, #65, #100, #114, #43	Regulatory
cassed to		Instituted (licked to one potient) have to be identified before the dearing process PROPOSED by US Team; must trik instrumenta identified with a sorbal member at One until tree with one patient before entering the cleaning process.	A dithrest cirening (desirection) process is necessary for instruments which have been used with a potentially infected patient (CJD disease) Volter's Comment: ER covered by £64a is CK. Please 2dd the rational to £64a, too 1		Closed	surgical instrument s #15	Anituse
60 Extense interved the Outy	Hospital	Instrument at unit level (Bertal No) has to be identified before and/or after the chearing process. PROPCSSD by US Trave, must be solde to Identify an instrument with a sectol member at the unit ferel before and/or after the citraring process.	To manage incoming instruments into the CSSD (before I after a deprecting on local rules, if the instruments are pre-cleared at CR, then instruments at unit level (Serial Not can be read before clearing at CSSD)	Mandaloy		rotument s #17	Atributo
es Consider Marks Stronger		in kind of patient contact we need to associate a loaned implient.  A tray must be able to be identified as a loan.	provide a history of a unique loan implant To assure accounting of loan			E20	Manager
11.204.0		any if it is a loan tray to be returned.  A tray must be able to be identified as a loan.	trays  To assure accounting of iden tray			surpcal instrument 1 84	Marketing Marketing
78306		tray if it is a loan tray for long term use in this hostinal. Trade level(s) of packaging - minimum transaction information anabiling electronic transaction activity, accurately and uniformly.	ethininess functionality and methodology - needs to be expanded			ristrament s #5 medical devices #15	Vaketro
El brion Montered Chief S4	Hospital	Peri packs, thy & container have to be identified PROPOSID by US Toese: must be able to lebestly peri packs, thay and container.	To manage the journey of goods in the CISO (planning purposes, informing users should shoulded evertablely, etc.) Voticer's Commont theoretical into 655 at 90 Kr. Pinase and the rational is affice, and it	Wandslery	Closed		Mercification

diacous er (diacos		the unit quantly (safet, case, inner pack, unit)			1	3/6/07	
Tale Color	Retailer	Product information (GTM) should also convey	Used to especific handling	-	├	Wateriari	_
			and microbial contaminal			04001/07	
	manufacturer)		such as light, moisture, pressure		1	recommen	
	Hospital Assocings a	the solution (a region). Eti Team Propose remove as it is covered by	THE GRUP and its provide protection against environmental influences		1	Single Dose	
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	(EAHP IS the	draughe the content of the drug with additional information regarding the lotal amount and	drug and additional information up to final control at bedade and		by EU. US	brief presentati	
of other	Prospetal Charattarost	for empowers and wars, the label must precisely	to describe the content of the	Mandalory	Closed	EARP	I
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S 1944	physical acted	the content of the drug.	Grug up to final control at because	,	by EU-	brief	
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992	European	EU Team Propose Replace with 104s and 1045			Teem	on of	
200	pharmedist (EAHP is the	end with with a bercode on each engle dose on a label (not engraved on the glass)	i		by EU-	total presentati	
A CHIEFE	hospital	must produce single dose-packed empoules		Mendatory	Closed	EAHP	
709 S.W.			tracentify up to the patient level			680008. 04/21/07	
	manufecturer)		This will also improve the			recommen	
Section 1	Associated a		increase the patient's eafery			Dose	
2021	Nempital		edministration of drugs to petients. This will significantly		Fear	on of Single	
40.00	EURP is the	EU Team Propose Replace with 104s and 104b	control just before the		US.	presentari	
WW 246-	phemacist	include a barcade on each pingle goes.	procedures and allow a final	merselly.	by EU-		
or constru	PORTER DESCRIPTION AND ADDRESS OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY	must be similar to what is deminsed must produce single does packed drugs and	To improve the efficiency of Later		Closed	£1110	
	Assec net a	euto-10 tag on it (her-code or RFIO). The data				1	
8.025	Hospital	means that manufacturers would deliver products packaged at the unit does level with an			Team	point	
	is the American	pharmacountrals at the unit-dose level. This				#2 bullet	
वर्षे क्षान्त्रक	Hospital (ANA	I would advocate adding labeling on		Mandatory	Cosed	ANA email	
		personally those that come in contact with t					
230	[	medical drylcos and augpties, and					
	1	PROPOSE: Delete and add and relevant			Team	~	
	l	medical devices and supplies, and particularly those that come in contact with the patient.			by EU.	#1 buffet coint	
33 milete	hospitals	the expiry data will also be referred to any		Mandalory	Clered	AHA email	
					Team		i
	ł	EU & US Team proposes we delete after adding the word inscrebility to the rationale for #3			U3		
		hospital and what is in the box	tracest-Afr	- Cally	by EU.		France
A SOCIETY	Hospital	a way to identify what is coming into the	as the steeting place for	Mandatory	ICHANI	Address in	Regulatory 6
	1		watetewe			#114	
	į.	WWW NEXT	Identify instruments needs per period to enable efficient product			#57, #50, #85, #100	
(12)	1	the lend to the retionale of 64s as follows: F,	beyond recommended Sfeepen			\$45, \$54,	
3323	1	EU & US Team proposes we delete after address	acresped before, not used		1000	#20, #40.	
		minting ones). CAN THIS BE COMBRIED WITH BS47	mattle efficient lifespan management e.g. instruments not		US Team	1 89 HS.	
		spentifiable (not only the new ones, but also the	tycle record of the instrument. To		by EU-	DESCRIPTION	
Contract of	Hospital	All mathements at unit level (Settal No) must be	To initialit or marken the life	Mandatory	Closed	Negen	Attribute
	1					#114	
200	1				1	#57, #60, #65, #100.	
	1	solution (SN)	1		1	845 AS4	l
120		relionate to 64a white removing reference to the			1	F20, #40,	
967	l	EU & US team acrees to delete and has moved	eneraments.		EU-US Team	1 #12 HS	
200		(Serial No.) PROPOSED Delete and edd addoptionale to 954	intensive maintenance instruments		by the	instrument.	Regulatory
			Special tracking of high value and			11/201	Attitude I