IMDRF International Medical Device Regulators Forum

Atsushi TAMURA, Ph. D.

IMDRF Management Committee

AHWP, Taipei, November 2012

IMDRF International Medical Device Regulators Forum

International regulatory collaboration

- Strategic international engagement is vital to our ability to respond to global regulatory challenges
- Experience, skills, expertise of one regulator will be relevant to others
- Reducing the market for substandard products
- Lower time to market for innovative health technology

IMDRF International Medical Device Regulators Forum

About IMDRF

Conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.

The Forum builds on the work of GHTF with the aim of accelerating international medical device regulatory harmonization and convergence.

Oversight by a Management Committee comprised of a voluntary group of medical device regulators from around the world and the World Health Organization.

IMDRF International Medical Device Regulators Forum

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

IMDRF International Medical Device Regulators Forum

Stakeholder involvement

- Stakeholders currently contributing to Working groups
- Continue to have Open Stakeholder Forum as part of IMDRF Management Committee meetings
- Website has information on stakeholder participation
  - New work items
  - Mailing list
  - Guidance document update

IMDRF International Medical Device Regulators Forum

Progress to date

- First face-to-face meeting held in Singapore, February 2012
- Second meeting Sydney, September 2012
- China and Russian Federation Observers – membership pending
- Terms of Reference developed and published
- Operating Procedures almost finalised
- Website developed – prototype
- Process to maintain GHTF documents established

IMDRF International Medical Device Regulators Forum

Priority work items

- A review of the NCAR system – led by Europe
- Roadmap for implementation of UDI system – led by Europe
- Medical Device Single Audit Program (MDSAP) – led by the USA
- Recognized standards – led by Europe
- Regulated product submission/Table of Contents – led by Canada

Priority work items

- A review of the NCAR system – led by Europe
- Roadmap for implementation of UDI system – led by Europe
- Medical Device Single Audit Program (MDSAP) – led by the USA
- Recognized standards – led by Europe
- Regulated product submission/Table of Contents – led by Canada

NCAR

Background

➢ Current scope:

- exchange of (confidential) info on serious Adverse Event (AE) concerning MD with global distribution

➢ Participants

- GHTF Reg. Authorities
- Reg. Authorities fulfilling the criteria of N38 & successfully trained on N54 & N79

NCAR

To Revise the NCAR Exchange Program

Critical Review for current GHTF NCAR system

- Does NCAR Exchange provide **useful information?**
- Why are so **few (GHTF) jurisdictions** using the NCAR Exchange Program?
- **Is NCAR early access** to relevant safety-related information;
  knowledge about action taken (FSCA, recall,..)?

Priority work items

- A review of the NCAR system – led by Europe
- Roadmap for implementation of UDI system – led by Europe
- Medical Device Single Audit Program (MDSAP) – led by the USA
- Recognized standards – led by Europe
- Regulated product submission/Table of Contents – led by Canada

IMDRF International Medical Device Regulators Forum

UDI

STARTING POINT

GHTF/AHWG-UDI/N2R3:2011

GHTF UDI GUIDANCE

FINAL DOCUMENT

Global Harmonization Task Force

Title: Unique Device Identification (UDI) System for Medical Devices

Authoring Group: GHTF SC UDI Ad Hoc Working Group

Endorsed by: The Global Harmonization Task Force

Date: September 16, 2011

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

UDI

The fundamental concepts of a global UDI System include:

- The UDI and UDI Carrier are based on global standards
- A UDI applied to a medical device anywhere in the world should be able to be used globally to meet the UDI requirements of any regulatory authority
- National or local identification numbers should NOT be a substitute for UDI
- Regulatory Authorities should not specify how to modify these standards
- The UDI Database core elements should not be modified
- The UDI Database should use the HL7 SPL for data exchange

GHTF/AHWG-UDI/N2R3:2011

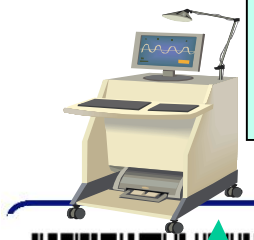
UDI

A globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating the:

1. Traceability : traceability of devices, especially for recalls and other field service corrective actions,
2. Identification : adequate identification of the device through its distribution and use,
3. Adverse Event Reporting : identification of devices in adverse events,
4. Medical Errors : reduction of medical errors,
5. Documentation : standard way to input device identification into registries

GHTF/AHWG-UDI/N2R3:2011

UDI System?



Bar-coding
for every Medical Devices

(01) 1 49875 8 12345 0 (17) 251210 (10) ABC12345

DI
Device Information
- Company
- Product ID

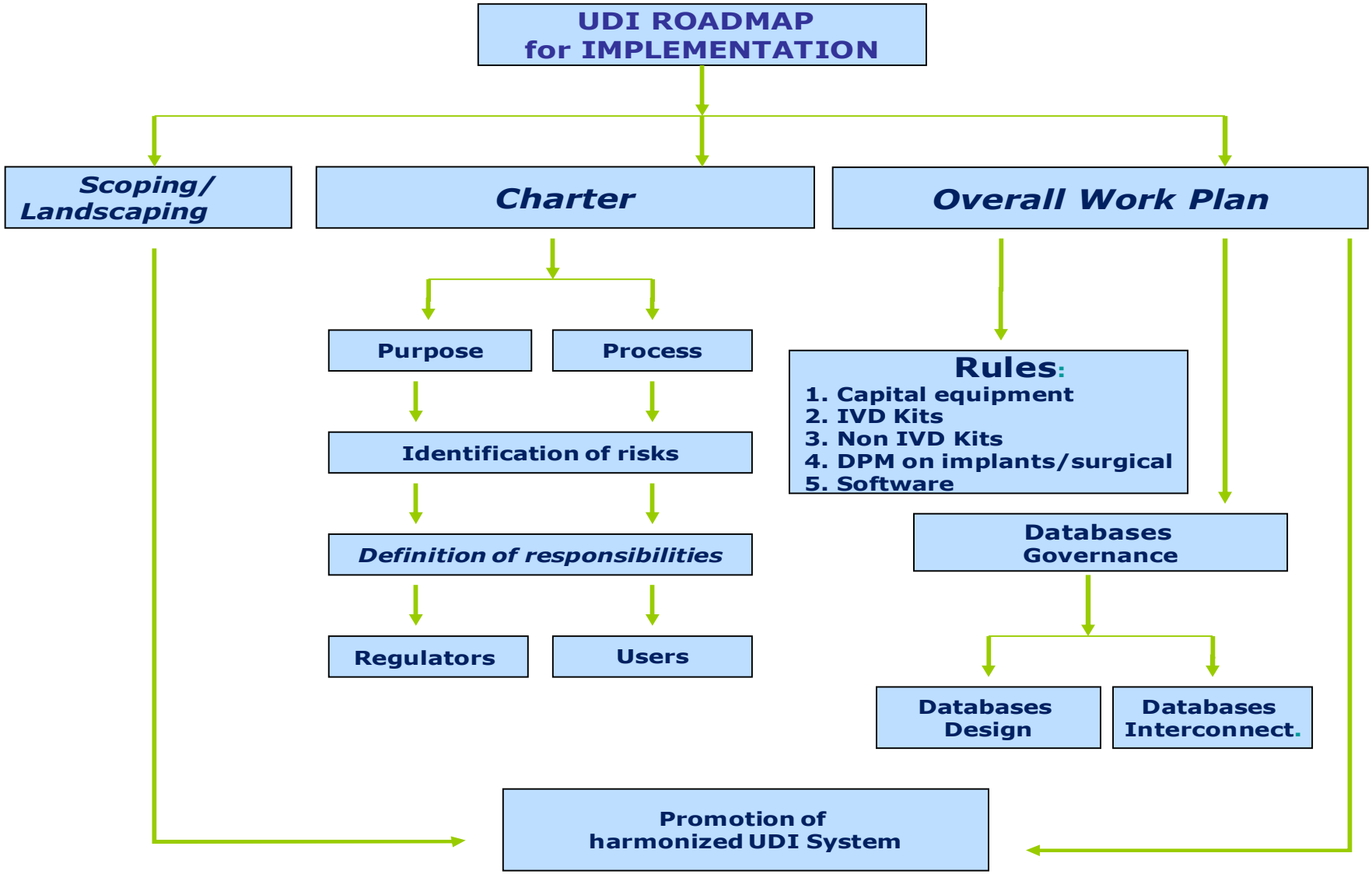
PI
Production Information
-Life
-Serial or Lot Information

UDID
Data Base
For DI part Only

DI
-Company Name
Address
-Product Name
.
-GMDN
-code
-term
.
. etc

UDI

WORK BREAKDOWN STRUCTURE (WBS)



UDI

5 sub-groups (topical expertise)

5 Consultations

1."Capital equipment and other systems (incl. Imaging - refurbished/remanufactured)"

1.Direct Part Marking (DPM) of Implants and Instruments"

2. "IVD Kits"

3. "Non IVD Kits"

4. "Medical Device Software"

IMDRF International Medical Device Regulators Forum

Examples of questions still to be answered

Practical aspects of the implementation

1. When does a device need a new UDI?;

1. Interface with the nomenclature (GMDN application);

1. Reprocessing/reprocessed issues;

1. Which "bits" of a device need a UDI;

1. UDI placement;

1. UDI on device (DPM) versus UDI on packaging;

1. Are there packaging levels not needing a UDI?;

– Are there exceptions and alternative placement issues?;

1. Components VS spare parts.

Brief explanation for the further understanding

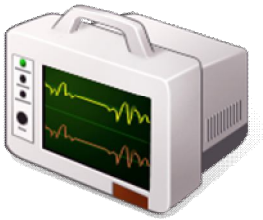
GMDN ?

How do we call for those devices ?

NOT the individual Name of the Product itself,
But the name of the Group of those Products.

Ultrasound DI

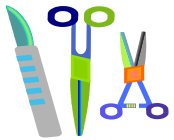
ECG



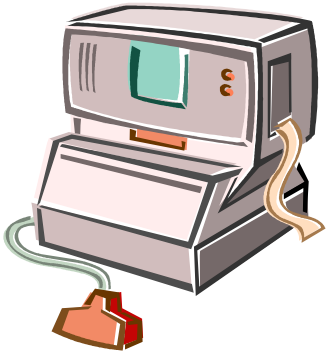
Surgical Knife

.....

Surgical KIT

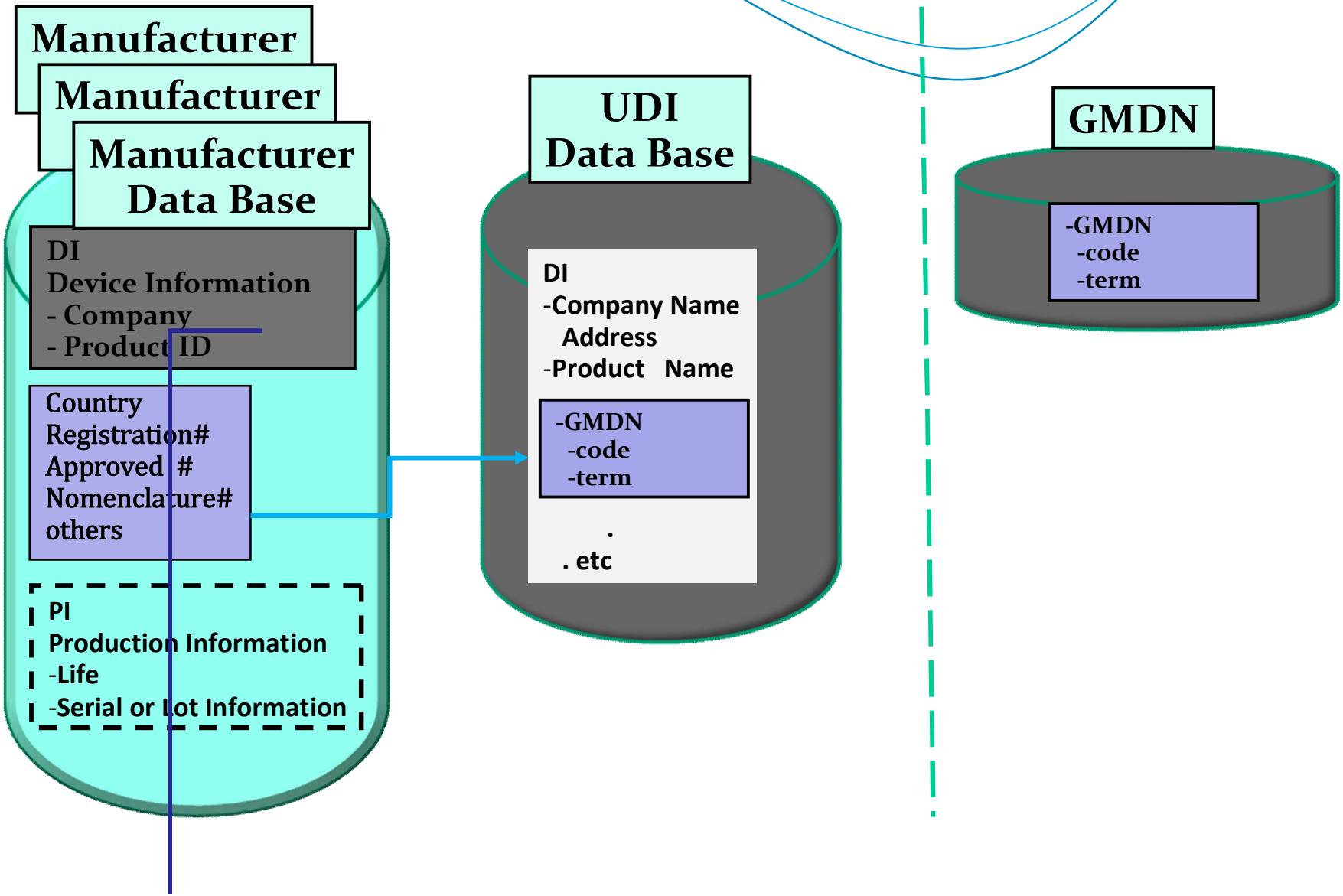


.....



MRI

Brief explanation for the further understanding



IMDRF International Medical Device Regulators Forum

IMDRF Revised UDI GUIDANCE
(Vers. 2.0 + Supplement)

Priority work items

- A review of the NCAR system – led by Europe
- Roadmap for implementation of UDI system – led by Europe
- Medical Device Single Audit Program (MDSAP) – led by the USA
- Recognized standards – led by Europe
- Regulated product submission/Table of Contents – led by Canada

MDSAP

Background

The Work Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.

MDSAP

Invitation to comment on proposed document

WG (PD1)/N3R3 - Recognition Criteria for Medical Device Auditing Organizations

A proposed document has been released by the Medical Device Single Audit Program Working Group (MDSAP). Comments are invited by **Friday 14 December 2012** to the Working Group Chair.

http://www.imdrf.org/

MDSAP

- Draft proposed document
  - ISO/IEC 17021:2011 + Regulatory Authority requirements drawn from the source documents in each countries' regulation.
    - Special attention and additional requirements regarding Impartiality, Appearance of Conflict of Interest, Outsourcing Auditing Activities, Arrangements with Medical Device Manufacturers for the Sharing of Audit Information

MDSAP

- Sub-Tasks from ISO/IEC 17021 requirements and Annexes:
  - Auditor Competency
  - Auditor Maintenance of Competency
  - Code of Ethics
  - Criteria for Special Audits

Priority work items

- A review of the NCAR system – led by Europe
- Roadmap for implementation of UDI system – led by Europe
- Medical Device Single Audit Program (MDSAP) – led by the USA
- Recognized standards – led by Europe
- Regulated product submission/Table of Contents – led by Canada

Recognized Standrads

Background:

The GHTF paper "Role of Standards in the Assessment of Medical Devices" GHTF/SG1/N044:2008 states:

> International standards, such as basic standards, group standards and product standards, are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices. …

- ➔ Regulatory Authorities should encourage the use of international standards.
- ➔ Regulatory Authorities should establish a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating conformity with the Essential Principles. This mechanism should also include a procedure for withdrawal of recognition. …
- ➔ …..

Every Region should have established (or should be in the process of establishing) or is using a list of recognized standards.

Recognized Standrads

Mandate:

2 Steps

1. Gathering information and creating a list of standards used for medical devices regulatory purposes that are recognized by IMDRF Management Committee members
2. Development of a procedure to continuously enhance the established list

Priority work items

- A review of the NCAR system – led by Europe
- Roadmap for implementation of UDI system – led by Europe
- Medical Device Single Audit Program (MDSAP) – led by the USA
- Recognized standards – led by Europe
- Regulated product submission/Table of Contents – led by Canada

RPS

- Composed of two complementary components:
  - Beta testing of RPS Standard to confirm it is fit for purpose for medical devices
  - Develop common, modular Table of Content (ToC) for device applications (IVD and non-IVD)
- Project takes account of existing work:
  - Beta testing: HL7 RPS WG and ICH
  - ToC: GHTF STED documents
- Project seen as important step towards ultimate goal of common premarket requirements for device applications

RPS

- Beta testing:
  - Validation RPS “Fit for Purpose” or necessary changes introduced to Standard
  - Timelines dictated by HL7/ICH around HL7 meetings
  - Target for Normative Standard September 2013
  - “Comfort level” testing could extend beyond April 2013 beta test window
- Phase 2: Implementation of RPS
  - Work would begin during Phase 1, building on work required for beta testing (Implementation Guides, controlled vocabularies)
  - Essential to allow for use of RPS compliant electronic applications

RPS

TOC

- Will allow for filing of applications to IMDRF jurisdictions and beyond according to common format and modular structure
- Will build upon content guidance of existing STEDs (particularly for IVDs)
- Goal: to deliver a product that is of operational use and accepted by both industry and agencies: lessons learned from GHTF STED
- To help achieve this goal, run pilot with some test cases that will:
  - Confirm have right level of granularity
  - Identify concerns or gaps
  - Allow for necessary refinements before “locking down” structure
- Test with a few low-medium risk devices in parallel with industry consultation period

Next IMDRF meeting

Roles of Chair and Secretariat rotate to Europe from

1 January 2013

Next meeting: 19 – 21 March 2013 - France

IMDRF International Medical Device Regulators Forum