The Global Language of Business

Dr. Nazeeh S. Alothmany
Meshal A. Al-Amri

Saudi Food & Drug Authority

The Global Language of Business

Saudi UDI expectations and barcode requirements

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نظام الترميز الموحد للأجهزة والمنتجات الطبية

Saudi UDI Expectations & Barcode Requirements -Part I-

April 20 2016

Presented by:
Dr. Eng. Nazeeh S. Alothmany

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Content – part I

- Background & role of SFDA Medical Devices Sector
- Medical Devices Sector Responsibilities
- Vision of Success
- Medical Devices Regulatory Scheme
- Conformity Assessment Bodies
- Regulatory Procedures' map
- Statistics for MDNR, MDEL, MDMA and Classification
- Statistics for Inspection Visit, Seized products, Shipments, FSN & adverse events
- International Achievements

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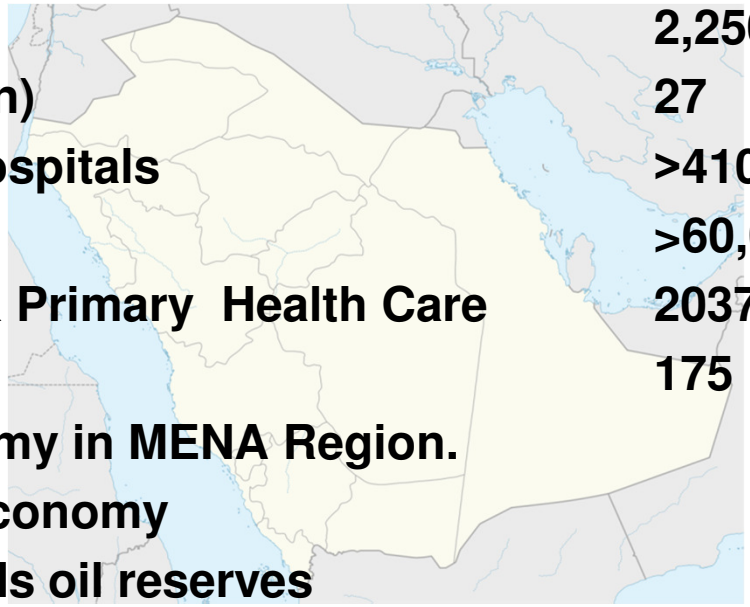
Kingdom of Saudi Arabia



- Area 2,250,000 sq. km
- Population (million) 27
- Total number of hospitals >410
- Number of beds >60,000
- Medical Centers & Primary Health Care 2037
- Kidney Centers 175
- The largest Economy in MENA Region.
- The 24th largest Economy
- It has 25% of worlds oil reserves

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Background

- The Saudi Food & Drug Authority (SFDA) was established under the council of ministers resolution no (1) dated March 10, 2003.

- A royal decree was issued on Feb. 13, 2007 to establish the law of SFDA.

- A council of ministers resolution no (181) was issued on June 18, 2007 giving the SFDA a full authority to regulate the medical device market in Saudi Arabia.

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Background (cont)

SFDA mission

To ensure the safety of food; the safety, quality and efficacy of drugs; and the safety and effectiveness of medical devices, by developing and enforcing an appropriate regulatory system.

MDS mission

To ensure safety, effectiveness and quality of medical devices and their performance according to their intended purpose and to ensure the safety of related electronic products.

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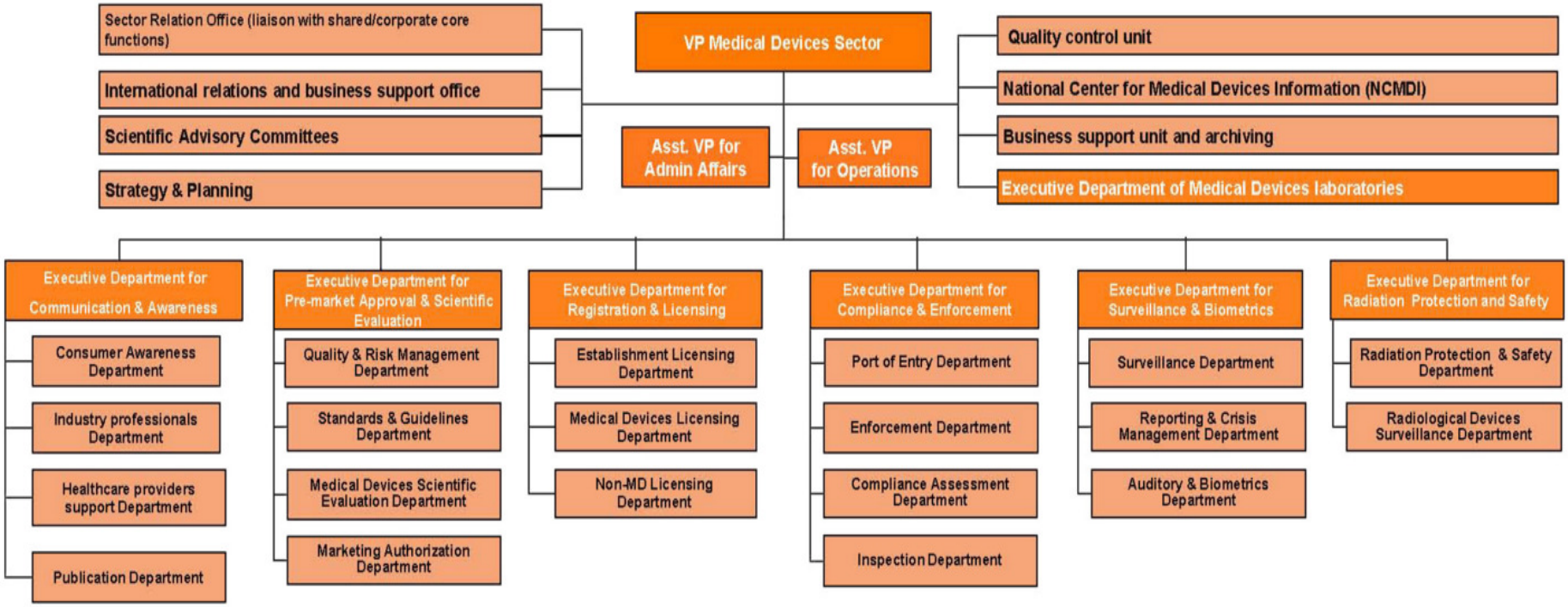
Organization Structure for Medical Devices Sector



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MDS Objectives

Short and long term objectives; including:

- Setting up Medical Devices Regulatory Scheme
- Implementing Regulatory System
- Licensing procedures for Medical Device manufacturers & suppliers and their products
- Surveillance & Monitoring of the Market
- Cooperation with other International Regulatory Agencies
- Implementing Rules & Standards

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MDS Responsibilities

- Medical Devices
- IVD Devices
- Prescription Eye Glasses
- Contact Lenses and their Solutions
- Radiation Emitting Electronic Products

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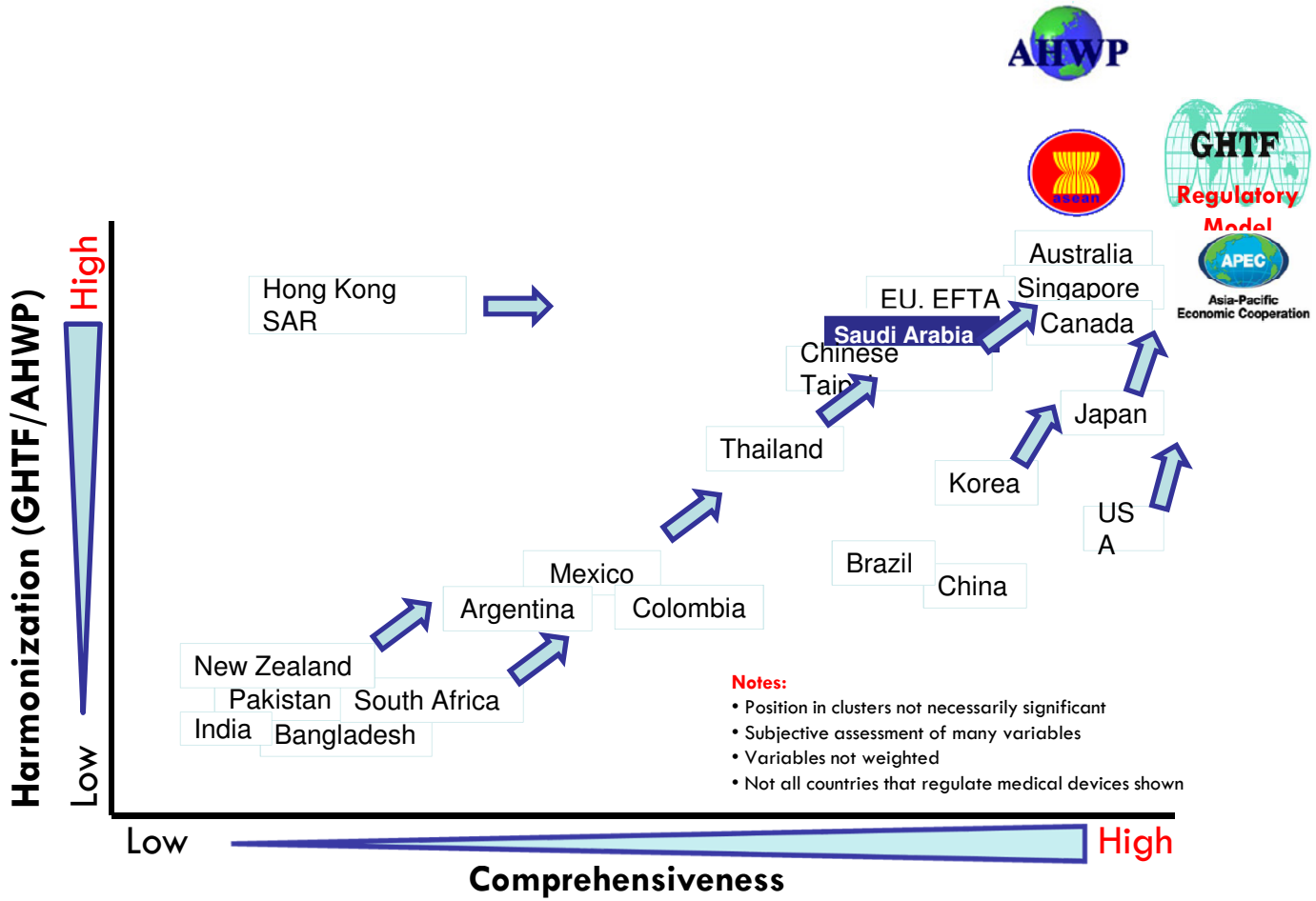
Vision of Success



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Medical Devices Regulatory Scheme

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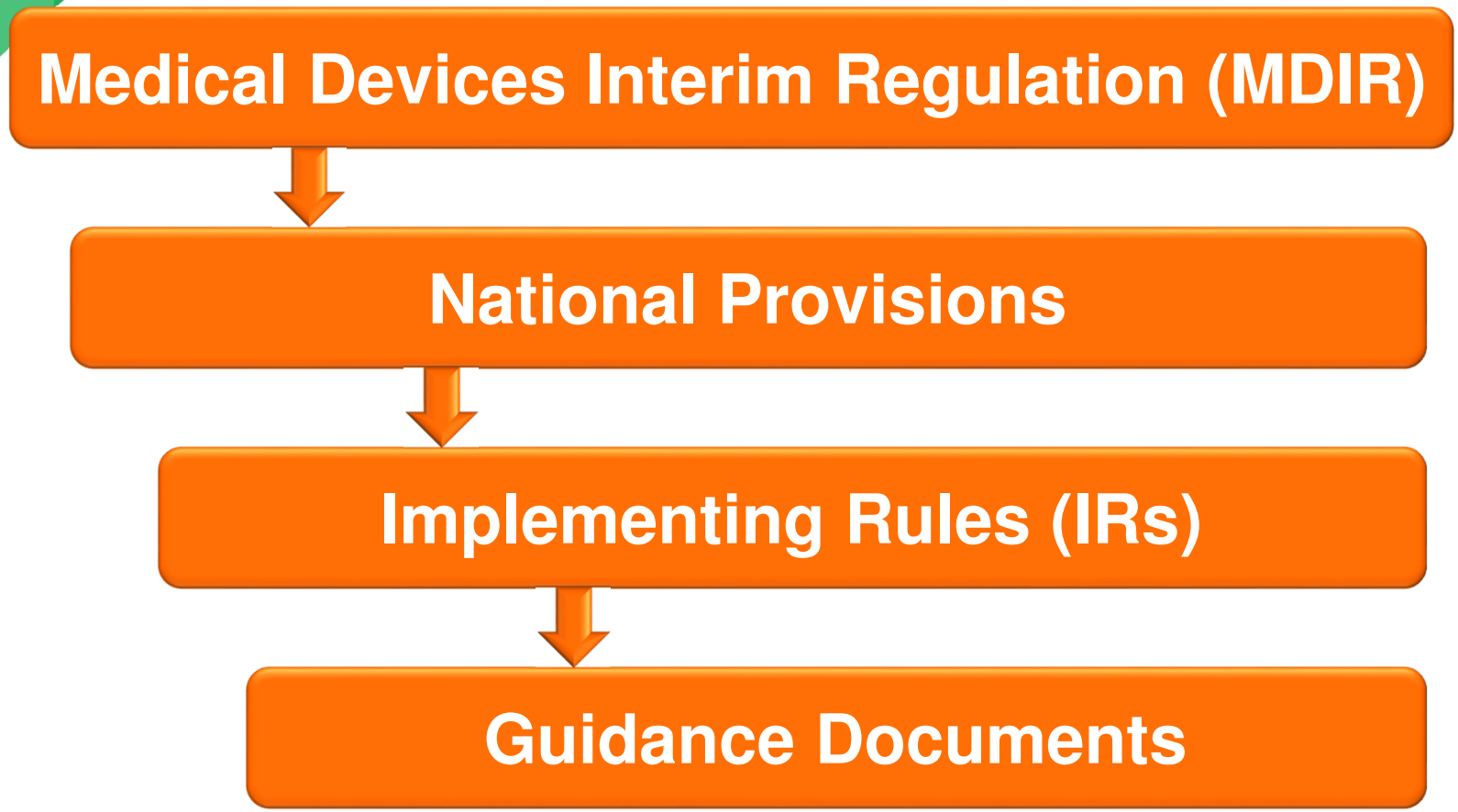

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Medical Devices Interim Regulation (MDIR)

- SFDA has adopted MDIR System that complies with GHTF guidance.

- MDIR was issued by the SFDA Board of Directors Decree number 1-8-1429 on 27th December 2008.

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Medical Devices Interim Regulation (MDIR)

- Medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Interim Regulation as signified by the SFDA issuing the manufacturer with a written Marketing Authorization. (Chapter Two, Article Four, MDIR)

- To obtain marketing authorisation, medical devices shall comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labelling and conditions of supply and/or use. (Chapter Two, Article six, MDIR)

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Guidance Documents

12 guidance until Jan 2016

1. Guidance for Medical Device Importers and Distributors
2. Guidance for Local Manufacturers
3. Guidance for Medical Device Authorized Representatives
4. Guidance for Overseas Manufacturers
5. Guidance on Marketing Authorization Procedures
6. Guidance on Post-Marketing Surveillance
7. Guidance on Medical Devices Intended for Demonstration or Training Purposes only
8. Guidance on International Quality and Efficiency Samples
9. Clinical Investigations for Medical Devices
10. Guidance on Labelling Requirements for Medical Devices
11. Guidance on Medical Devices Advertising Requirements
12. Guidance on Medical Devises Bundling / Grouping Criteria

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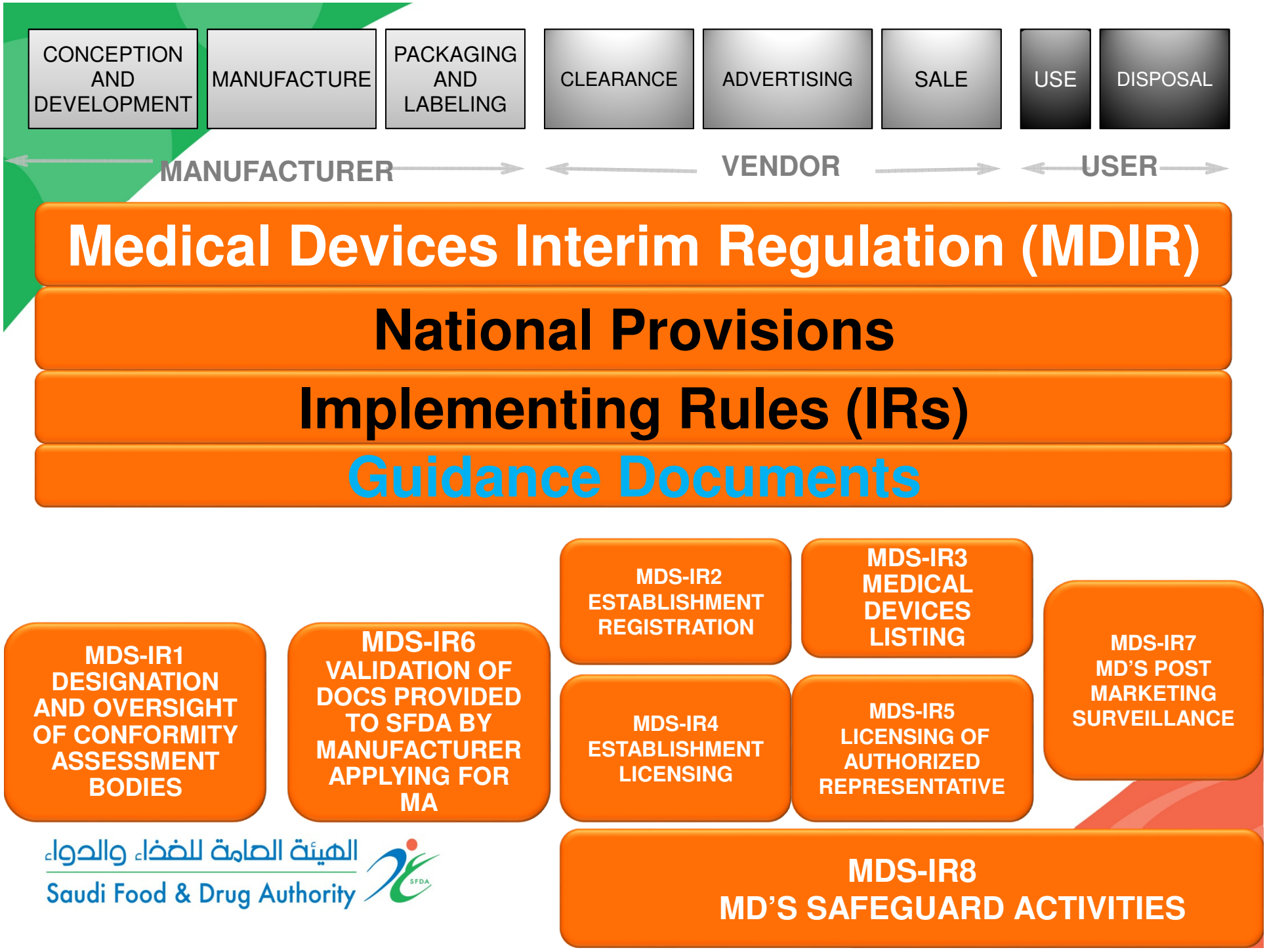
CONCEPTION AND DEVELOPMENT
MANUFACTURE
PACKAGING AND LABELING
CLEARANCE
ADVERTISING
SALE
USE
DISPOSAL
MANUFACTURER
VENDOR
USER
Medical Devices Interim Regulation (MDIR)
National Provisions
Implementing Rules (IRs)
Guidance Documents
MDS-IR1 DESIGNATION AND OVERSIGHT OF CONFORMITY ASSESSMENT BODIES
MDS-IR6 VALIDATION OF DOCS PROVIDED TO SFDA BY MANUFACTURER APPLYING FOR MA
MDS-IR2 ESTABLISHMENT REGISTRATION
MDS-IR3 MEDICAL DEVICES LISTING
MDS-IR4 ESTABLISHMENT LICENSING
MDS-IR5 LICENSING OF AUTHORIZED REPRESENTATIVE
MDS-IR7 MD'S POST MARKETING SURVEILLANCE
MDS-IR8 MD'S SAFEGUARD ACTIVITIES
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SFDA

Conformity Assessment Bodies

Underwriters Laboratories	COSMOS corporation	TUV Rheinland	British standards institution

Duties of Conformity Assessment Bodies:

A. Examine the documents submitted for medical device market authorization purposes.

B. Ensure that the medical device complies with the relevant provisions of this Interim Regulation.

C. Recommend to the SFDA that it may issue the marketing authorisation.

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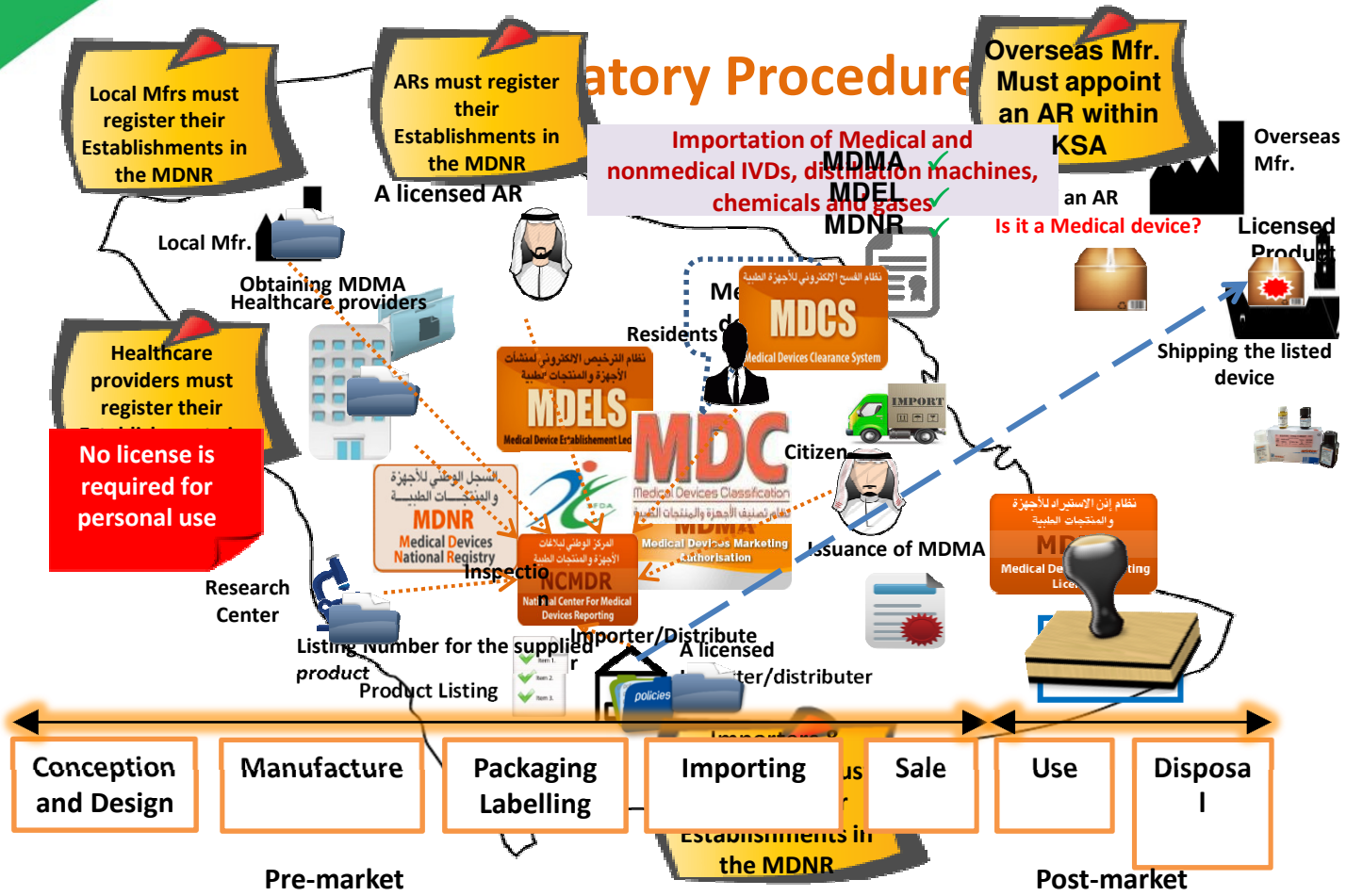

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MDNR Statistics

السجل الوطني للأجهزة والمنتجات الطبية
MDNR
Medical Devices National Registry

MDNR
Medical Devices National Registry

MDNR							
Year	**2007-2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Establishments	1082	266	282	485	299	394	**2808**
MD	64730	34,675	57,986	63,820	47,699	51,261	**320171**
Total	**65812**	**34,941**	**58,268**	**64,305**	**47,998**	**51,655**	**322979**

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Saudi Food & Drug Authority
SFDA

MDELS Statistics

نظام الترخيص الالكتروني لمنشآت الأجهزة والمنتجات الطبية
MDELS
Medical Device Establishement Lecince

MDEL Medical Device Establishment License

MDEL						
Year	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
Establishment (Importer/Distributor)	585	664	690	692	697	**3328**
Authorized Rep.	344	405	480	511	520	**2260**
Manufactures	1820	2370	2913	3180	3300	**13583**
Total	**2749**	**3439**	**4083**	**4383**	**4517**	**19171**

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Saudi Food & Drug Authority
SFDA

MDMA Statistics

MDMA						
Year	**2011**	**2012**	**2013**	**2014**	**2015**	**Total**
MDMA	59	413	907	1554	3426	**6359**
No. of MD	351	2261	6711	8056	20869	**38248**
Total	**410**	**2674**	**7618**	**9610**	**24295**	**44607**

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Saudi Food & Drug Authority

MDIL Statistics

نظام إذن الاستيراد للأجهزة والمنتجات الطبية
MDIL
Medical Devices Importing License

MDIL	
Category	**Licensed**
IVD	39086
Non-IVD	1631
Distillation	244
Chemical	1608
Biological Products Started 2014	91
Quality Assurance Sample (QAS) Started 2014	192
Research Devices- Started 2014	297
Exhibition Devices- Stated 2014	161
Local Manufactures- Started 2015	842

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MDs Classification Statistics

Classification							
Year	2008	2009	2010	2011	2012	2013	2014/9
Requests	**16**	**45**	**119**	**329**	**722**	**2804**	**5972**

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Inspection visits Statistics

Year	Establishment visits	Medical Devices visits
2011	438	26
2012	510	181
2013	601	161
2014	694	440
2015	831	849
Total	**3074**	**1657**
	4731	

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Quantities Of Non Compliant Medical Products Seized

Year	Seizing Medical Products
2011	1,594,070
2012	933,505
2013	415,686
2014	1,932,138
2015	354,745
Total	**5,230,144**

Field inspection visits Statistics
2011-2015

Year	2011	2012	2013	2014	2015	Total
Retailers field inspection visits	-	124	48	255	136	**563**
Warehouses field inspection visits	-	-	-	-	204	**204**

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Medical Device Shipments Statistics

Cleared Medical Device and IVD Shipments

Value of cleared items	Quantity of cleared items	Number of cleared Items	Number of cleared Shipments	Year
3,811,895,770	706,898,114	20,924	9,654	2011
3,971,027,439	553,716,312	22,578	10,953	2012
5,943,011,354.30	1,386,694,869.23	28,942	14,510	2013
6,382,906,129.50	1,475,562,923.90	35,732	16,043	2014
7,847,624,769.52	2,496,649,511	26,997	17,974	2015

Rejected Medical Device and IVD Shipments

Value of rejected items	Quantity of rejected items	rejected Items	rejected Shipments	year
24,519,744	3,014,176	2921	458	2011
104,000,605	39,652,279	6,043	750	2012
66,574,325.09	5,739,831	4,815	633	2013
87,587,056.63	12,791,982	7,169	798	2014
60,559,967	4,636,723	4,149	673	2015

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Field Safety Notice –FSN / Recall

Source	Type	2008	2009	2010	2011	2012	2013	2014	2015	Total
BfArM	New	0	0	0	35	101	256	255	182	829
	Update	0	0	0	0	4	996	631	488	2119
MDCO	New	0	0	0	0	5	0	0	0	5
	Update	0	0	0	0	0	0	0	0	0
Swissmedic	New	0	0	0	10	10	146	154	133	453
	Update	0	0	0	0	0	351	377	285	1013
TGA	New	0	0	0	0	0	191	254	160	605
	Update	0	0	0	0	0	364	276	225	865
ECRI	New	7	492	653	387	500	347	237	207	2830
	Update	0	0	0	0	134	940	990	823	2887
FDA	New	1080	1195	515	1238	1198	1004	1314	890	8434
	Update	0	0	0	0	159	1129	1575	981	3844
Health Canada	New	0	0	0	0	0	4	18	19	41
	Update	0	0	0	0	0	14	96	53	163
HPRA	New	0	0	0	0	0	15	19	40	74
	Update	0	0	0	0	0	89	354	309	752
MHRA	New	0	149	479	471	440	396	269	207	2411
	Update	0	0	0	0	45	502	580	348	1475
NCAR	New	59	70	61	85	123	113	105	97	713
	Update	0	0	0	0	14	252	206	119	591
NCMDR	New	8	52	164	115	109	64	86	65	663
	Update	0	0	0	0	9	127	120	72	328
Total	New	1154	1958	1872	2341	2486	2536	2711	2000	17058
	Update	0	0	0	0	365	4764	5205	3703	14037

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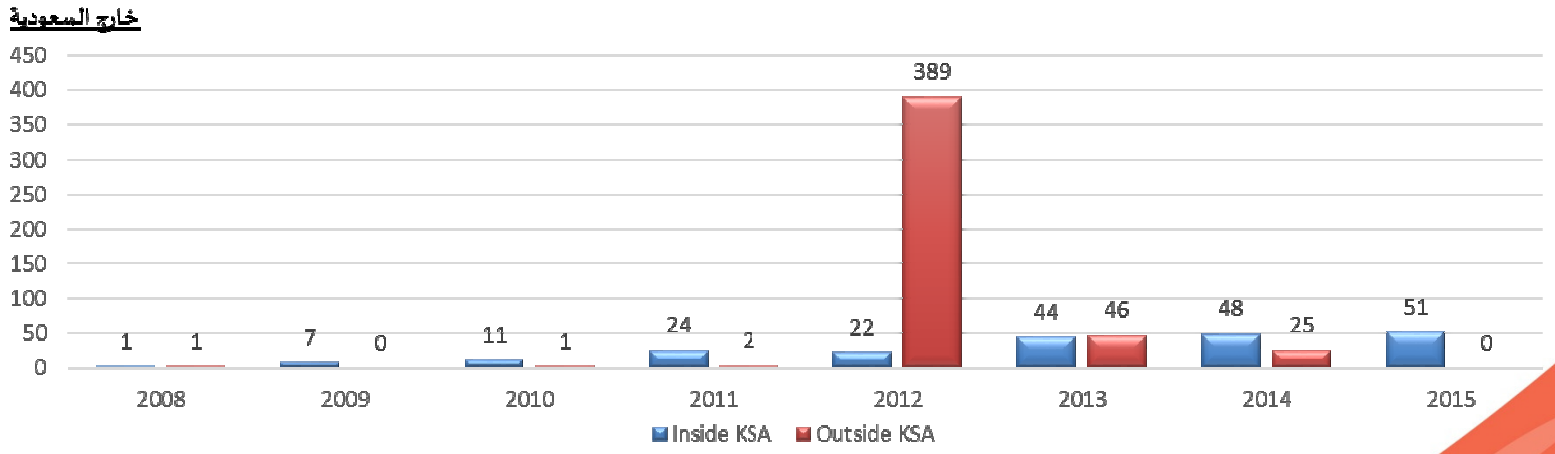
Adverse Events Reporting

Location	2008	2009	2010	2011	2012	2013	2014	2015	Total
Inside KSA	1	7	11	24	22	44	48	51	208
Outside KSA	1	0	1	2	389	46	25	0	464
Total	2	7	12	26	411	90	73	63	684



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International Achievements

Medical Devices Sector is a member of:

1. Asian Harmonization Working Party (AHWP)

- ✓ **Chair of AHWP Technical Committee.**
- ✓ **AHWP working groups**
  - **Chair Pre- Market (WG1).**
  - **Member Post Market (WG2).**
  - **Chair Quality Management System (WG3).**
  - **Chair of Quality System Audit (WG4).**

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International Achievements Cont..

2. The Global Harmonization Task Force (GHTF)

- ✓ **Member Pre Market (SG1).**
- ✓ **Member Pre Market IVDD (SG1a).**
- ✓ **Member Quality System (SG3).**
- ✓ **Member NCAR.**

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Saudi UDI Expectations & Barcode Requirements - Part II -

April 20 2016

Presented by:
Eng. Meshal A. Alamri

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Content – Part II

- **UDI Definition , Construction , Benefits**
- **Challenges for the Healthcare Stakeholders**
- **SFDA UDI Project Objectives**
- **Saudi UDI time plan and milestones**
- **Regulations & Guidance to be Affected by UDI Rule**
- **Saudi UDI Data Base (SUDID)**
- **SFDA UDI Data Elements**
- **Proposed SFDA UDI System**

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Definition

- ***Unique Device Identification (UDI)***

It's a series of numeric or alphanumeric characters created through a globally accepted device identification and coding standard.

It allows the unambiguous identification of a specific medical device on the market.

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UDI Structure

UDI consists of two parts

A common, worldwide system for product identification, to be applied to all medical devices placed on the market

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UDI System Construction

SFDA UDI
Regulation

Bar-coding
for every Medical Device

DI
Device Information
- Company
- Product ID

PI
Production Information
-Life
-Serial or Lot Information

UDID
Database
For DI part Only

DI
-Company Name
Address
-Product Name

-GMDN
-code
-term

. etc

Benefits of UDI System

- **Increase Global Visibility**
- **Helps in MDs Recalls & accurate Adverse Events Reporting**
- **Help improving Post-market surveillance**
- **Reduce medical errors**
- **An easy access source of device info for patients, clinicians, and public**
- **Tracking and tracing (reduced counterfeiting)**
- **Increase Supply chain security and efficiencies**

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The Need to align on a Global UDI framework Not National one

The Whole World is Watching

- **Raise levels of patient safety beyond borders**
- **Global harmonized MDs identification systems**
- **Allow for consistency in UDID across countries**

IMDRF -Guidance on UDI for MDs on *Dec 9th, 2013*
(Bar Coding Structure, Carrier, Core element for MDs Data Base)

Healthcare & Medical Device Industry are global

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Challenges for the healthcare stakeholders

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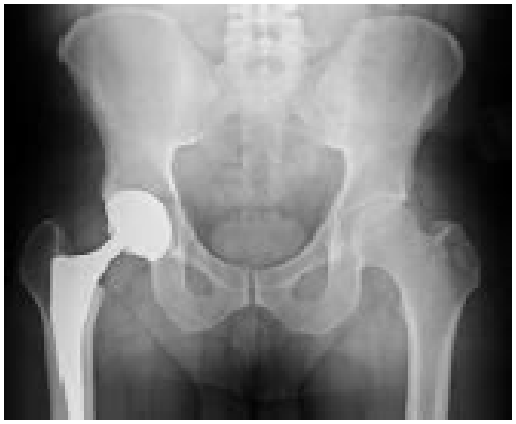
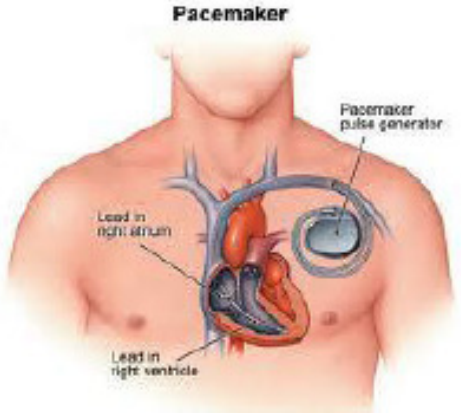
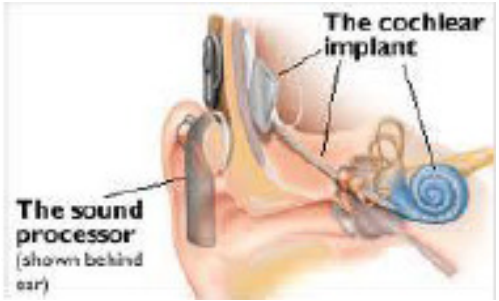
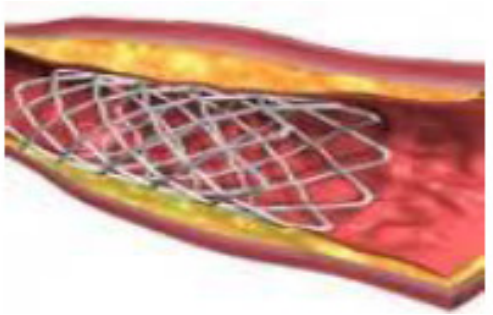
Challenges for the healthcare Cont..

Large Varity of Medical Devices









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Challenges for the healthcare Cont.

- **Cost , investments in infrastructure and resources to comply with UDI regulations w/out seeing any immediate benefits.**

- **MD Manufacturers must redesign label content and reconfigure existing production/inventory/distribution systems with UDI info.**

- **Healthcare providers to reconfigure existing hosp. solutions , EHR , Inventory, billing systems & codes ..etc to include the new UDI info.**

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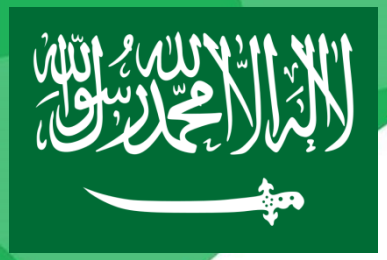

SFDA UDI Project Objectives

- **Developing and publishing UDI guidelines, and accreditation of UDI issuing agencies**

- **Create Saudi UDI Database which is linked to the needed MDS electronic systems and facilitate the full track and trace of medical devices**

- **Implement UDI guidelines to all medical devices entering on several phases**

- **Leverage the benefits of SFDA mobile application to provide more accurate information to the final consumer (including Home Users) which will provide lay persons with a tool to help them in identifying counterfeited devices.**

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UDI Issuing Agencies to be accredited for SFDA

Global Standard (GS1)	
The Health Industry Business Communications Council (HIBCC)	
Int' Council for Commonality in Blood Banking Automation (ICCBBA)	

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Examples of GS1 coding from MDMA

Cyberonics®

VNS Therapy® Patient Essentials
Model 220

⚠ **Important — Make sure the patient receives this kit.**

مهم — تأكد من حصول المريض على هذه المعدات

Contents — Documentation, Watch-style Magnet, Pager-style Magnet

محتويات — االمستندات، المغناطيس على شكل ساعة اليد، المغناطيس على شكل جهاز إشعار

Do not drop magnets. Keep magnets away from computers and computer disks. Keep magnets away from credit cards. Do not store magnets near other magnets.

لا تسقط المغانط، أبق المغانط بعيدة عن أجهزة الحاسوب والأقراص المدمجة، أبق المغانط بعيدة عن البطاقات الائتمانية، لا تحفظ المغانط بالقرب من مغانط أخرى

EC REP Cyberonics Europe
Airport Plaza - Kyoto Building
Leonardo Da Vincilaan 19
B-1831 Diegem, Belgium

(-4 °F) -20 °C — +55 °C (+131 °F)

CYBERONICS, INC.
100 Cyberonics Boulevard
Houston, Texas 77058 USA

LOT XXXXXXXXXXXXXXXXX

REF 10-0008-3200

CE 0344

26-0008-3516/0

www.VNSTherapy.com

Label 1

(01)05425025751006
(11)140227
(17)151101
(21)74783
(99)10-0006-4200

26-0008-3516/0

Label 2

Saudi Food & Drug Authority

Examples of Barcode using HIBCC

HIBCC Barcode Code 128	Same data with HIBCC Data Matrix
+M2354352/S$315071561350R	2354352/$$31507156135

The UDI with the HIBCC AIDC Format

Labeller Identification Code (LIC): M235
Item Number: 435
Expiration Date: 07/15/2015
Batch Number: 61350
UDI-DI: M2354352
UDI-PI: 1507156135
HIBCC concatenated data: +M2354352/$$315071561350R

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Saudi Food & Drug Authority

Examples of Barcode using ICCBBA

The UDI with the ICCBBA AIDC Format

Processor (Manufacturer) Identifier A9997
Catalogue Number: T9017Z012
Lot Number: A999713123456
Serial Number: 102
UDI-DI: A9997T9017Z012
UDI-PI: A999912123456102

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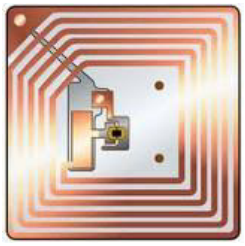
UDI requires a Carrier & Reader

Product Label (Carrier)

- Linear Bar Code
- 2D Bar Code (Data Matrix)
- RFID

Hardware to read labels

- Bar code Reader
- Bar code Image Scanner
- RFID Scanner



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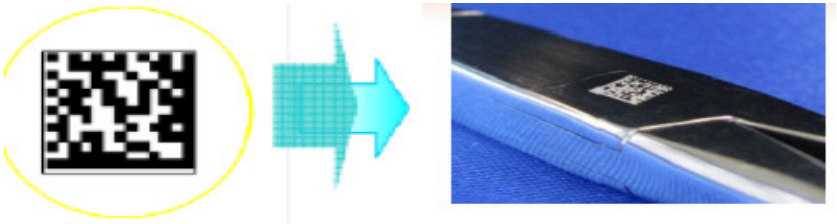
Direct Marking



Direct Marking

Exmp. Reusable devices that require reprocessing (cleaning by disinfection or sterilization) before reuse, must have the UDI directly marked on the device.

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SFDA UDI time Plan & Milestones

Phase	Phase Description		Expected Accomplishment Date
Phase 1	Milestone A	Activate Barcode Readers at SFDA Mobile App (for Home Use Devices)	Q4 2015
	Milestone B	Developing Regulation , accreditation of issuing agencies then regulation publications	Q4 2016
Phase 2	Create Saudi UDI Database.		Q4 2017
Phase 3	Enforce UDI to all medical devices on several phases		Start at (Q1 2018) Finish at (Q1 2020)

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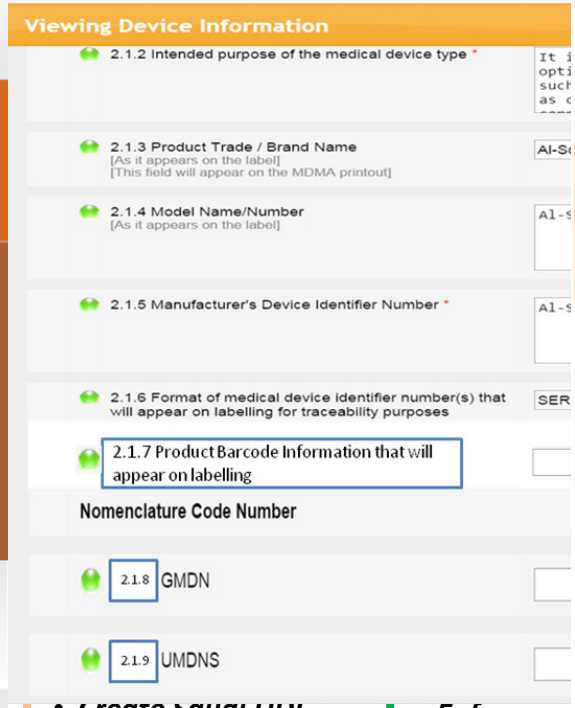
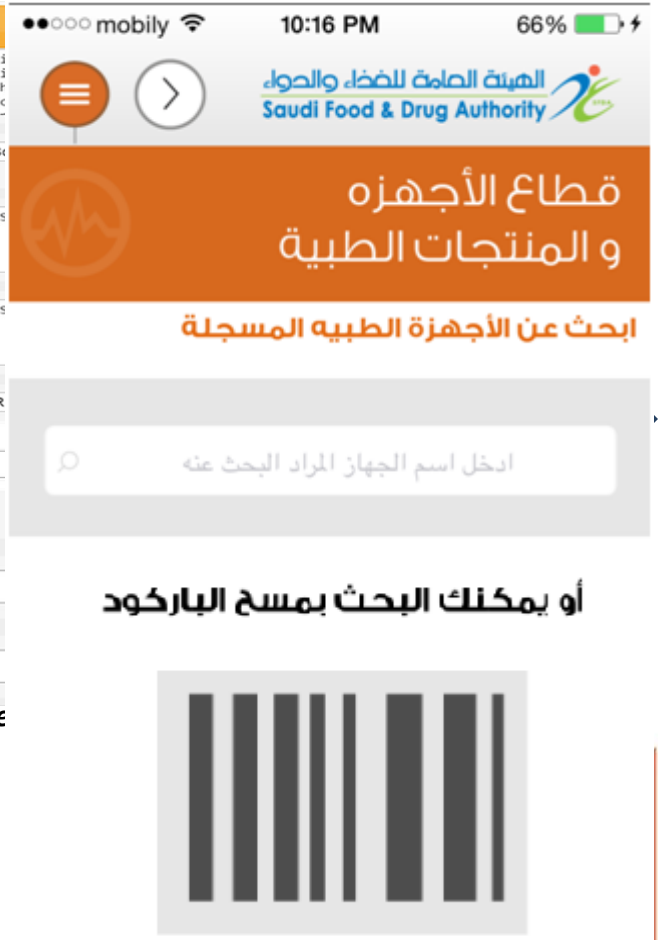
SFDA UDI time line cont.

Barcode Reader Activation





- ***Create Saudi UDI Database***
- ***Enforceme***

✓ ***Regulation publication***

Regulation & Guidance affected by UDI Rule

- MDIR- MDs Interim Regulation
- IR3 - MDs Listing
- IR5 – Licensing of AR
- IR6 – Marketing Authorization (MDMA)
- IR7 - Post-Marketing Surveillance
- IR8 – Safeguard Procedures
- G5 - Marketing Authorization Procedures
- G6 - Post-Marketing Surveillance
- MDS-G7 -MDs Bundling / Grouping Criteria
- MDS – G10 - MDs Labelling Requirements

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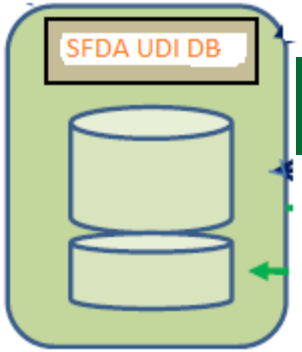
Saudi UDI Database (SUDID)



- **Saudi Unique Device Identification Database (SUDID)** will be a publicly searchable database administered by the Saudi FDA

- **Two options for SUDID Interface**
  - SUDID Web Interface - enables structured input of device information as one DI record at a time
  - Health Level 7 Structured Product Labeling HL7 SPL submission - enables submission of device information as xml files

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Global & SFDA Data Attributes

Data Element	FDA	IMDRF	SFDA
Device Information			
Primary DI Issuing Agency	FDA		
Primary DI Inumber	FDA	IMDRF	SFDA
Device Count	FDA	IMDRF	
Unit of Use DI Number	FDA	IMDRF	SFDA
Lablers DUNS Number	FDA		
Company Name	FDA	IMDRF	SFDA
Company Physical Address	FDA	IMDRF	SFDA
Brand Name	FDA	IMDRF	SFDA
Version or Model	FDA	IMDRF	SFDA
Catalog Number	FDA	IMDRF	SFDA
Device Description	FDA	IMDRF	SFDA
DI Record Publish Date	FDA		
Commerical Disribution End Date	FDA	IMDRF	
Commerical Disribution Status	FDA		
Device Subject to DM, but Expempt?	FDA		
DM DI Different from Primary DI	FDA		
DM DI Number	FDA		
Senodary DI Issuing Agency	FDA		
Secondary DI Number	FDA	IMDRF	SFDA
Package DI Number	FDA	IMDRF	
Quantity per Package	FDA	IMDRF	SFDA
Contains DI Package	FDA	IMDRF	
Package Type	FDA		
Package Dicontinue Date	FDA		
Package Status	FDA		
Customer Contact Phone	FDA	IMDRF	
Customer Contact Email	FDA	IMDRF	
Device Status			
HCT/P?	FDA		
Kit?	FDA		
Combination Product?	FDA		
Device Exempt frm Premarket Submm	FDA		
FDA Premarket Submiision Number	FDA		
FDA Supplement Number	FDA		
FDA Product Code	FDA		

Data Element	FDA	IMDRF	SFDA
FDA Listing Number	FDA	IMDRF	
GMDN Code	FDA	IMDRF	SFDA
GMDN Name	FDA		
GMDN Definition	FDA		
Device Characteristics			
For Single-Use?	FDA	IMDRF	SFDA
Lot or Batch Number Control?	FDA	IMDRF	SFDA
Manfacturing Date Control?	FDA	IMDRF	SFDA
Serial Number Control?	FDA	IMDRF	SFDA
Expiration Date Control?	FDA	IMDRF	SFDA
Donation Identification Number Contr	FDA		
Device required to be lables as Contac	FDA	IMDRF	SFDA
Device labled as "Not made with natur	FDA		
Prescribtion Use (Rx)?	FDA		
Over the Counter (OTC)?	FDA		
What MRI Saftey information does the	FDA	IMDRF	
Size Type	FDA	IMDRF	SFDA
Size Value	FDA	IMDRF	SFDA
Size Unit of Measure	FDA	IMDRF	SFDA
Size Type Text	FDA	IMDRF	
Storage and Handling	FDA	IMDRF	SFDA
Special Storage Conditions	FDA	IMDRF	
Device Packaged as Sterile?	FDA	IMDRF	SFDA
Reuires Steralizsation Prior to Use?	FDA	IMDRF	SFDA
Steralization Method	FDA	IMDRF	
Authorized Representative's name		IMDRF	SFDA
Authorized Rep. contact information		IMDRF	SFDA
SaMD version;		IMDRF	
Restricted number of reuses		IMDRF	SFDA
URL for addittional information		IMDRF	SFDA
Labled as containing DEHP?		IMDRF	SFDA
Critical Warnings or contrindications		IMDRF	SFDA

Proposed SFDA UDI & Track and Trace System

Manufacturer

Web User Interface

Bulk Data Entry Using XML

Manufacturer Database

Retailer

Inventory Control

IN → OUT

Database

Hospitals

Inventory Control

IN → Patient

Database

Obtain UDI Code

Data Register

Accredited UDI Issuing Agency

Saudi FDA UDI Database

Public

Mobile Application

IN → Lay Person

MDMA — Medical Devices Marketing Authorisation

MDNR — Medical Devices National Registry

MDELS — Medical Device Establishement Lecince

NCMDR — National Center For Medical Devices Reporting

MDC — Medical Devices Classification

MDIL — Medical Devices Importing License

POE

Clinical Investigation

Thank you !

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