EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

# EMA/EU-FDA Activity Update

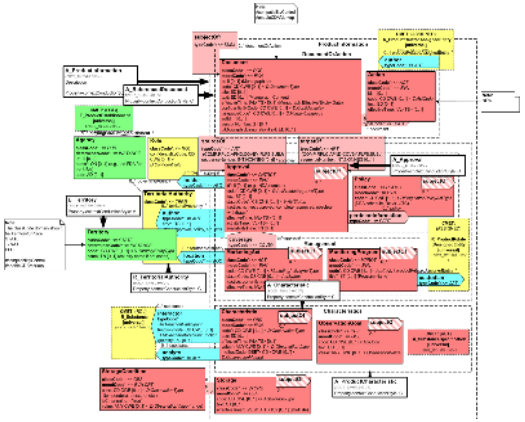
Vada A. Perkins

# HL7 SPL(R7) Publication

- HL7 SPL(R7) Publication:  To be submitted by this Friday (ballot approved)
- SPL Release 7 as the data exchange format to support ISO IDMP Technical Specifications.  The ISO IDMP Technical Specifications describes the data exchange for the five (5) ISO International Standards
- Incorporates European Union (EU)/European Medicines Agency (EMA) requirements for EU implementation of the five IDMP standards utilizing HL7 SPL to support their legislative requirements for product registration and pharmacovigilance.
  - 92 data elements
  - SmPC requirements

# ISO IDMP ***Normative*** Standard e-Message for Data Exchange: Common Product Model (CPM)

- The Health Level Seven (HL7) Common Product Model (CPM) provides:



✓ **Overarching information model**

✓ **Reusable Common Message Element Types (CMETs)**

✓ **Consistent data types and conformance rules**

✓ **Vocabulary domains**

✓ **Schemas for data exchange**

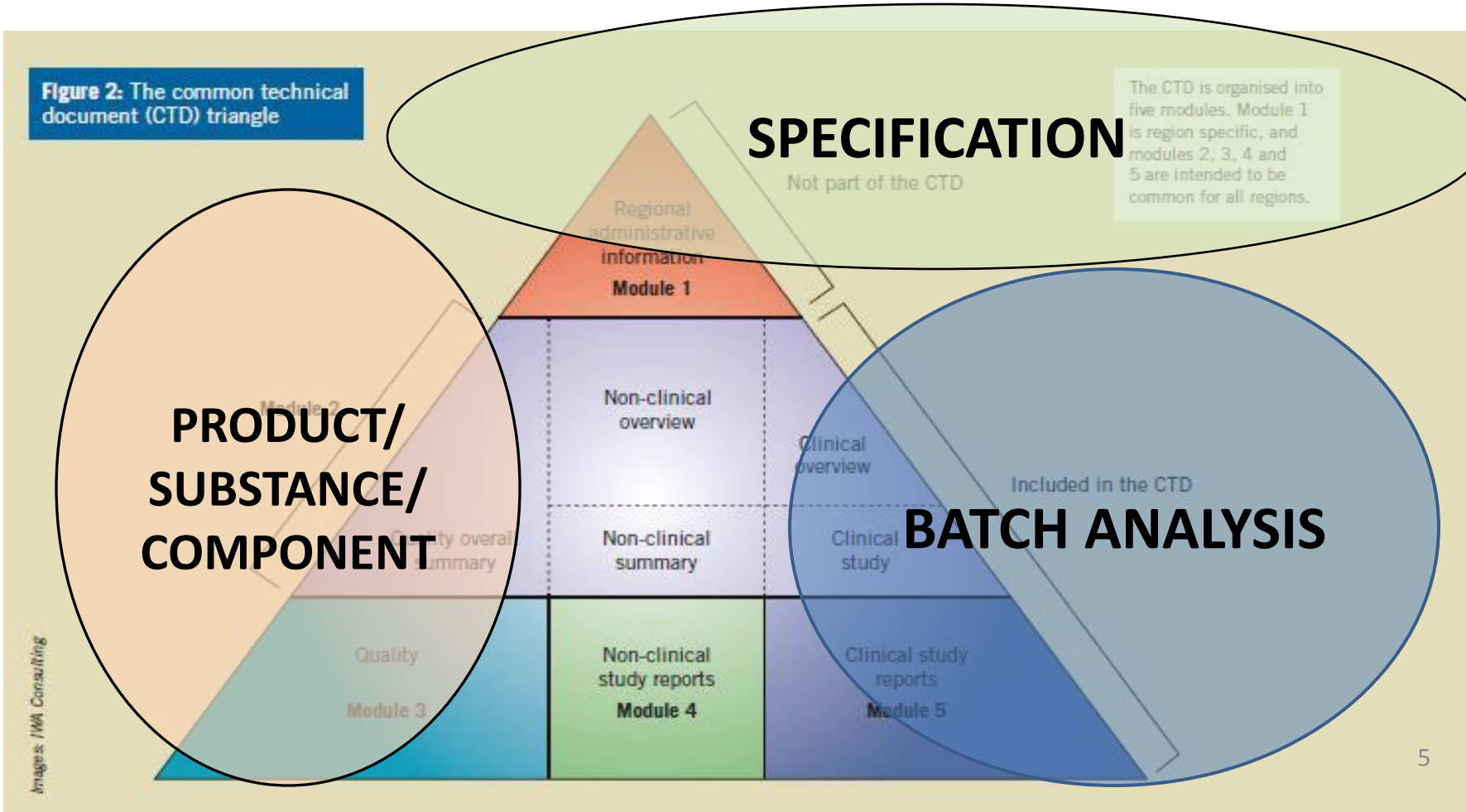
# Style Sheet View/Source Code (XML)

**CONTRAINDICATIONS**

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson&amp;#8217;s disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

# Common Technical Document (CTD): Module 3 (Quality)



# FDA Relevant "SP***OR***"

- **Registrant**
  - Contact
  - Address
  - Telephone number
  - Email address
- **Establishment/Facility**
  - Name (business)
  - Contact
  - Address
  - Telephone number
  - Email address
  - ***ID (DUNS, FDA ID, EMA/EU ID)***
  - ***Business Operations***
  - ***GPS coordinates***
- **Importer**
  - Contact
  - Address
  - Telephone number
  - Email address
  - ***ID (DUNS, FDA ID, EMA/EU ID)***
  - **GPS coordinates**
- **In Country Contact (e.g., US Agent)**
  - Name (business)
  - Contact
  - Address
  - Telephone number
  - Email address
  - ***(DUNS, FDA ID, EMA/EU, ID)***

# EMA/EU Data Elements

| Medicinal Product |
|---|
| MPID |
| Combined Pharmaceitical Dose Form |
| IMPID Corss-Reference |
| Additional monitoring indicator |
| Orphan Designation Status |
| Name (Med.Product) |
| Invented Name Part |
| Scientific Name Part |
| Strength Name Part |
| Pharmaceutical Dose Form Part |
| Formulation Part |
| Intended Use Part |
| Target Population Part |
| Container or Pack Part |
| Device Name Part |
| Trademark or Company Name Part |
| Time/Period Part |
| Flavour Part |
| Classification System |
| Classification System Value |
| Version Date |
| Version Identifier |
| Document Type |
| Document Identifier |
| Regulated Document |
| Document Effective Date |
| Country |
| Language |

| Marketing Authorisation |
|---|
| Marketing Authorisation Number |
| Country |
| Legal Status of Supply |
| Authorisation Status |
| Authorisation Status Date |
| Date of First Authorisation |
| Procedure Identifier/Number (e.g. MRP number) |
| Procedure Type (e.g. MRP/DCP) |
| Country (national authorisation) |
| Marketing Authorization Number (national authorisation) |

| Organisation (e.g. MAH, QPPV, PSMFL) |
|---|
| Identifier |
| Role |
| Location Address |
| Location Role |
| Entity Identifier (according to Role e.g. PSMF ID) |

| Marketing information |
|---|
| Country |
| Marketing Status |
| Marketing Date |
| Risk of shortage supply |
| Risk of shortage supply comment |

| Indication |
|---|
| Indication Text |
| Indication as "Disease/ Symptom/ Procedure" |
| Co-Morbidity |
| Intended Effect |

| Pharmaceutical Products |
|---|
| Administrable Dose Form |
| Unit of Presentation |
| Route of Administration |
| PhPID Identifier Sets |
| Device Type (combined medical device ATMP) |
| Device Trade Name (combined medical device ATMP) |

| Ingredient |
|---|
| Ingredient Role |
| Substance |
| Specified Substance |
| Confidentiality Indicator |
| Strength Range (Presentation) |
| Strength Range (Concentration) |
| Reference Strength Substance |
| Reference Strength Specified Substance |
| Reference Strength Range |

| Package description |
|---|
| PCID |
| Package Description |
| Package Item (Container) Type |
| Package Item (Container) Quantity |
| Material |
| Component Type |
| Component Material |
| Manufactured Dose Form |
| Unit of Presentation |
| Manufactured Item Quantity |
| Device Type |
| Device Trade Name |

- Around 20 data elements were removed/ streamlined/ re-modelled
  → **74 Data elements in PMS Iteration 1**

- If it is agreed to include 5 data elements to cover Shortage and Marketing information
  → **Total 79 Data elements in PMS Iteration 1**

# Medicinal Product

MPID

Combined Pharmaceitical Dose Form

7. (Proposed) Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

If yes, provide the Orphan Designation number for this indication:

Continuation Page for #7

Scientific Name Part

Strength Name Part

Pharmaceutical Dose Form Part

Formulation Part

Intended Use Part

Target Population Part

Container or Pack Part

Device Name Part

Trademark or Company Nam

Time/Period Part

Flavour Part

Classification System

Classification System Value

Version Date

Version Identifier

Document Type

Document Identifier

Regulated Document

Document Effective Date

Country

Language

**Influenza Virus Vaccine**
**Fluvirin®**
**2015-2016 FORMULA**

# Language/Code

```
<!-- SPL header -->
<document>
  <id root="1d90e8f0-2065-4f8c-a85a-9a186904fc14"/>
  <code code="34391-3" displayName="human prescription drug label"
        codeSystem="2.16.840.1.113883.6.1"/>
  <languageCode code="en_US" codeSystem="2.16.840.1.113883.6.121">
```

and the section:

```
<section>
  <id root="be362bdc-9458-4625-ba03-d663b4534962"/>
  <code code="34089-3" displayName="description section"
        codeSystem="2.16.840.1.113883.6.1"/>
  <text>Description</text>
  <text>Goodmedicine is a white to off-white powder ...</text>
  <languageCode code="en_US" codeSystem="2.16.840.1.113883.6.121">
```

# Link to the Original Source of Translation

```
<!-- SPL header -->
<document>
 <id root="e56fef83-7eff-41d1-a122-fa5cac99317c"/>
 <code code="34391-3" displayName="human prescription drug label"
      codeSystem="2.16.840.1.113883.6.1"/>
 <languageCode code="fr_FR" codeSystem="2.16.840.1.113883.6.121">
 <setId root="20d9b74e-e3d8-4511-9df9-cec2087372fc"/>
 <versionNumber value="1"/>
 <relatedDocument typeCode="DRIV">
   <relatedDocument>
    <id root="1d90e8f0-2065-4f8c-a85a-9a186904fc14"/>
   </relatedDocument>
 </relatedDocument>
```

# Package and Submission of Multiple Translations

- When required, each SPL file (having one language) should be packaged in its own folder. The name of the folder may contain the language code

| Marketing Authorisation |
| --- |
| Marketing Authorisation Number |
| Country |
| Legal Status of Supply |
| Authorisation Status |
| Authorisation Status Date |
| Date of First Authorisation |
| Procedure Identifier (e.g. MRP Number) |
| Procedure Type (e.g. MRP/DCP) |
| Country (national authorisation) |
| Marketing Authorization Number (national authorisation) |

| Organisation (e.g. MAH, QPPV, PSMFL) |
| --- |
| Identifier |
| Role |
| Location Address |
| Location Role |
| Entity Identifier (acc |

| M |
| --- |
| Country |
| Marketing Status |
| Marketing Date |
| Risk of shortage supply |
| Risk of shortage supply con |

5.1.5.13 If the qualifiers Intent to compound 506e (drug shortage) drugs (C112087), No int
fr NCI concept code for SPL Lot Distribution Data - Distribution Codes: C106324
(C
ste
ou

| SPL Acceptable Term | Code |
| --- | --- |
| Distributed per reporting interval | C106325 |
| Returned | C106328 |

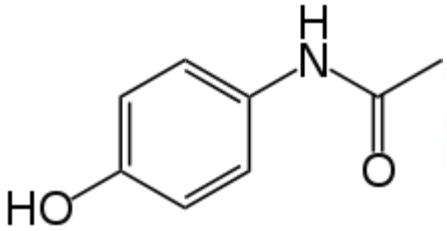
| Indication |
| --- |
| Indication Text |
| Indication as "Disease/ Symptom/ Procedu |
| Co-Morbidity |
| Intended Effect |

**Guidance for Industry**
**Indexing**
**Structured Product Labeling**

| Pharmaceutical Products |
| --- |
| Administrable Dose Form |
| Unit of Presentation |
| Route of Administration |
| PhPID Identifier Sets **(Product Concept (US)-Algorithm (in test))** |
| Device Type (combined medical device ATMP) |
| Device Trade Name (combined medical device ATMP) |

| Ingredient |
| --- |
| Ingredient Role |
| Substance |
| Specified Substance **(Group 1 SS: G-SRS (US rollout APR 2016))** |
| Confidentiality Indicator |
| Strength Range (Presentation) |
| Strength Range (Concentration) |
| Reference Strength Substance |
| Reference Strength Specified Substance **(Group 1 SS: G-SRS)** |
| Reference Strength Range |

# Paracetamol (aka acetaminophen)




apomedifot.de


# Paracetamol/Acetaminophen

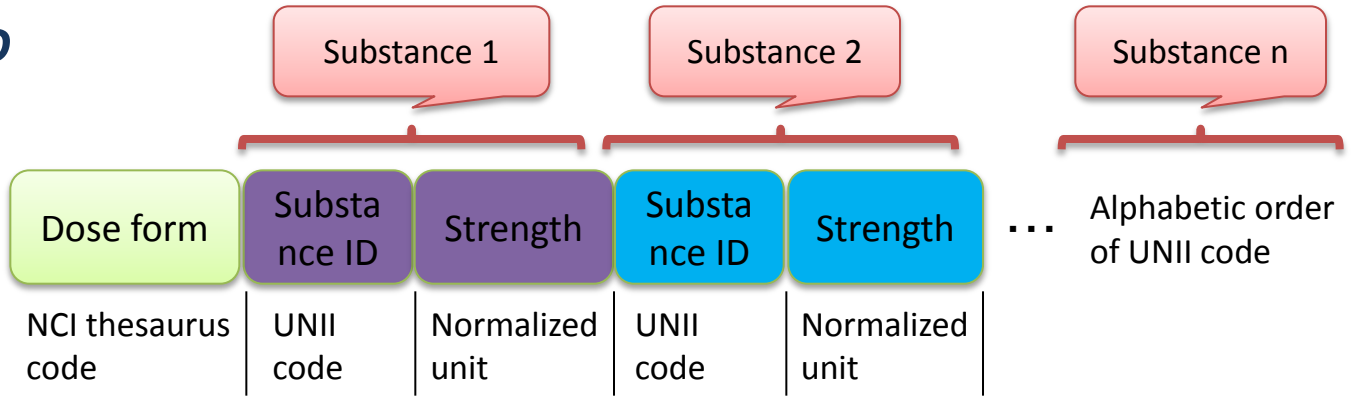
- **PhPID_SUB_L1 →** paracetamol
- **PhPID_SUB_L2 →** paracetamol, **1000 mg**
- **PhPID_ SUB _L3 →** paracetamol, **tablet**
- **PhPID_ SUB _L4 →**paracetamol, **1000 mg**, **tablet**

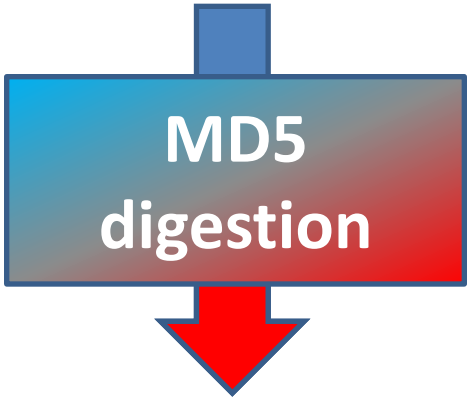
- **PhPID_SUB_L1 →** paracetamol
- **PhPID_SUB_L2 →** paracetamol, **750 mg**
- **PhPID_ SUB _L3 →** paracetamol, **tablet-film coated**
- **PhPID_ SUB _L4 →**paracetamol, **750 mg**, **tablet-film coated**

- **PhPID_SUB_L1 →** paracetamol
- **PhPID_SUB_L2 →** paracetamol, **500 mg**
- **PhPID_ SUB _L3 →** paracetamol, **capsule**
- **PhPID_ SUB _L4 →**paracetamol, **500 mg**, **capsule**

# *FDA algorithm (beta) for PhPID Generation*

## Input



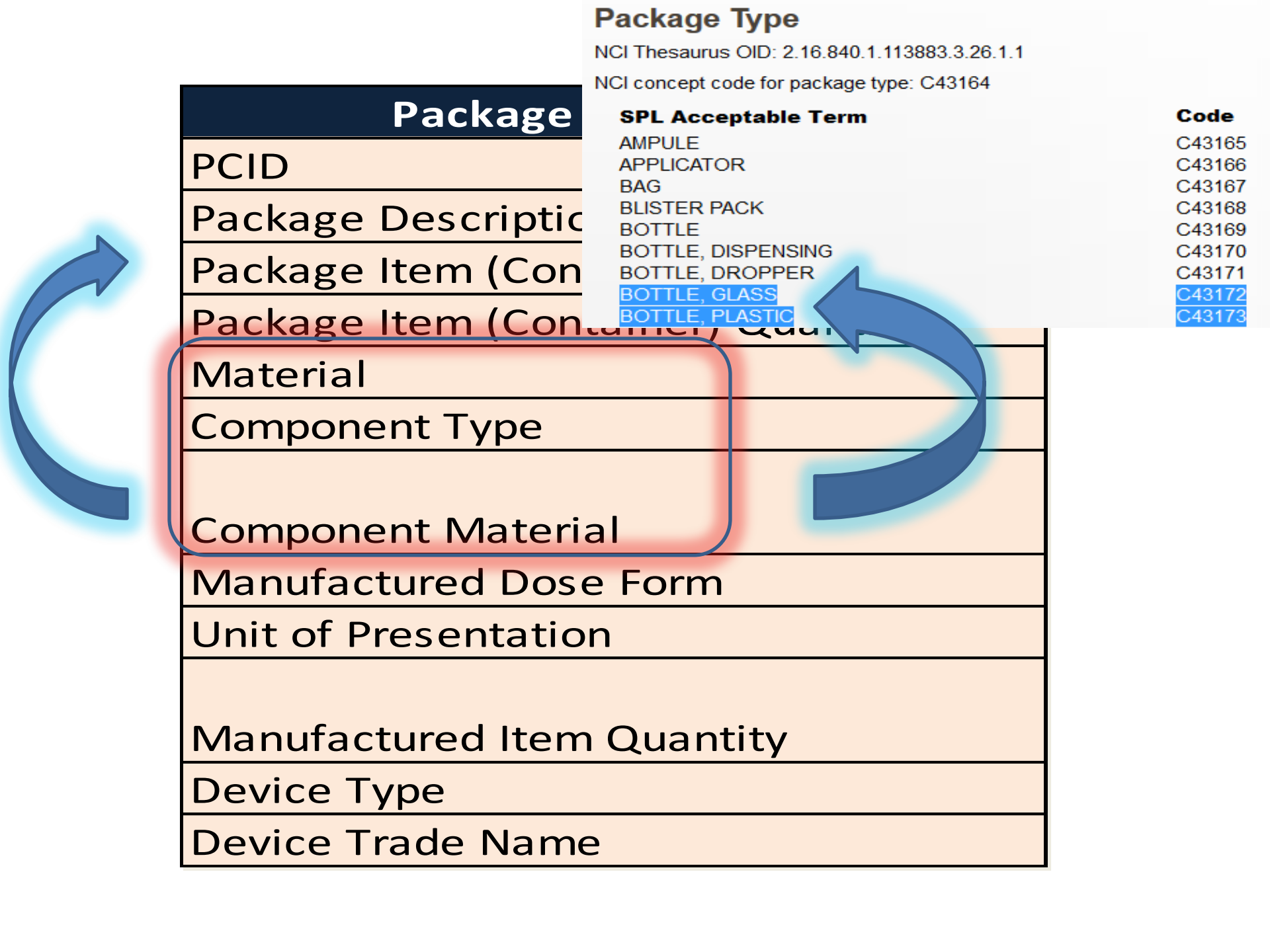




**MD5 i**s a widely used algorithm for hash function.

## Output

**PhPID code (example)**

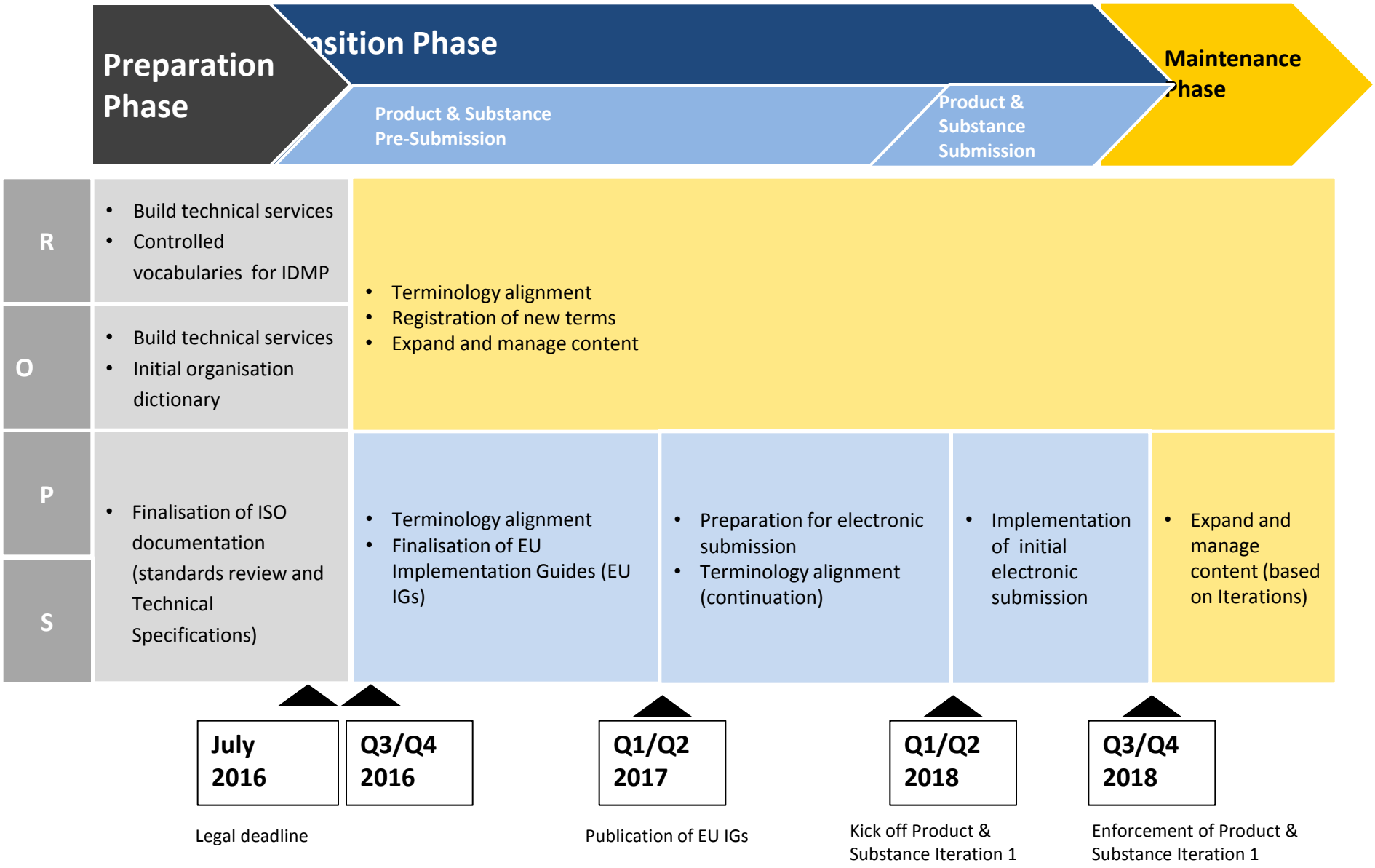
128 bit (16 byte) number which, in hexadecimal presentation, is 32 digits long formatted in groups of 8-4-4-4-12 digits separated by hyphens
-Globally Unique Identifier (GUID)

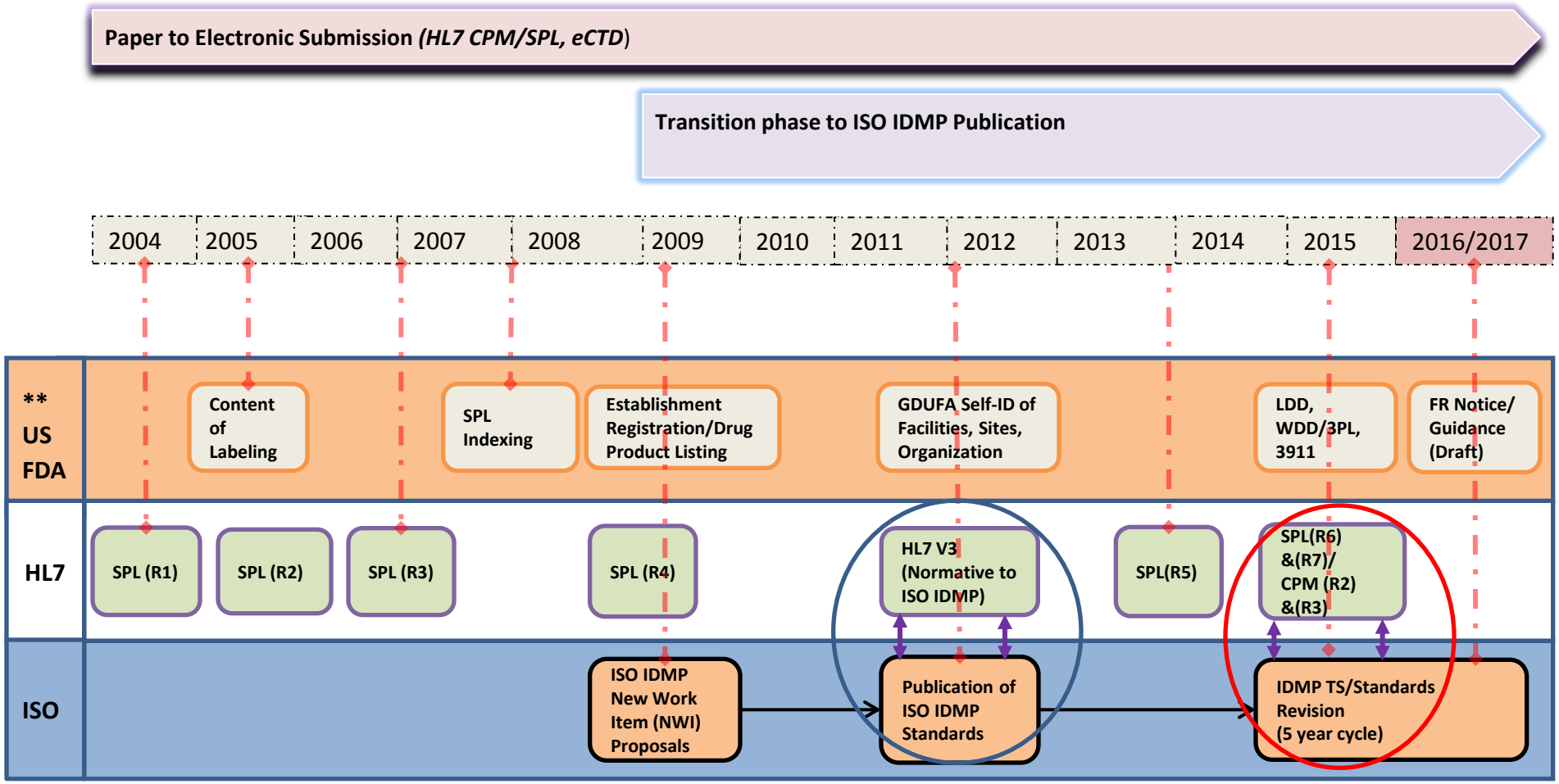

Package Type
NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1
NCI concept code for package type: C43164
SPL Acceptable Term
Code
AMPULE C43165
APPLICATOR C43166
BAG C43167
BLISTER PACK C43168
BOTTLE C43169
BOTTLE, DISPENSING C43170
BOTTLE, DROPPER C43171
BOTTLE, GLASS C43172
BOTTLE, PLASTIC C43173
Package
PCID
Package Descriptic
Package Item (Con
Material
Component Type
Component Material
Manufactured Dose Form
Unit of Presentation
Manufactured Item Quantity
Device Type
Device Trade Name

# ISO "SPOR": Global Harmoni(sz)ation

- Medicinal Product ID (MPID)
  - **Regional Identification**
- Pharmaceutical Product ID (PhPID)
  - IDMP (algorithm)
    - Based on core elements for identification of medicinal products
    - **Demands harmonization of terminologies/IDs for globally unique identification (internal and external to EU).**
- Substances
  - **Global Substance Registration System (G-SRS)**
    - **EMA/EU-FDA Bilateral (governance)**
- Units of measurement
  - **Unified Code for Units of Measure (UCUM)**
- Dosage forms-mapping exercise (ongoing)
  - **European Directorate for the Quality of Medicines (EDQM)**

# Overall high level plan for SPOR (updated)






# US FDA IDMP Roadmap

***US FDA SPL Implementation Guide (technical specification) updated with corresponding Guidance for Industry (incorporated by reference)***
http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm2005542.htm

Reference:
Vada Perkins
ISO /FDA IDMP Topic Lead/Expert

***Technical Specifications Document***

This Document is incorporated by reference into the following Guidance Document(s):

***Guidance for Industry – Electronic Submission of Lot Distribution Reports***

***Guidance to industry - Providing Regulatory Submissions in Electronic Format – Content of Labeling***

***Guidance for Industry - Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing***

***Guidance for Industry - SPL Standard for Content of Labeling Technical Questions and Answers***

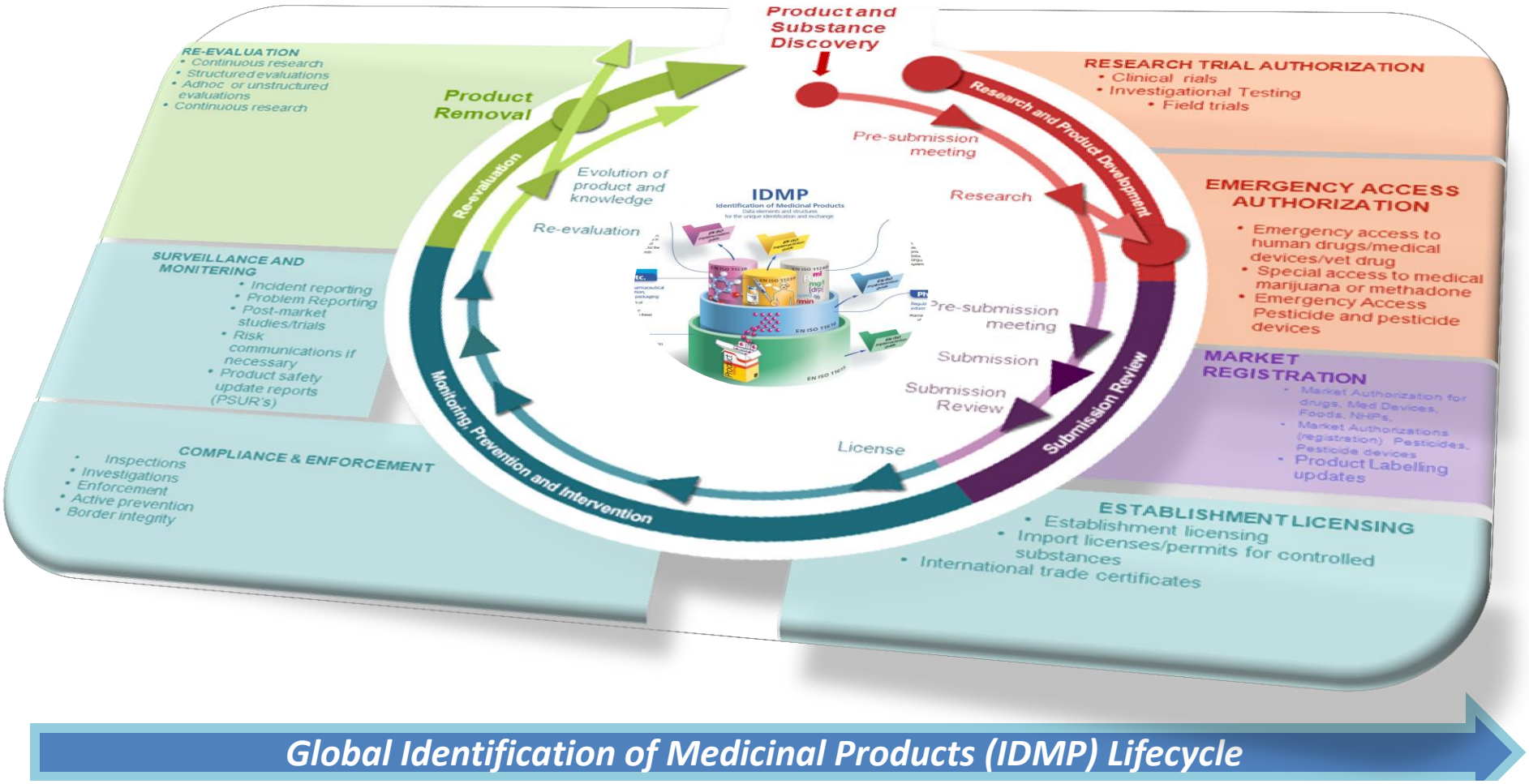
***Guidance for Industry - Indexing Structured Product Labeling (Final)***

***Guidance for Industry: Self-Identification of Generic Drug Facilities, Sites, and Organizations***

***Guidance for Industry - Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act***

***Guidance for Industry - Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act***

***Guidance for Industry - DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics***




*Global Identification of Medicinal Products (IDMP) Lifecycle*

# Thank You