International Standards & Quality Management Systems:
The Framework for Incorporating Sustainable UDI Processes within your Organization

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Learning Objectives

• Hierarchical relationship of regulations & standards
• Relevant international standards & guidance documents
• Key considerations for integration of UDI processes into the QMS
• Sustainability & adaptability of UDI process
Regulation vs Standards

Europe
- Medical Device Regulation
- Harmonization
- Standards
- Guidance Documents
- Local Procedures

US
- 21 CFR
- FDA Recognition
- Standards
- Guidance Documents
- Local Procedures
Regulations vs Standards

**Regulations** are legal requirements written at a high level and do not state necessarily how to do something, but state typically what must be achieved

- **Outcome rather than instruction**

**Standards** are much more prescriptive; as well as giving requirements, they give much more detail on how to do something

- **Detail of requirements to achieve desired quality outcome**

Guidance documents provide more of a ‘cookbook’ approach.
EN Standards

• EN documents have to be implemented into every EU member state (currently 28 countries...)

• They must be implemented unaltered; national deviations are not permitted

• Any conflicting national standard has to be withdrawn
Harmonized EN Standards

**Harmonized** to a European directive or regulation

**Presumption of conformity** to corresponding Essential Requirements/General Safety & Performance Requirements of that directive or regulation when complying to a standard

**Annex Z** contains a cross-reference table of clauses from the ER/GSPR to clauses of the standard
Annex Z

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

<table>
<thead>
<tr>
<th>Clauses/subclauses of this European Standard</th>
<th>Essential requirements (ERs) of EU Directive 93/42/EEC</th>
<th>Qualifying remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>1, 4, 3, 6, 7.1, 8.1, 9.1, 7.2, 9.2</td>
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<td>5.1</td>
<td>2, 7.3</td>
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<td>5.1.3</td>
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<td>The WD shall comply with the requirements of IEC 61010-2-045</td>
</tr>
</tbody>
</table>
FDA Recognition

Identifies standards to which manufacturers of medical devices may submit a Declaration of Conformity to demonstrate they have met relevant requirements in the FD&C Act

Assesses the impact of new consensus standards and revisions of existing standards on the premarket review process and recognizes these standards

Recognizes consensus standards wholly or in part

Recognized Consensus Standards database

Non-Recognized Standards database
# FDA Recognized Consensus Standards

<table>
<thead>
<tr>
<th>Date of Recognition</th>
<th>Standard Number</th>
<th>Title of Standard</th>
<th>Extent of Recognition</th>
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</table>
## FDA Recognized Consensus Standards

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This standard is under revision to include 21 new symbols, including one for UDI:

- meets a regulatory requirement that medical device packaging required to bear Unique Device Identification, can be **readily identified** as the UDI carrier
- **enables recognition** of the UDI information at the point of care
- is **placed adjacent** to the UDI carrier, when multiple bar-codes are used
- is **optional**
## IMDRF Guidance Documents

<table>
<thead>
<tr>
<th>Date Posted</th>
<th>Document Number</th>
<th>Title of Guidance</th>
<th>URL</th>
</tr>
</thead>
</table>
# Medical Devices Coordination Group (MDCG)

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 May 2019</td>
<td>MDCG 2018-1 v2</td>
<td>Guidance on basic UDI-DI and changes to UDI-D</td>
</tr>
<tr>
<td>15 Apr 2019</td>
<td>2019-4</td>
<td>Timelines for registration of device data elements in EUDAMED</td>
</tr>
<tr>
<td>15 Apr 2019</td>
<td>2019-5</td>
<td>Registration of legacy devices in EUDAMED</td>
</tr>
<tr>
<td>19 Feb 2019</td>
<td>MDCG 2019-2</td>
<td>Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017</td>
</tr>
<tr>
<td>25 Jan 2019</td>
<td>MDCG 2019-1</td>
<td>MDCG guiding principles for issuing entities rules on basic UDI-D</td>
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<th>Title</th>
<th>Publication</th>
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<tbody>
<tr>
<td>10 Oct 2018</td>
<td>MDCG 2018-6</td>
<td>Clarifications of UDI related responsibilities in relation to article 16</td>
</tr>
<tr>
<td>10 Oct 2018</td>
<td>MDCG 2018-7</td>
<td>Provisional considerations regarding language issues associated with the UDI database</td>
</tr>
<tr>
<td>10 Oct 2018</td>
<td>MDCG 2018-3</td>
<td>Guidance on UDI for systems and procedure packs</td>
</tr>
<tr>
<td>10 Oct 2018</td>
<td>MDCG 2018-4</td>
<td>Definitions/descriptions and formats of the UDI core elements for systems or procedure packs</td>
</tr>
<tr>
<td>10 Oct 2018</td>
<td>MDCG 2018-5</td>
<td>UDI assignment to medical device software</td>
</tr>
<tr>
<td>9 April 2018</td>
<td>MDCG 2018-2</td>
<td>Future EU medical device nomenclature - Description of requirements</td>
</tr>
</tbody>
</table>
Project vs Process

**Project** – creates change
  - objectives & plans can be changed by stakeholders
  - how process work gets improved

**Process** – resists change
  - actions performed repeatedly to create value
  - how work gets standardized
QUALITY

The race for Quality has no Finish Line—
so technically, it's more like a Death March.
Integrating UDI into a QMS

1. Involve & engage all departments

   • UDI is not a silo process
   • identify key UDI contact from each department
Integrating UDI into a QMS

2. Create Quality Plan

- define scope/extent of UDI
- provide comprehensive detailed course of action
- re-evaluate as goals & milestones are accomplished or changed
- build in flexibility
Integrating UDI into a QMS

3. Gap Analysis

- documents
- processes
- resources
Integrating UDI into a QMS

4. Update Documentation

• incorporate risk-based approach
• connect processes to minimize overlap & repetition
• allow flexibility
• assign responsibility & authority
• part number = UDI
Integrating UDI into a QMS

4. Education & Awareness

• awareness of role each department has in UDI
• train all employees on UDI
• confidence in processes
• culture of quality
Integrating UDI into a QMS

4. Data Management

- apply good great **excellent** data management & documentation practices
- secure & centralized data repository
- think GLOBAL, not regional
Sustainability & Adaptability

- use recognized standards and guidance documents
- stay informed of changes
- national UDI programs – more similar than different
YEAH, IF YOU COULD ALL COME TO MY PARTY

THAT WOULD BE GREAT