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Q&A-Unique Device Identification (UDI)

Q1 Are you aware of the new UDI regulation?

A1 In order to provide an outstanding support for our customers WOM has set up a **UDI Task Force**. Our interdisciplinary team – consisting of our experts from R&D, Global Sales, Product Management, Regulatory Affairs, Supply Chain Management and ERP Consulting – is engaged in the implementation of UDI requirements until the below mentioned deadline. Please find the **project phases and status** on the next page.

According to the released FDA compliance dates

- Our medical products' **labels** have to be adapted by **Sep. 24th, 2016**.
- Devices intended to be used more than once and intended to be reprocessed before each use are required to bear a direct marking affixed to the device. This permanent UDI labeling is necessary from **Sep. 24th, 2018**.

In the European Union, UDI liabilities will be regulated in the Medical Devices Regulation (MPV). Here, it is expected that UDI labeling will be binding for WOM products 3 years after coming into force.

Q2 Which issuing agency are you working with?

A2 WOM has signed a license agreement with the FDA accredited issuing agency **GS1**. Thus, we will be able to provide our products with FDA-2011-0090 conform barcodes. In general, at least two types of barcodes can be applied:

- **GS1-128-Barcode**

- **GS1 DataMatrix**

UDI Labels must always contain the following information:

- **Device Identifier**
  (01) GTIN (Global Trade Item Number), provided by GS1
- **Production Identifier*, e.g.**
  (17) Expiration Date
  (10) Lot Number
  (21) Serial Number
  (11) Production Date
- **Possible data combinations and syntax within the GS1 barcodes**
  AI 01(GTIN)+ AI 11(DoM)+ AI 21(SN), e.g. for capital equipment
  AI 01(GTIN)+ AI 11(DoM)+ AI 17(DoE)+DB10(LOT), e.g. for disposable tubing sets
  AI 01(GTIN)+ AI 11(DoM)+ AI 10(LOT), e.g. for other accessories
  (foot switch, remote control etc.)

WOM may create, print and scan UDI conform labels.

* a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device

Q3 What are the major challenges in the implementation of UDI labeling? Is there any information that we can provide WOM?

A3

- In cases where the OEM customer is legal manufacturer of WOM products it will be a challenge to coordinate the individual elements of the UDI barcode (e.g. serial number) and manage the codes in our ERP system.
- A process for the exchange of UDI codes between WOM and its customers and suppliers has to be defined.
- Coordinate customer specific requirements on the UDI carrier (e.g. DataMatrix or GS1-128 Barcode)
- We aim to consider your time-related goals for the implementation. For this, please refer to our project coordinator (see Q6).

Q4 Is the UDI required equipment and software validated?

A4 The validation of UDI required equipment and software will be conducted as part of our implementation process (see page 2 for the current state), coordinated by the UDI Task Force.

Q5 Are the new UDI requirements affecting the registration of products? Who is responsible for label changes?

A5 From the regulatory point of view the UDI implementation is nothing more than a label change which is covered by our change management. The SOP for label changes will be applied. All creation/adaption activities are performed by our Technical Documentation Dept. supervised by the dedicated R&D Project Manager, Regulatory Affairs Manager and Product Manager.

Q6 Who is our contact person for inquiries on this topic?

A6 For further questions please send an e-mail to **UDI.Info@wom.group**
Mr. Thomas Christmann – Coordinator of the UDI Task Force – will take care of your request.

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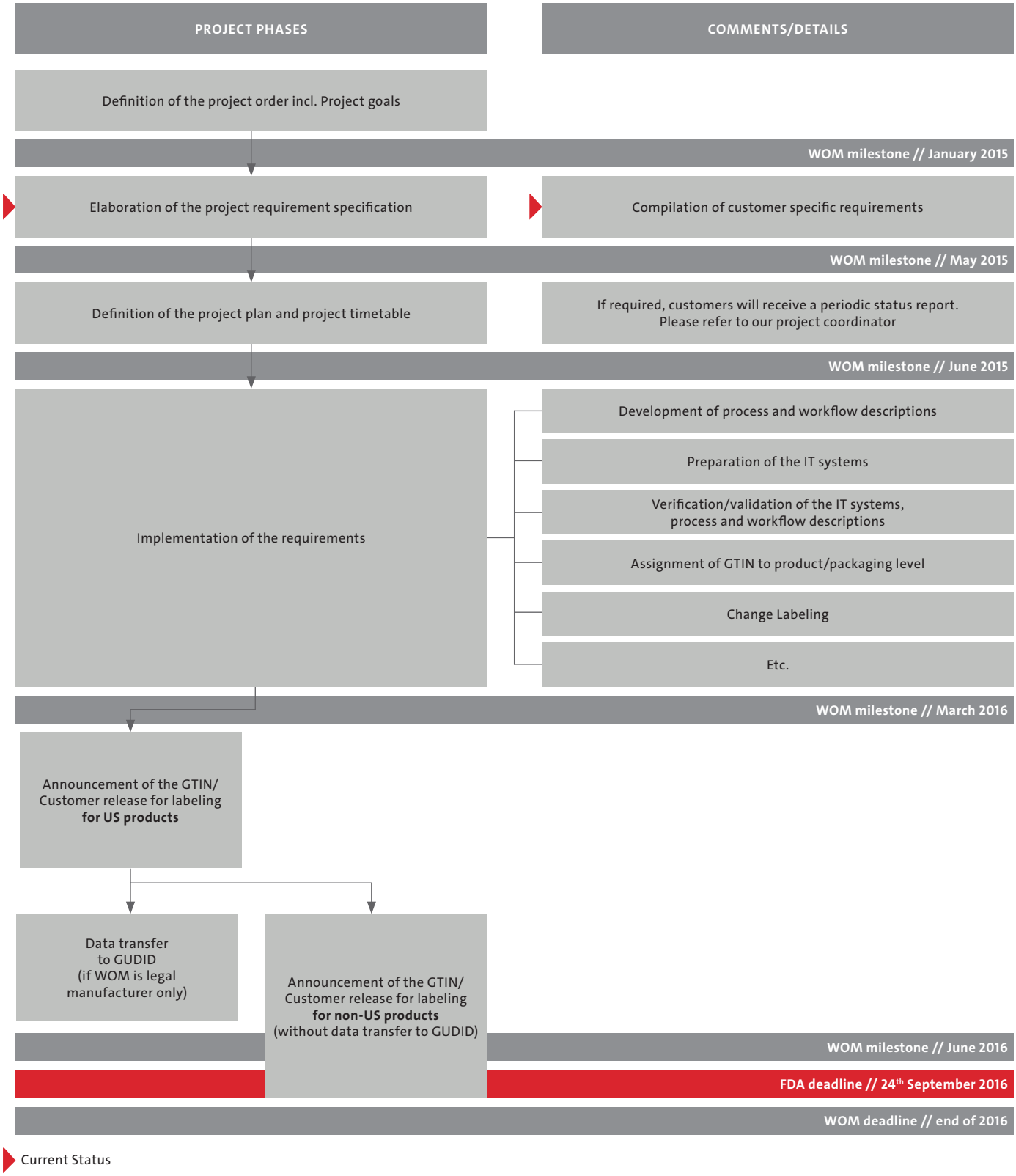
UDI Task Force – Project Status



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