# IVDR Transition Project – A Brief Guide

**anteris medical GmbH**
**Dr. Bernd Krämer**

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The new IVD regulation (IVDR) entered into force on May 26th 2017 - almost one and a half years ago. As the date of application for the IVDR is May 26th 2022, this means that only three and a half years are left to implement the IVDR. Considering the huge amount of work involved, it is wise to start implementing as soon as possible, if you have not already done so. But how to be effective and efficient? In this article we briefly introduce a simple but practical tool to lead you through your transition project.

## INTRODUCTION TO THE IVDR TRANSITION PROJECT

When viewed in light, the IVDR can be seen as a list of requirements. Thus, the transition to IVDR can be handled in analogy to a simple development project. The requirements have to be specified as tasks that have to be implemented by activities and the activity output has to be verified. But regardless of this simplified representation, be aware that this project is somehow multidimensional. The IVDR transition project has implications at nearly every business level and requires support and collaboration from all departments. Therefore, it is recommended to get the whole company on board and behind your project, but just as important is maintaining normal business. Some essential elements, that have to be included in the project plan are illustrated in Figure 1. In order to estimate the required implementation effort, it might be helpful to conduct a pilot project.

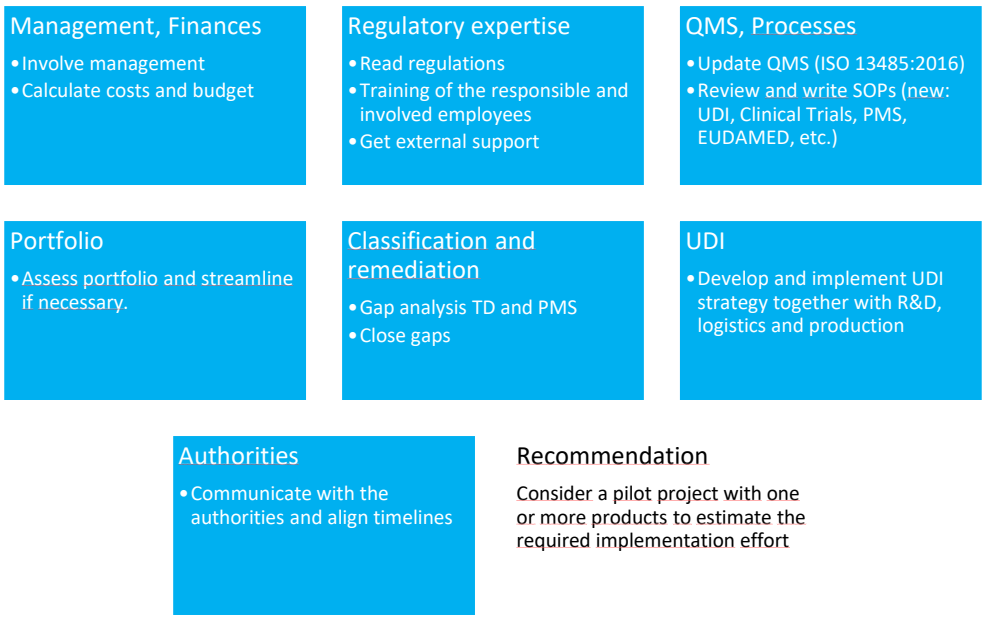


Figure 1: Essential IVDR transition project elements

**IVDR REQUIREMENTS MANAGEMENT**

To come back to requirements, the first step to start with, is to conduct a gap analysis. With a gap analysis the differences between your actual compliance and the required compliance with IVDR are identified. Gaps are identified for each requirement of the IVDR and broken down into discrete requirements if appropriate. All gaps are translated into task specifications as input for implementation activities. Requirements can be organized into logical groups if appropriate and by this be allocated and managed independently. For all tasks, activities, dates, resources needed, and responsibilities are defined.

For reasons of practicability, a structured tool like a table is recommended for the gap analysis. Once set up, this tool can be reused as a template for each product entity. The IVDR is available for download and can easily be translated into a table with one table row for each requirement - contact us at info@anteris-medical.com, anteris medical has already created tables for some chapters and annexes of the IVDR and we are happy to provide you with our templates as far as available. In the following, the process is described on basis of ANNEX II TECHNICAL DOCUMENTATION of the IVDR.

**Step 1:** The applicable requirements of the IVDR are identified, where appropriate marked as gap and the gap is described.

| Title | Applicable | Gap(s) | Gap(s) description | Task(s) | Ressources | Responsible | Start | End | Status | Implementation [%] | Verification |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ▼ IVDR 2017-746 Annex II Gap-Analysis Tool | ⊟ | ⊟ | | | | | | | | | |
| ▼ 1. Device description and specification, including variants and accessories | ☑ | ⊟ | | | | | | | | | |
| ▼ 1.1. Device description and specification | ⊟ | ⊟ | | | | | | | | | |
| (a) product or trade name and a general description of the device including its intended purpose and intended users | ☑ | ☑ | Missing: Information on intended users | | | | | | | | |
| (b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability | ☑ | ☐ | | | | | | | | | |
| ▼ (c) the intended purpose of the device which may include information on: | ☑ | ⊟ | | | | | | | | | |
| (i) what is to be detected and/or measured | ☑ | ☐ | | | | | | | | | |
| (ii) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic | ☑ | ☐ | | | | | | | | | |
| (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate | ☑ | ☐ | | | | | | | | | |
| (iv) whether it is automated or not | ☑ | ☐ | | | | | | | | | |
| (v) whether it is qualitative, semi-quantitative or quantitative | ☑ | ☐ | | | | | | | | | |
| (vi) the type of specimen(s) required | ☑ | ☐ | | | | | | | | | |
| (vii) where applicable, the testing population | ☑ | ☐ | | | | | | | | | |
| (viii) the intended user | ☑ | ☑ | Missing: Information on intended users | | | | | | | | |
| (ix) in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s) | ☑ | ☐ | | | | | | | | | |
| (d) the description of the principle of the assay method or the principles of operation of the instrument; | ☑ | ☐ | | | | | | | | | |
| (e) the rationale for the qualification of the product as a device; | ☑ | ☐ | | | | | | | | | |
| (f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII; | ☑ | ☐ | | | | | | | | | |
| (g) the description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers; | ☑ | ☐ | | | | | | | | | |
| ▼ and where applicable: | ☑ | ☐ | | | | | | | | | |
| (h) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use; | ☑ | ☐ | | | | | | | | | |
| (i) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays; | ☐ | ☐ | | | | | | | | | |
| (j) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation; | ☐ | ☐ | | | | | | | | | |
| (k) a description of any software to be used with the device; | ☐ | ☐ | | | | | | | | | |
| (l) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market; | ☑ | ☐ | | | | | | | | | |
| (m) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device. | ☑ | ☐ | | | | | | | | | |
| ▼ 1.2. Reference to previous and similar generations of the device | ☑ | ☑ | | | | | | | | | |
| (a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; | ☑ | ☑ | Update: Overview of the previous generations | | | | | | | | |
| (b) an overview of identified similar devices available on the Union or international markets, where such devices exist. | ☑ | ☑ | Missing: Overview of identified similar devices available on the Union or international markets | | | | | | | | |

**Step 2:** In the second step the identified gaps are selected and the specific tasks including all relevant information are defined.

| Title | Applicable | Gap(s) | Gap(s) description | Task(s) | Ressources | Responsible | Start | End | Status | Implementation [%] | Verification |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ▼ IVDR 2017-746 Annex II Gap-Analysis Tool | ☐ | ☐ | | | | | | | | | |
| ▼ 1. Device description and specification, including variants and accessories | ☐ | ☐ | | | | | | | | | |
| ▼ 1.1. Device description and specification | ☐ | ☐ | | | | | | | | | |
| ▷ (a) product or trade name and a general description of the device including its intended purpose and intended users | ☑ | ☑ | Missing: Information on intended users | Describe intended users | R&D | DT | 12.11.2018 | 23.11.18 | Revision | 30 % | |
| ▼ (c) the intended purpose of the device which may include information on: | ☑ | ☐ | | | | | | | | | |
| ▷ (viii) the intended user | ☑ | ☑ | Missing: Information on intended users | Describe intended users | R&D | DT | 12.11.2018 | 23.11.18 | Revision | 30 % | |
| ▼ 1.2. Reference to previous and similar generations of the device | ☑ | ☑ | | | | | | | | | |
| ▷ (a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; | ☑ | ☑ | Update: Overview of the previous generations | Update list of prvious product generations | Product Management | PM | 03.12.2018 | 14.12.18 | Revision | 10 % | |
| ▷ (b) an overview of identified similar devices available on the Union or international markets, where such devices exist. | ☑ | ☑ | Missing: Overview of identified similar devices available on the Union or international markets | Compile list of similar devices on the market | Product Management | PM | 03.12.2018 | 25.01.19 | Revision | 10 % | |

**Step 3:** Activities are implemented, and the outcome is verified for each gap in order to confirm, that the gap has been filled according to the requirements.

| Title | Applicable | Gap(s) | Gap(s) description | Task(s) | Ressources | Responsible | Start | End | Status | Implementation [%] | Verification |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ▼ IVDR 2017-746 Annex II Gap-Analysis Tool | ☐ | ☐ | | | | | | | | | |
| ▼ 1. Device description and specification, including variants and accessories | ☐ | ☐ | | | | | | | | | |
| ▼ 1.1. Device description and specification | ☐ | ☐ | | | | | | | | | |
| ▷ (a) product or trade name and a general description of the device including its intended purpose and intended users | ☑ | ☑ | Missing: Information on intended users | Describe intended users in product description | R&D | DT | 12.11.2018 | 23.11.18 | OK | 100 % | Intended users are described in product description |
| ▼ (c) the intended purpose of the device which may include information on: | ☑ | ☐ | | | | | | | | | |
| ▷ (viii) the intended user | ☑ | ☑ | Missing: Information on intended users | Describe intended users in product description | R&D | DT | 12.11.2018 | 23.11.18 | OK | 100 % | Intended users are described in product description |
| ▼ 1.2. Reference to previous and similar generations of the device | ☑ | ☑ | | | | | | | | | |
| ▷ (a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; | ☑ | ☑ | Update: Overview of the previous generations | Update list of prvious product generations | Product Management | PM | 03.12.2018 | 14.12.18 | Approval | 80 % | |
| ▷ (b) an overview of identified similar devices available on the Union or international markets, where such devices exist. | ☑ | ☑ | Missing: Overview of identified similar devices available on the Union or international markets | Compile list of similar devices on the market | Product Management | PM | 03.12.2018 | 25.01.19 | Revision | 50 % | |

## Some practical recommendations and remarks

- Allocate gaps to QMS, product and other factors (Sales, Marketing etc.)
- Focus on the differences
- Consider the quality of the existing data rather than quantity

## ANTERIS MEDICAL

If you need any advice or assistance for your IVDR transition project, please do not hesitate to reach us at info@anteris-medical.com.
We are very happy to provide you with our templates, a first opinion quickly and **free of charge** and to help you with your specific project challenge.