In Vitro Diagnostics Regulation (IVDR) - Readiness Survey Report

MARCH 2021

EFFECTUM MEDICAL

YOUR START-UP TO MARKET

Contents

Introduction

On April 5, 2017, the European Commission adopted two new regulations, one relates to medical devices and commonly referred to as the MDR which was to come into effect in May 2020 and one related to in-vitro diagnostic products and commonly referred to as the IVDR which is planned to go into effect on May 26, 2022. The date of application of the MDR was postponed until May 26, 2021 to “take pressure off national authorities, notified bodies, manufacturers and other actors”. Now the medical device industry is close to finalizing the implementation of the MDR and is expected to be ready on the MDR going into effect on 26 May 2021, with some companies having benefitted from the “last minute decision” on extending the transition phase. For the IVDR, no postponement of the date of application is expected and thus, are all IVDR companies prepared and ready, until May 26, 2022? Fourteen months might seem like a long lead time, but for those who have not yet started with the preparational activities and a remediation process, it could be rather tight.

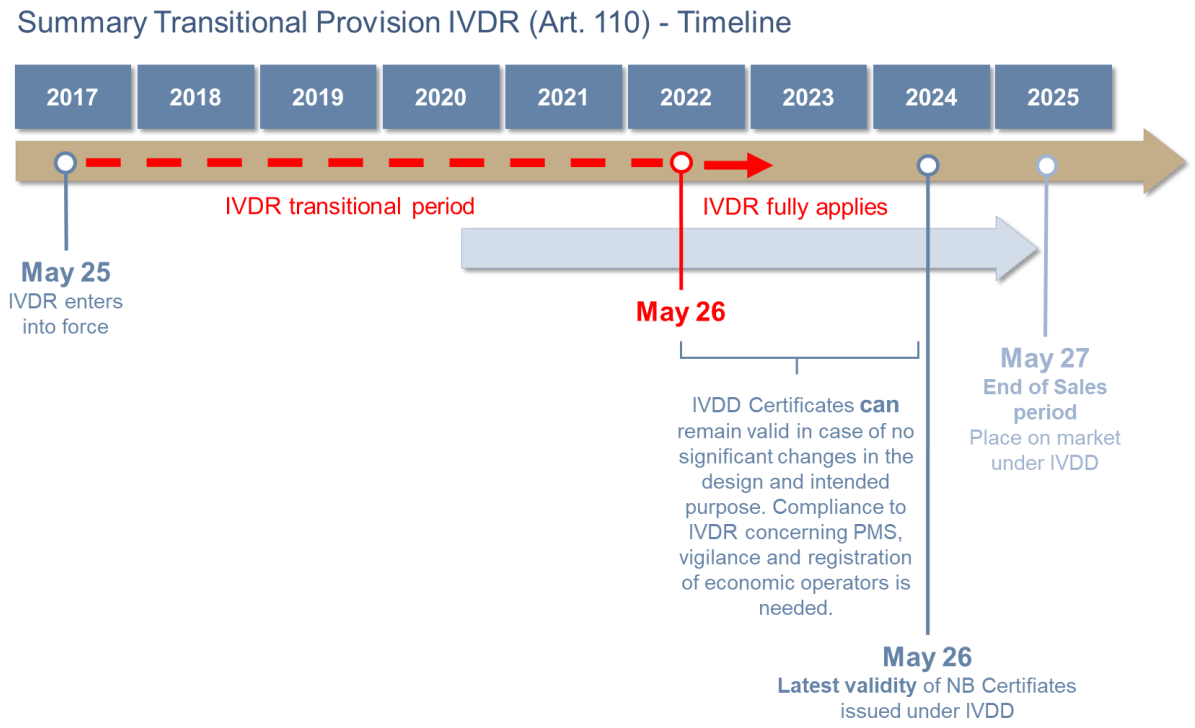
In our report, the biggest changes and requirements of the IVDR are summarized. Additionally, we present the results of our market survey “IVDR readiness” which was conducted at the end of 2020 together with our partner Expand Healthcare Consulting. The aim was to obtain a market intelligence on companies with regards to IVDR implementation and to understand the threats and challenges they are facing. Apart from the status quo, our report provides suggestions of how IVDR challenges can be solved so that diagnostics companies can continue to market their products successfully and without interruption.

Transition timelines

The deadline is approaching, and the transitional period is getting tighter, transitional provisions allow different options

With the inception of IVDR coming into effect on May 26, 2022, diagnostic medical devices will have to be compliant with IVDR before being placed on the market. Nevertheless, there are transitional provisions, e.g. certificates issued by notified bodies in accordance with IVDD prior to May 25, 2017 becoming void at the latest on May 27, 2024 (IVDR article 110, section 1 and 3). Also, diagnostic medical devices that are placed on the market prior to May 26, 2022 with a valid IVDD certificate may be sold until May 26, 2025.

These transitional timelines allow diagnostics companies to consider whether it is worthwhile updating their current IVDD Certificate, which prolongs the possible sales for three years (until May 26, 2025), or to become IVDR compliant before May 26, 2022 and to then have freedom to operate.

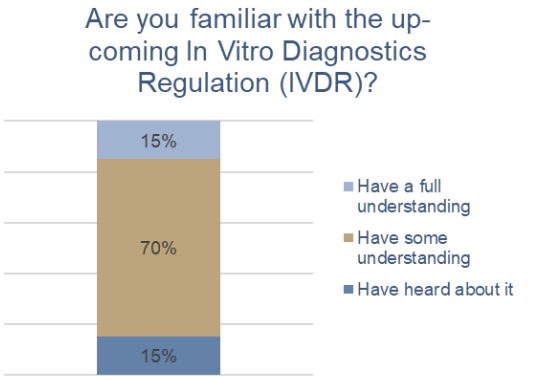


Understanding of the IVDR

Only a minority of companies currently has a full understanding of IVDR

In our survey we asked companies how familiar they feel with the upcoming IVDR. It seems that all are aware of the upcoming IVDR, but the level of understanding varies. Only 15% confirm that they have a full understanding and the majority claims to have some understanding of the IVDR. There might be a difference in the level of understanding between multinationals, which seem to have detailed knowledge, and smaller market players which may struggle more to respond to the constraints of the new requirements.

Most respondents, 70%, are aware of the major changes such as the need of a Notified Body (NB) for most products and the appointment of a Person Responsible for Regulatory Compliance (PRRC). Our survey reveals that companies are not doing enough due to lack of information or a lack of understanding. To be compliant, actions which will impact the whole organisation need to be taken (see key changes).



Source:
Online survey Expand & Effectum, Sep-Nov 2020

Key changes:

- Reclassification of devices.
- Increased requirements for quality management system.
- Clear documentation of product development process.
- Enhanced clinical evidence.
- Premarket approval approach for self- and near patient testing.
- Assignment of Person Responsible for Regulatory Compliance (PRRC).
- Enhanced requirements for Post Market Surveillance.
- Expanded need of Notified Bodies.
- Implementation of UDI.
- No grandfathering provisions.

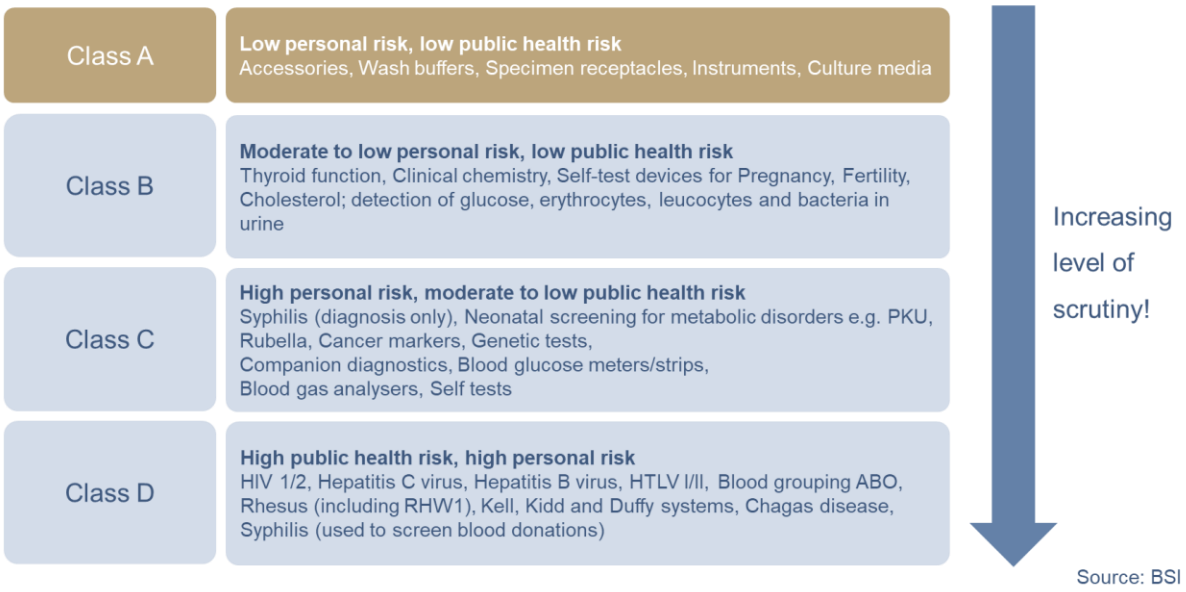
Risk based re-classification

70% of respondents are aware of the new classes and the consequences thereof

As one of the goals of IVDR is to increase patients' safety and create transparency along the entire process, the implementation requires more documentation from all angles – scientific, analytical, and clinical.

It all starts with the re-classification of devices. The new IVDR foresees four different product classes, ranging from A (=low risk) to D (=high risk). Manufacturers need to review their product portfolio and perform a risk assessment to define the adequate class according to IVDR. The analysis covers two dimensions: personal risk and public health risk. The adequate classification is crucial as it defines among other things, the requirements for the quality management system and whether a NB is needed or not. It is expected that under IVDR, 80% of all diagnostics products will be class B or higher, thereby requiring a NB.

Classification of IVD according to IVDR



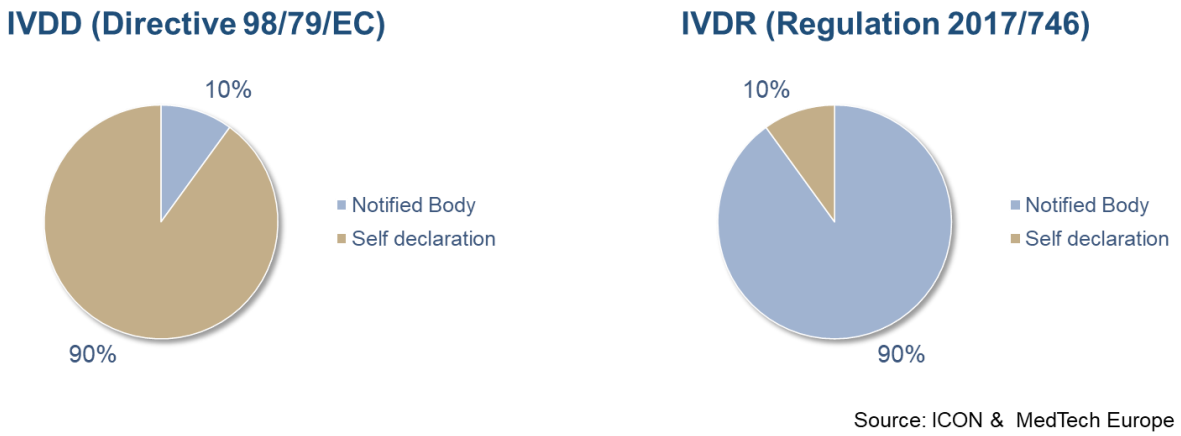
Source: BSI

Expected Shortage of Notified Bodies

Bottlenecks diagnostic device companies are likely to face

Based on the new classification system, products in classes B-D need to be reviewed by a NB designated by the European Commission which will use the formal conformity assessment process. This means that as of May 2022, approx. 50'000 IVD products currently on the market will require NB conformity assessments. In case all these products were to remain on the market, the NBs would need to certify approx. 330 devices per week to meet the 2022 deadline.

IVDR dramatically increases the need for a Notified Body



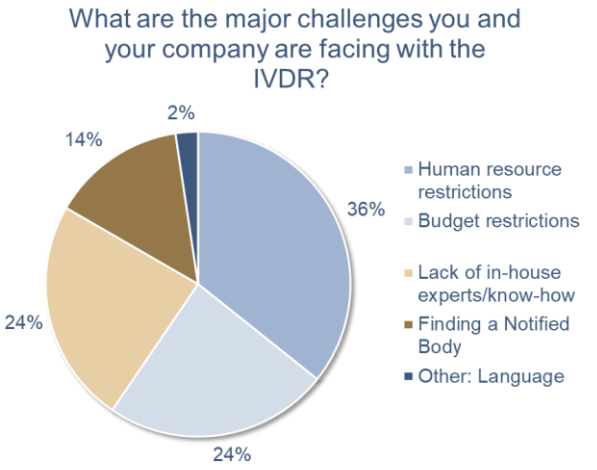
Source: ICON & MedTech Europe

At the beginning of January 2021, four EU Notified Bodies were designated under the EU IVDR (2017/746) and seven others have applied and are waiting for IVDR designation. Currently it is unclear how many others will seek IVDR designation. According to MedTech Europe, 11 NBs under IVDR have sent completed applications to the European Commission, and of those, only 6 have had on-site inspections. Under the former IVDD, 21 NBs were active in Europe. Thus, it is obvious that there will be a shortage as the scope of work is increasing:

the **number of devices** will be **4 times higher than before** and at best, **50% of the previous NB** will have been **designated to perform IVDR conformity** assessments.

Is there a gap between real market situation and stakeholder perception?

It seems that the existing bottleneck has not yet been recognized by most industry stakeholders. According to our market survey only 14% evaluated the NB as a challenge, whereas the majority prioritize internal objections e.g. budget or human resources.



Source:Online survey Expand & Effectum, Sep-Nov 2020

The need for Notified Body in figures:

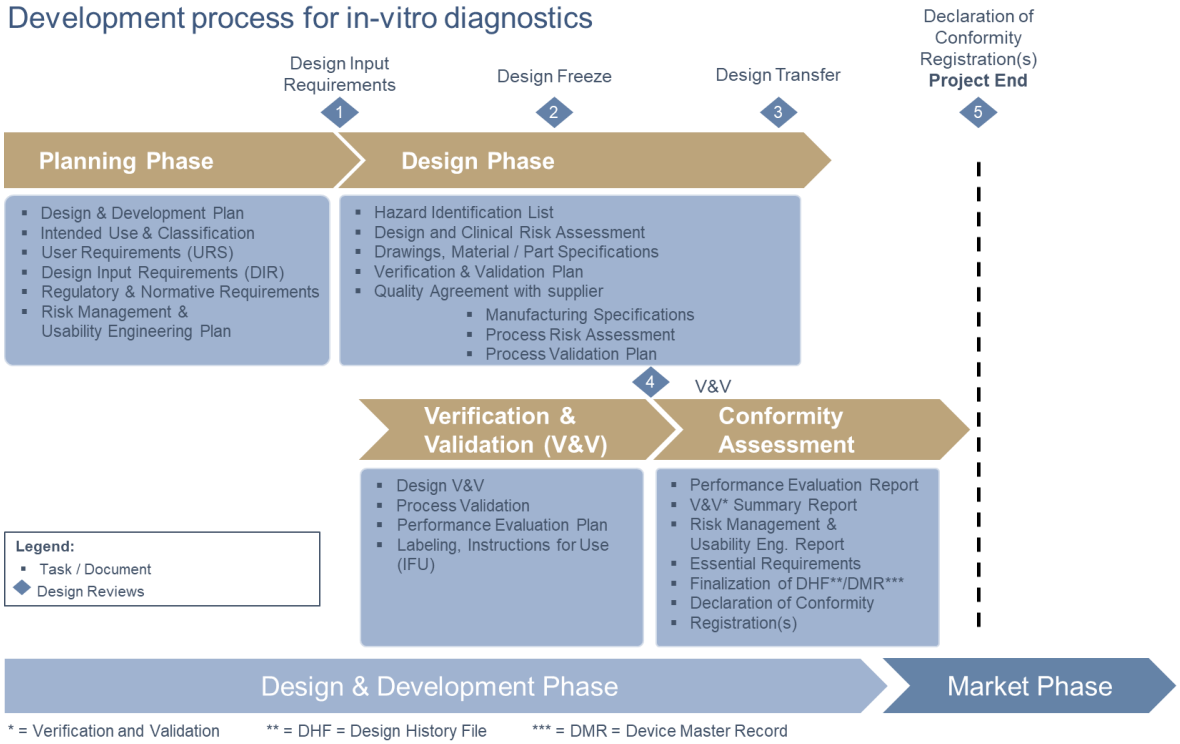
- Approx. 50'000 IVDs will need a NB conformity assessment under IVDR before May 26, 2022.
- Approx. 330 devices per week need to be certified.
- Under IVDD, 21 NBs were active.
- Under IVDR only 11 NB's have applied to be designated
- To avoid disruption, certification needs to be sought in early 2021.

Quality system & technical documentation

Companies do not yet feel well prepared to face the increased regulatory requirements

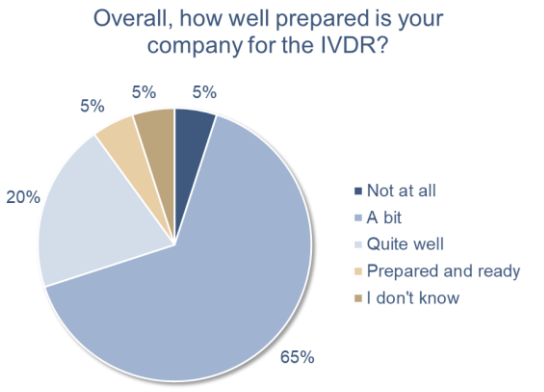
Based on the re-classification of products, manufacturers know if they have to fulfil the minimum requirements of a quality manual (class A products) or if they need a full quality management system (class B-D). In all cases, a thorough review and adaptation of processes is necessary to ensure compliance. The assessment needs to include the core process of product development, the supportive activities (e.g. labelling) and management processes (e.g. post market surveillance).

Furthermore, all technical documentation needs a remediation process. It is not sufficient any longer to prove compliance with the new regulation based on former clinical market data. “Grandfathering” is not allowed and a verification and validation process to fulfil conformity of the device under IVDR is required.



Companies have to take on multiple tasks in various dimensions to fulfil the goals of IVDR: increasing patient safety, creating transparency of industry stakeholders, providing evidence of performance based on scientific, clinical and analytical data. Considering the scope of work and the new prerequisites arising with IVDR, it seems understandable that most of the respondents see budget and human resources constraints thus expressing their sentiment of being only “a bit prepared”.

Our research reveals a discrepancy between global players and other companies. The need of expertise and additional resources seem to be higher in SME’s and start-ups and these companies also tend to feel less prepared compared to multinationals.



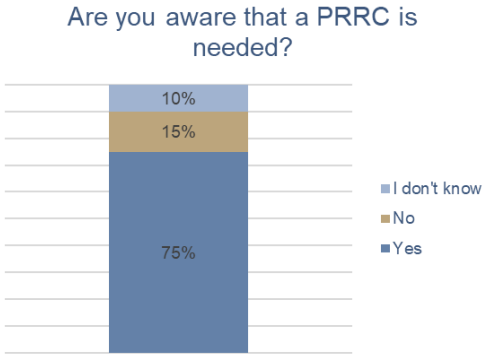
Source:Online survey Expand & Effectum, Sep-Nov 2020

New role: Person Responsible for Regulatory Compliance

Profile is known but human resource restrictions seem to be a challenge

Along with the extended scope of tasks, every company needs to assign a Person Responsible for Regulatory Compliance (PRRC). This person needs to ensure that all necessary tasks and documentation are appropriately fulfilled before a device is released. Furthermore, he/she needs to ensure compliance with all post market surveillance obligations, for which complexity have slightly increased and reporting timelines have been shortened.

These requirements and person's role are well described, and it seems that most companies are aware of them. However, the human resource restrictions linked to the lack of in-house expertise and know-how underlines the need of a clear roadmap to be ready by May 2022. On one hand companies might not have an internal person who meet the requirements (see "summary of the PRRC role"). On the other it might be hard to find equivalent resources as also the demand for these professional profiles is high in the medical device area.



Source:
Online survey Expand & Effectum, Sep-Nov 2020

Summary of the PRRC Role :

Requirements

- A university degree (or equivalent) in law, medicine, pharmacy, engineering, or another relevant scientific discipline and at least one year of experience in QM or RA relating to medical devices, or
- Four years of experience in QM or RA relating to medical devices.

Responsibilities

- Check the conformity of the devices appropriately, in accordance with the quality management system under which the devices are manufactured before a device is released.
- Ensure that the technical documentation and the EU declaration of conformity are drawn up and kept up to date.
- Comply with the post-market surveillance obligations in accordance with Article 10 (10).
- Fulfil the reporting obligations referred to in Articles 87 to 91.
- In the case of investigational devices, issue the statement referred to in Section 4.1 of Chapter II of Annex XV.

IVDR implications for diagnostics companies

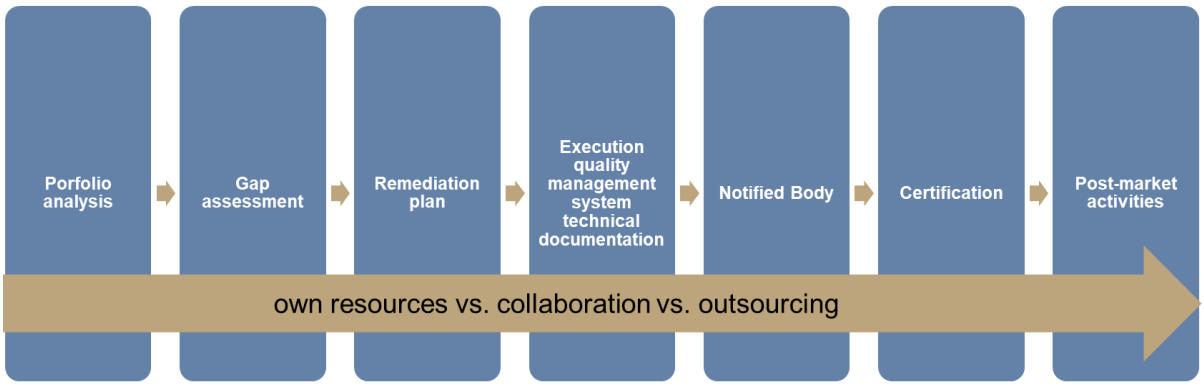
Cross-functional teams - sound understanding of QM/RA requirements, experienced in project execution

A portfolio analysis as well as a gap assessment of current QM system and technical documentation might be a good starting point to address the requirements of the IVDR. It could be a good opportunity to assess the current portfolio and to reflect on aspects like profitability, marketability, and patient needs. Furthermore, the decision matrix should also include the amount of work required to update the technical documentation and the feasibility and costs to generate clinical data as proof point for performance evaluation.

Once the products for the remediation program are defined, the kick-off to manage the quality management system and technical documentation can be done. A program manager is recommended to oversee dependencies, to manage constraints and backlogs and to support the operative teams to work effectively and efficiently.

All this workload is on-top of the companies' daily business. Apart from additional resources, a profound knowledge of QM/RA requirements is needed, especially if time and budget are limiting factors.

But companies should also be aware of the post-market activities which will have higher requirements under IVDR. The post-market surveillance (PMS) does not only include the complaint management but also a post market performance follow-up (PMPF) which confirms the safety, performance, and scientific validity of a device throughout the product lifecycle.



How to solve existing constraints

Identify your biggest need and decide on the adequate collaboration options

Large companies might have their own teams and in-house experts to do the assessment and execute the project plans. Smaller companies may benefit from the support of external partners and may opt for different solutions.

Collaborate with external QM/RA consultants for gap assessment and best practice training sessions

The advantage is to do a one-time investment and get your own employees trained quickly and specifically to the business of the company.

Request support for writing the technical documentation

Often the writing of technical documentation is a bottleneck in companies. It might be because the product development pipeline is bigger than the resources available in Regulatory Affairs. Or, considering the current transition from IVDD to IVDR, internal resources are occupied by updating the existing documentation to be compliant and to guarantee continuous sales. In both cases an external partner could help to close existing gaps. The chosen partner could cover only the update of technical files or could have the overall lead of a IVDR remediation program.

Outsource the Quality Management System

This option might be interesting for different use cases.

- The diagnostics products might not be part of the company's core business and the update to the IVDR not recommended considering e.g., a cost-/benefit- evaluation. By using an external QM system which is compliant with the new IVDR, the company can lower its operating expenses.
- Another reason to outsource the quality management system is that the company's employees are absorbed with the remediation processes and no resources are left to certify new innovative products in time. Thus, the use of an external QM system closes the current gap, and the product will be integrated in the company's own QMS, once the processes are ready and the product has proven market success.

Outsource the Legal Manufacturer

This solution is an option for companies who prefer to focus on their core activities, i.e., product, business, and market development rather than investing resources in changes of standards, regulations and ISO certifications. A legal manufacturer supports and maintains the technical file of customer's branded products and is responsible for all product certification and re-registration activities, e.g., validation plan, post market surveillance. Furthermore, the legal manufacturer takes over all liability risks related to the product. A company opting for this set-up, benefits from lower costs for quality assurance, faster product certification, does not need to hire or train a PRRC, will be better positioned regarding the bottleneck of NB's and the product liability risks will be mitigated. The customer can purely focus on core competencies.

A strong partnership with a comprehensive offering for IVD companies

Proven MDR success model can be transferred to IVDR and supported with IVD business expertise

Effectum Medical is a young company which is breaking new ground in the areas of quality management and regulatory affairs in the medical device and in-vitro diagnostics industry.

The vision of the founding team is to facilitate and accelerate medical device product innovation by offering an affordable, outsourced quality management system (QMS) and legal manufacturing. Their team combines hands-on MedTech business and management experience with in-depth knowledge of regulatory affairs and quality management. The customers range from start-ups to global healthcare companies.

Independent of which service companies choose (outsourced quality management, regulatory affairs and project management, legal manufacturing) they can concentrate on bringing their own technology and business forward by outsourcing tasks which do not belong to their core competence. A novel approach to accelerate innovation for MedTech and IVD-companies

Expand Healthcare Consulting provides expert business support to the In-Vitro Diagnostics industry through a network of seasoned professionals with insights, skills, and expertise where and when you need it most. Headquartered in Canton Zug, Switzerland, Expand's network spans the world with an office in the USA, and partners in China, France, Sweden, Switzerland, India, Korea, and Japan.

With a particular focus on patient centric and point of care solutions, Expand is dedicated to providing insightful advice and support for strategic business decisions. Whether assisting a new start-up with first concepts for a novel IVD or working for an existing successful global company, the team can address issues at all stages of the business:

- Product Development
- Market & product requirement specifications
- Requirement specifications
- New market analysis & penetration
- Partnerships & alliances guidance
- Distributor network growth
- Long-range strategic planning
- Finding business and distribution partners
- Commercial set-up

The team has undertaken many successful projects around the world.

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Sources:

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