CHAPTER 1

WELCOME

Welcome to this practical guide to implementing the EU IVDR.

This guidebook is all about the brand new European regulation and how to apply the requirements into your business. This is part of the Meddev Solutions Guidebook Series, which provides practical tools and guidance for In Vitro Diagnostic Device manufacturers and anyone else with a need to understand exactly how to implement the IVDR.

This book is a reference guide, and as such, is not designed to be read from cover to cover. It is broken into sections that can be quickly navigated through, giving reference to the original IVDR text, and what requirements must be met. However, it does not replace the IVDR text, which should be used in conjunction with this guidebook.

We hope you find this guidebook extremely useful and we will be updating the book as things move forward and new versions of the regulation or additions are made.

Please note, the official IVDR text is the law and this guidebook should not be used to replace or modify the intention of the law.

From the Meddev Solutions team

CHAPTER 2

BACKGROUND TO THE IVDR

Many people reading this guidebook will be aware of how and why we have a new regulation for In Vitro Diagnostic Devices coming to Europe. If you are not aware here is a brief history to bring you up to speed.

Due to public outcry over medical device scandals such as metal on metal hip implants and the infamous PIP breast implant incident, European regulators have recognised the shortcomings of the directives in protecting users and created a more expansive, stricter regulation for both medical and In Vitro Diagnostic devices.

Also considering the advancing technology of diagnostics, the ability of member states to interpret directives at a local level and the inadequate device traceability within the supply chain, the existing directives required review.

The legislative process for this review involved three parties, the European Commission, the European Parliament and the European Council.

In September 2012 the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic devices to replace the IVDD. The proposal states 'The existing regulatory framework for In Vitro Diagnostic Devices has demonstrated its merits but has also come under criticism in recent years. This revision aims to overcome these flaws and divergences and to further strengthen patient safety. A robust, transparent and sustainable regulatory framework for In Vitro Diagnostic Devices that is 'fit for purpose' should be put inplace. This framework should be supportive of innovation and the competitiveness of the In Vitro Diagnostic Device industry and should allow rapid and cost-efficient market access for innovative IVDs to the benefit of patients and healthcare professionals.'

In June 2016, the new proposed regulation on In Vitro Diagnostics was agreed at political level as the result of a "Trilogue" negotiation between the three European parties. The European Regulation 2017/746 on In-Vitro Diagnostic Devices was formally published in the Official Journal of the European Union on 5th May 2017, which started a transition period of 5 years to full application of the IVDR by the 26th of May 2022.

The legislation, now being in the form of a Regulation rather than a Directive, means it is directly applicable to a member state, without requiring transposition through specific national legislation (and subsequent inconsistencies).