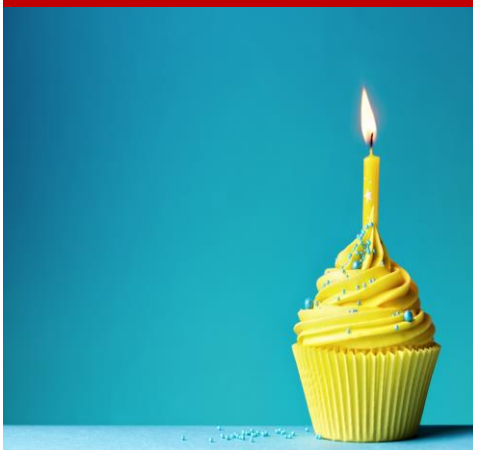
IVDEOLOGY NEWSLETTER

Issue 1 – Q1 2021

GROWTH IN DIFFICULT TIMES

IVDeology is coming up to its 3rd year anniversary and we have come a long way from Stuart and Nancy working out of their home offices (however there is an unwelcome return to the home office due to the COVID-19 lockdown).

We have made significant investment in bringing in experienced, friendly people to join our organization to continue to support our customers.



Happy 3rd Birthday to us!

2021 – A FRESH CHALLENGE!

We wish all our customers a wonderful new year as we venture into a new era of UK regulation.

COVID-19 PUTS IN-VITRO DIAGNOSTIC DEVICES ON THE MAP

Last year the IVDeology team helped many IVD companies support the national initiative to develop and place on the market IVD products associated with SARS-CoV 2. This ranged from developing Research Use Only tests, CE marking of lab-based testing platforms and reagents and collection kits. The process utilized standard CE marking under the IVD Directive (98/79/EC) and the MHRA Derogation process.

"Covid-19 offered a significant challenge to the IVD industry that allowed enhanced flexibility and collaboration"

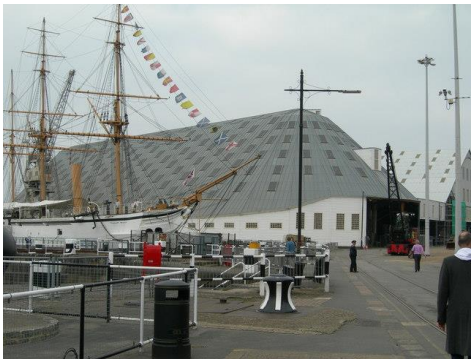
UK ENTERS A NEW ERA AS A STANDALONE REGULATOR

As of the 1st January 2021 the UK has left the European Union. It has been a tricky 4 years while the UK government and EU separate themselves, the result of this came at a very late stage where a 'deal' was agreed on Christmas eve last year.

For the UK IVD market, IVD devices will need to comply with the new UKCA mark from 2023, in the meantime, CE marking under the current IVD Directive is still valid. This will result in a divergence from EU which will be gearing up to the IVD Regulation (2017/746/EU) in May 2022.

Manufacturers who are not based in the UK, need to appoint a UK Responsible Person which is broadly equivalent to the EU Authorised Representative. Appointment of the UKRP should be made as soon as possible. New devices need to be registered within the MHRA Device Registration portal from the 1st January 2021 although a grace period has been given for this.

IVDeology is now offering a UKRP service to support this process.



IVDeology HQ is situated at [The Historic Dockyard Chatham - Your Big Day Out in Kent (thedockyard.co.uk)]

IVD KEY DATES

01 Jan 2021 – UK leaves EU

26 May 2022 – IVDR comes into force

30 June 2023 – CE mark no longer recognized in the UK

Contact Us

IVDeology Group
22-23 The Joiners Shop
Historic Dockyard
Chatham
info@ivdeology.co.uk
www.ivdeology.co.uk

EUROPEAN IVD REGULATION IS ON THE HORIZON

With less the 16 months until the EU IVD Regulation comes fully into force, most IVD manufactures who place product onto the EU market should now be transitioning their IVDs to meet the new regulation. EU Notified Bodies designated to the IVDR are still light on the ground although more are expected in the coming months.

Points to consider for IVDR transition

- Technical file remediation
- Performance data reviews
- Quality Management System update
- Economic Operator responsibilities

"The new IVDR is not just a hurdle to jump over, it is jumping over a hurdle onto a higher platform"

It is critically important that Manufacturers, Importers and Distributors review their involvement in the IVD supply chain to understand their responsibilities. It may have changed due to the new regulation.

QUESTIONS? QUESTIONS? QUESTIONS?

During this difficult and continuously evolving period for the IVD industry, if you have any questions or need some quality or regulatory support, IVDeology can offer consultancy and training to give you a better understanding of the new requirements.

Find us on