White Paper

Unannounced Audits Are Here

Are You and Your Suppliers Ready?

Authors:

Lynn Stephenson, PhD, Diagnostics Manufacturing Marketing Manager, MilliporeSigma

Brigitte Mangiarotti, EMEA Quality Services Manager, MilliporeSigma

Eric Reyes, Customer Insight Manager, MilliporeSigma

In May 2017, the **European Union's In Vitro Device Regulation (IVDR 2017/746)** went into effect, replacing the In Vitro Diagnostic Device Directive (IVDD). The new regulation is more comprehensive than the IVDD and was introduced to reduce inconsistencies in the way directives were interpreted by member countries. This new regulation introduces risk-based classification rules for *in vitro* diagnostic (IVD) devices and strengthens the role of notified bodies (NBs) in their oversight of the supply chain, including unannounced audits of critical suppliers and subcontractors. NBs are organizations designated by EU member states to conduct conformity assessments against the specific requirements of a directive or regulation.

Under the new regulation, **manufacturers are subject to random unannounced audits** at least once every five years, a change from every three years under the IVDD. These audits may also include a manufacturer's supplier if that supplier is considered crucial for the manufacturing of the IVD devices. The risk-based classification introduced under the new regulation also increases the scope of devices that require NB involvement and are thus subject to unannounced audits. Under the directive, approximately 20% of devices required NB conformity assessments, whereas under the new regulation, devices classified as Class B-D, approximately 80% of devices currently on market, will require NB involvement. These regulations apply to all manufacturers that sell devices into the EEA market, regardless of the location of the manufacturing facility. Manufacturers have a five-year transition period to certify their products under the new regulation. After certification under the new regulation, products will then be subject to unannounced audits by NBs.

What Is An Unannounced Audit?

Unannounced audits are simply that — audits occurring without prior notice. These checks are in addition to — not in lieu of — scheduled surveillance audits. Under the new regulations, NBs have a right and duty to conduct unannounced audits. Unannounced audits are designed to ensure that a product is being manufactured in compliance with the quality management system.

Companies selected for audit must provide full access to their manufacturing processes, as well as quality, batch, and purchasing records. IVD manufacturers, and if appropriate, their critical suppliers or subcontractors, must comply.

Why Is This Happening?

The IVDD was passed in 1998 to regulate the free movement of IVD devices within the EEA. By 2010, the identification of several weaknesses within the directive, the development of new technologies, and a need to align with international guidelines led to public consultations to assess a need to update the IVDD. The PIP scandal also highlighted weaknesses in the NBs' system of certification.

In 2010, French breast implant manufacturer Poly Implant Prothèse (PIP) was exposed and fined for using industrial-grade silicon instead of medical-grade in its products. A 2012 UK report found that industrial-grade implants are twice as likely to rupture, causing scar tissue, pain, inflammation, or changes to the shape and feel of the breast. Approximately 300,000 women received PIP implants, and those who suffered leakage received €3,000 — roughly $3,400 — each. European courts ordered both PIP and the German firm that granted the implants' safety certificates to pay the compensation totaling nearly €6 billion.[1]

To increase the safety of IVD devices and prevent future scandals, the European Commission passed recommendations that all IVD and medical device manufacturers must submit to NB-conducted unannounced audits.

The Goal and Challenges

The intent of unannounced audits is to ensure manufacturers continually and consistently comply with all quality management requirements. Arriving without warning gives auditors a more realistic reflection of a company's day-to-day compliance and activities.

However, zero-warning audits have challenges. Key employees might be unavailable or auditors could arrive when products aren't being manufactured. All employees must understand unannounced audits will occur, and they must know how to contact quality management and production personnel at all times. Turning away auditors or any failure to comply jeopardizes a company's certification.

While the new IVDR is not significantly different from the IVDD, it does introduce changes that will be challenges to both IVD manufacturers and the NBs. The amendments implemented in the new regulation will mean that more IVD devices require the involvement of a NB and thus will be subject to mandatory unannounced audits. As products will not be grandfathered into the new regulation, the onus will be on manufacturers to determine which of their products are within the scope of the new regulations.

How Do You Prepare?

To be ready for unannounced audits, manufacturers should develop and implement concrete plans to ensure these events run smoothly. Manufacturers must educate their suppliers and subcontractors that any problems during an audit can pose a risk to compliance certificates. Running mock audits to identify possible weaknesses in compliance and production processes could be helpful.

Most importantly, manufacturers should review and revise existing quality contracts — or create new ones — with their critical raw material suppliers and subcontractors. At minimum, contracts must ensure auditors won't be turned away and will receive full access to the production chain and pertinent records.

Maintaining an open dialogue with your critical supplier will be key to ensuring they have the correct quality policies in place and are prepared for unannounced audits. **Some points to consider are**:

- Have you ensured that suppliers of critical materials used in an IVD or medical device are aware that the product they supply could be subject to an unannounced audit under the new EU regulation?
- Are your crucial suppliers willing and/or able to enter into a Quality Agreement or contract permitting these unannounced audits?
- What quality policies do your suppliers currently have in place that would prepare them for an unannounced audit?
- Are your suppliers able to ensure complete supply chain transparency?

To be most effective however, suppliers and subcontractors must do more than merely open their doors to NB auditors. They must actively take steps to help manufacturers consistently meet regulatory requirements.

How MilliporeSigma Can Help

As a critical raw material and component supplier to the IVD and medical device industries, MilliporeSigma understands the need for supply chain transparency, critical control parameters in manufacturing, and a documented manufacturing process that has stringent quality control procedures. We recognize the importance of these unannounced audits, and we're ready to partner with you and help you prepare. Our teams of over 10,000 quality and supply chain professionals have established best-in-class programs to ensure quality compliance and effective supply chain management.

As part of our Enhanced Quality Program, MilliporeSigma offers multiple quality levels. The highest two levels in this program, Elite and cGMP, are well aligned and have the proper controls needed to comply with the regulatory guidelines for IVD and medical device manufacturing. Products in these groups come with complete supply chain documentation, change control notification and recommended product use information, allowing the manufacturer to feel confident they have mitigated any supply chain risk or disruption. MilliporeSigma works in partnership with our IVD and medical device manufacturing customers to make sure regularly used products are continuously being upgraded to Elite and cGMP for commercial manufacturing use.

For an additional level of security, MilliporeSigma offers quality agreement policies for companies purchasing Elite and cGMP products, which include specific support for unannounced audits. These policies will ensure the manufacturer's compliance within the ever-changing regulatory environment. For more information or to contact us about establishing these agreements, interested manufacturers can visit **SigmaAldrich.com/IVDquality**.

You can count on MilliporeSigma for high quality, fit-for-use products that offer the consistency and documentation necessary for your IVD and medical device manufacturing.

To learn more about unannounced audits and the services and support we offer the IVD and medical device industry, please visit **SigmaAldrich.com/diagnostics**.

Reference

1. BBC News. Last accessed 18-Oct-2017: www.bbc.com/news/world-europe-25831237.

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

SigmaAldrich.com/diagnostics

Lit. No. MS_WP1124EN
2017-08109
11/2017