Press release:

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DiagnosticGrade - New quality seal for reagents ensures performance and compliance of IVD components.

The Johner Institute and myPOLS Biotec GmbH are creating a cooperation and working together on quality-tested reagent products. These products can be applied as component in your IVD in order to contribute to safe and efficient test results. Reagent development and production meet the relevant requirements of the EU In Vitro Diagnostics Regulation (IVDR), which the cooperation partners express with the "Diagnosticgrade" seal.

With the Diagnosticgrade seal, the partners combine product performance and conformity under the specifications of the IVDR: IVD manufacturers obtain reagents developed and produced by myPOLS Biotec under ISO 13485 with an IVDR-compliant analytical performance (AP). The Johner Institute provides tested templates for the AP and confirms with the Diagnosticgrade seal that the reagents meet the relevant requirements. Thus the maturity level for diagnostics is guaranteed.
The special feature of this cooperation: both companies have core competencies in in-vitro diagnostics, but with different focuses. The cooperation combines myPOLS Biotec's experience in the development and production of reagents with the Johner Institute's expertise in the quality and safety of medical devices and IVDs in particular.

Why analytical performance evaluation is so important right now

The IVDR, which will be valid from 26 May 2022, increases the requirements for the development, production and documentation of IVDs. It introduces a new, risk-based classification system. Herewith the IVDs of the vast majority of manufacturers will then count to classes B, C and D. This means that a Notified Body is required for product approval. The implementation of the IVDR requirements must take place in 2021, as they are very comprehensive. Furthermore, additional clinical data may be required additionally, otherwise a timely approval by 26 May 2022 is no longer realistic. A large part of the required documentation consists of analytical performance data and the technical verifications of the product.

All IVD products, especially reagent-based products, require this analytical performance data as part of the performance evaluation. Both new and long-standing IVDs must meet these requirements. For existing IVDs, these data should already exist, but whether they are sufficient according to the state of the art and pass a test by the Notified Body at the first attempt is uncertain. IVD manufacturers are therefore obliged to check the analytical data and, depending on the status, to generate them on the basis of studies in order to meet the regulatory requirements.

The benefits of Diagnosticgrade

This is exactly where the Diagnosticgrade seal comes in. With reagent products that for their part already demonstrably meet the requirements and with a service package that provides the analytical data, manufacturers can concentrate on the remaining tasks and thus ensure the approval of the product under the IVDR in 2022.

Developing a new IVD or adapting and optimising existing IVDs is lengthy and costly. However, in 2020, the priorities for many manufacturers were Covid-19 products. This poses the risk that the necessary preparations for the IVDR could not be started. The survey results of the DIHK on this topic published in November 2020 also show great uncertainty among manufacturers regarding the IVDR. (Manufacturers of in vitro diagnostics fear additional bureaucracy, DIHK survey on the consequences of the EU regulation that will apply from May 2022).
The Johner Institute and myPOLS Biotec are aware of these challenges and therefore offer this unique service at an early stage. At the customer’s request, the partners can also go beyond the range of Diagnosticgrade reagents: To relieve the burden on in-house quality teams and laboratory resources, the partners offer specialized plans for the specific AP of an IVD including all components as well as the performance of the specific AP studies compliant with the IVDR, including full laboratory service.

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