

Report on EU IVD Regulation Seminar

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Place: TKP Ochanomizu Conference Center

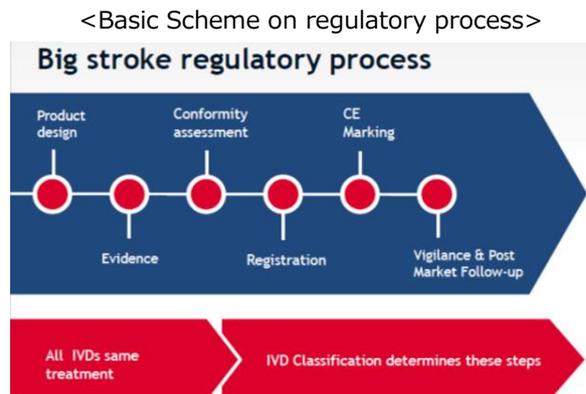
We have organized the seminar for our membership companies about the EU IVD Regulation (IVDR) by Mr. Jesus Rueda Rodriguez, who is the Regulatory Director of EDMA (European Diagnostics Manufacturers Association) and who is working on IVDR which will be issued in 2017.

117 members joined this seminar and it was very successful.

Here you can find the summary of his presentation.

The latest draft of IVDR has around 300 pages and more than 100 items might affect the manufacturers. The two most influential added items are following: "Advertising" and "Authorized Representative Liability".

There is no change on the basic scheme of the regulatory process; however, it will be defined in more detail and detailed rules will be added.



Product Design

The requirements for Product Design will be based on the current directive (IVDD), and mostly it will follow GHTF (Global Harmonization Task Force) requirements. Some new requirements are added which are related to the new technologies that have been developed in these twenty (20) years. For example, Design management for Software Usability, some requirements about Near

Patient testing. In addition, the risk management will be based on the best practice of ISO14971.

Evidence

One of the most important things is that "Evidence" on the performance and safety is required by IVDR to finally declare conformity and to have CE marking.

There are 3 Clinical Evidences; Analytical Performance, Clinical Performance, and Scientific Validity. The way of collecting these evidences and how to organize the clinical testing are also mentioned in IVDR. Of course, EMC (Electromagnetic Compatibility), Chemical Safety, Biological Safety, which is currently regulated, will be also regulated, as well.

Conformity Assessment

The Conformity Assessment of each product will be changed. Classification will be A, B, C and D which is same as GHTF. The highest risk from the view point of patient is "class D", and the lowest risk is "class A". Notified bodies, Reference laboratories will depend on the classification of each product.

Registration

All the Manufacturer and Products will be registered on the new data base called "EUDAMED" which is now under development. The manufacturers will be responsible for the maintenance of the data. Each Manufacturer will have its unique "Single Registration Number "(SRN)" and it will be registered on "EUDAMED". As for the products, each product will have "Unique Device Identification (UDI) " and it will be also registered on "EUDAMED".

CE Marking

CE marking process is unchanged.

Post Market Follow up- Vigilance

Reporting Timeline after Adverse event goes from 30 to 15 days and the reports will be uploaded via EUDAMED.

In addition, Post market performance follow-up (PMPF) needs to be planned and PMFP will need to be audited by notified bodies.

In addition to the regulatory process, the items about “Transparency” will be added. All the information about “Vigilance”, “Summary device performance”, and “Summary of studies” will be disclosed.

“Manufacturers” need to sign up the insurance or reserves to cover liability.

Furthermore, “Authorized Representative” will have to be liable for products placed on the EU market. They will have to keep “Technical File”, and they will have to give it to the regulatory authority in accordance with their request.

Finally, all the transition period to IVDR will be five (5) years (sixty 60 months) from the issued date.

