

CE certification for high-tech medical equipment

Advances in technology ,applications for medical devices that are gradually being expanded.

According to Existing medical has been applied to medical device(device biotechnology, nanotechnology, information technology) the user will be get more medical service.

Predict of direction of development of these technologies in the future seem to suggest the role of the compass for establishing business direction in connection with manufacturing technology development strategy.

According to recent news agencies said, Yale Institute for Nanoscience and Quantum Engineering team developed a small nano-sensor devices take 20 minutes to find the cancer diagnosis from fingertip with a needle stuck into a single drop of blood from the biological marker of prostate cancer and breast cancer (biomarker)

Blood test used in existing cancer diagnostic takes several days . Because blood samples are usually sent to laboratory for centrifuge to remove plasma and then it will be analyzed chemical composition. Nano-sensors are small and portable, so it is possible to test anytime and anywhere.

Thus.representative examples(high-tech medical) which is combined with three sectors upon mentioned are biosensors or biochips are capable of diagnostic medical device

2.Definition and regions of advanced medical devices In US FDA

Certification of advanced medical devices typically take the form of multiple authentication among CE certification.



If sector of biotechnology, pharmaceutical are to be applied as medical device it need to be incidental for using additionally.

The U.S. Food and Drug Administration Traditionally manages to separate high-tech fields as three divisions

A.Pharmaceutical industry

-Produce products by chemical processes

-Administration by CDER (Center for Drug Evaluation and Research)

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B. Biopharmaceutics / Biology

- Products produced by the biotechnological / Biological process
- Administration by CDER (Center for Drug Evaluation and Research)

C. Medical Device

- not including Chemical and biological processes, production by mechanical, electrical and telecommunications fields such as production.
- Classify 1, 2 and 3 class, according to risk
- Administration by CDER (Center for Drug Evaluation and Research)

However, recently medical devices have been developed as three convergence forms and the FDA called "It is Complex medical devices" and used it.

These products, high-tech medical devices are growing fastly in the future.

The below figure shows the area of advanced medical devices and the integration and various requirements. in the way of market access.

3. samples (regulated by CE certification and Combined Products for Advanced Therapy) of combination product are the following.

A Medical device + Medicines

B Medical device + Animals derivatives of not survival

C Medical device + Blood or plasma derivatives

According to Medical devices 93/42/EEC, these regulatory are being applied at the same time as the 2001/83/EEC and 2004/27/EEC if the products contain medicines. For example, if the insulin syringe with charging insulin sales this products are estimated not medical devices but medicines.

It means the syringes just classified medical devices and it could be charged insulin separately. Also used drugs as target to certified medical device have to be evaluated drug safety, quality and usefulness of used medicines, by requirements of MEDDEV 2.1 / 3 rev.2, Sec. B from competent authorities of the European Union (Notified Body)

Products containing medicines are to certify as medical it makes the intended use primarily is consistent as medical devices.

The function of medicine is just a role of assist for medical devices.

The way of products effect could be inferred is by scientific data about function could be verified product name,description and labeling manufacturer made. At this point, used medicines have to be proved it does not act pharmacology, immune function and metabolism in human body

The medical devices containing animals derivatives of not survival have to be managed according to requirement of 2003/32/EC. This is prerequisite about use of animal tissue can cause mad cow disease

Animals are likely to cause mad cow disease for example Cattle, sheep, goats, deer, elk and cat

if use of animal-derived cells is not cause mad cow disease, it is not classified 2003/32/EC directive,it is just improved that it des not affect Pharmacology, immunology and metabolism and it comes from tissues or derivatives of not survival

In EU, animal-derived ingredients can be induced Mad cow disease is evaluated through EDQM certification by other assessment institutes and to obtain cetificates,notify body has to progress the next procedure when the positive estimation comes by Medicines Technology Assessment for Management and Administration officials

In case of medical device containing human blood or plasma derivatives,Notify Body has to request for estimation and scientific view about products quality and safety from EMEA and progress the next stem according to the reasult.

In case of obtain certification, this kinds of blood derivatives have to be submitted the products data each patch and have to obtain assessment certificate for batch and show it to interested parties.

The next box is conformity assessment procedure for CE advanced medical device

4.Conclusion.

the demand for certification will be increased as faster speeds to develop advanced medical devices as well technological development.

Considering export,it is important that how to improve safety of advanced medical device and get certificate promptly in the first step.

To do this,it is also essential to co-operate with Notify Body which has enough experience