

Comparison of us fda and european authorities approach to medical devices essay e...

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The United States Food and Drug Administration US FDA is responsible for protecting the public health (FDA, 20). This is enforced by ensuring that efficacy and safety of all veterinary and human drugs or health apparatus. It is also the responsibility of the FDA to ensure that accurate information and data of science-based information to the public.

The European medicine agency was established to set medicine regulatory bodies on an even playing field. It is similar to the FDA but uses a decentralized style. The FDA uses a centralized system because it limits the states from imposing additional policies to manufacturers. EMA, however, puts in place directives but gives the responsibility to CAs and NBs. This results in poor coordination and minimal supervision. The FDA provides public access to high-risk PS decisions unlike EMA, which is subcutaneous in its approach (Bottomley, 347). A similarity however is both agencies are flexible in determining product-specific actions required and identifying different adverse effects of potential concern. The other difference in FDA and EMA is the approach to monitoring the implementation of actions in risk minimization.

Work Cited

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