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International Harmonization of Regulatory Quality Control and Quality Assurance of Drug

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After approval, the drug should be manufactured and maintained with uniform quality.
To assure the quality of drugs, the drug companies should comply with GMP guidelines and regulatory authorities should assess their compliance.
In this article, I want to review the definition of drugs as well as the quality surveillance system.
To be controlled as drugs, they ought to have their own specifications and test methods. The gold standard is pharmacopoeia. When the drug and drug products are submitted, KFDA review the application whether their specification and test method is valid or not including efficacy and safety. They can adopt specification of pharmacopoeia, or in house spec. I would like to summarize how to make the in house spec and how to show the validation data.
After approval, Drug Company's role is to comply with related regulations to assure the drug's completeness. And regulatory authorities work to keep the compliance in many ways.