

THE QUALITY CONSISTENCY EVALUATION OF INJECTIONS IS ON THE WAY

Within the recent three years, Chinese Government is going all out to solve the problem of the safety and effectiveness of drug, it is called Drug Quality Consistency Evaluation (QCE). Firstly the oral dosage form is put on list; many companies are putting material and financial resources into QCE. However this stage is not completed, the new stage is coming: the Quality Consistency Evaluation of injection. The notice of 54#, 2017 from CFDA reveal the starting of Quality Consistency Evaluation of Injection, it is said the manufacturer of injections need to re-evaluate the safety, effectiveness and quality controllability based on scientificity, and planning to complete the evaluation for marketed injections basically in 5~10 years.

As per the complexity of injections, the intravenous injections and hypodermic injections, Liposomes, microspheres, micro-emulsion and nanoparticles types, it will be a huge challenge for manufacturers of injections. Thus the details and guidelines about how to work on Quality Consistency Evaluation of injection are expected by manufacturers of injections.

Please do not hesitate to contact us:

Email: mike.wang@huapont.cn

Tel: 0086-23-67886928 | Fax: 0086-23-67886927

www.huapont.cn

Notice:

- CFDA: Chinese Food and Drug Administration
- The notice of 54#, 2017: <http://www.sda.gov.cn/WS01/CL0778/172569.html>
- QCE: Quality Consistency Evaluation
- Chongqing Huapont Pharmaceutical Co., Ltd.: A manufacturer of injections, focus on antibiotic and oncology drugs. The products have Rifampicin, methylprednisolone, Calcium levofolinate, Thymopentin, etc.

