



Spot Evaluation of Medical Device Inspection Institute

Qualification Determination

Based on the <The Measures for Medical Device Inspection Institute Qualification Determination>, the inspection institute applicant shall submit the required dossiers to CFDA, the schedule of the spot evaluation would be decided between CFDA and applicant after dossiers are approved.

CFDA will organize the expert panel and notice the panel members, evaluation schedule and related affairs to the applicant, if the applicant has any disagreement with the processing, they should let CFDA know timely. CFDA would determine whether adjust the processing or not and notice the applicant.

The expert panel processes the spot evaluation for technical ability and quality management of the medical device inspection institute applicant in terms of evaluation criterion released by CFDA.

The expert panel reports to CFDA and notify the unqualified items to the applicant in writing. CFDA will give the qualification determination certificate to qualified inspection institute; or ask the unqualified applicant to correct in appointed time, if the applicant failed to correct, CFDA will release the disqualification notice to the applicant.

The medical device inspection institute qualification determination certificate is valid for 5 years from the date of issue. And for the unqualified applicants, they can submit the application again in 6 months.