

Project Case Summary

PAI Audit in China

Client:	<i>Small-size Chinese pharmaceutical company</i>
FDA Reviewing Division:	<i>Oncology</i>
Project Profile:	<i>Active Pharmaceutical Ingredient used for Sterile Product</i>

1. Performed cGMP compliance audits for manufacturer of drug substance
2. Prepared and performed readiness program for Pre-Approval Inspection (PAI) by FDA
 - a. Prepared, reviewed and provided recommendations on adequacy of DMF, Type II
 - b. Assisted and provided guidance in the preparation of Drug Substance Development Report
 - c. Assisted and provided guidance in the development and validation of analytical methods and preparation of validation reports
 - d. Assisted and provided guidance in the development and validation of equipment cleaning validations and preparation of validation report
 - e. Assisted and provided guidance in the preparation of process validation protocols and validation reports
 - f. Assisted and provided guidance in the preparation of key Standard Operating Procedures (SOP)
3. Assisted during FDA's PAI of plant

Outcome:	<i>PAI successfully completed with no objectionable findings. Facility approved for production of drug substance under cGMP regulations.</i>
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