

Project Case Summary
Design of API Manufacturing Facility in China
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Client:	<i>Small Chinese company</i>
FDA Reviewing Division:	<i>NA</i>
Project Profile:	<i>Design and Support of construction of an API Manufacturing Facility</i>

1. Prepared facility layout design of API facility according to good manufacturing practices (GMPs)
 - a. Provided guidance concerning material flow, personnel flow, building surfaces, air classification, and the validation master plan
 - b. Assisted and provided guidance in the design of the infrastructure of API facility
 - c. Assisted and provided guidance in the design piping in the main production building.
 - d. Assisted and provided guidance in the lighting in the main production building.
 - e. Assisted and provided guidance in the waste management he main production building.
 - f. Assisted and provided guidance in the design of water purification system
 - g. Assisted and provided guidance in the design of HEPA air filtration system
 - h. Assisted and provided guidance for the gowning procedures in the main production building.
 - i. Assisted and provided guidance for the Environmental Monitoring procedures in the main production building
2. Provided oversight and guidance during the building of facility
3. Assisted and provided guidance in determining the correct process equipment to be installed in the facility.

Outcome:	<i>Facility approved for production of drug substance under cGMP regulations (2000).</i>
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