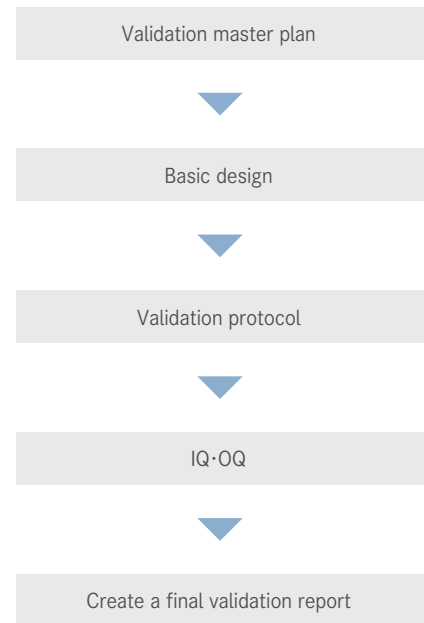


VALIDATION SERVICES

Validation services are provided to meet various standards based on the newest information.

Various validation services relating to a clean room are provided to meet revised standards of GMP, FDA, WHO-GMP, EU-GMP, PIC/S, etc., based on the latest information by utilizing our abundant experiences and worldwide network. In the final report, we will formulate an improvement plan and an air conditioning improvement plan, and conduct construction work accordingly.



| | |
|--|--|
| Basic plan | <ul style="list-style-type: none"> · Formulation of validation master plan, Basic design · Execution system, assignment · Basic policy · Schedule settings |
| Basic design, implementation of the design | <ul style="list-style-type: none"> · Create the validation master plan · Conduct design validation · Support the creation of SOP |
| Installation Qualification <IQ> | <ul style="list-style-type: none"> · Create IQ protocol · Conduct IQ / Conduct calibration · Prepare an IQ Report |
| Operational Qualification <OQ> | <ul style="list-style-type: none"> · Create OQ protocol · Conduct OQ · Prepare an OQ Report |

| Validation items | |
|----------------------|--|
| Examples of IQ items | <ul style="list-style-type: none"> · Equipment structure inspection · Equipment rotation check · Control device calibration · Duct inspection, etc. |
| Examples of OQ items | <ul style="list-style-type: none"> · Air volume measurement · Temperature measurement · Humidity measurement · Differential pressure measurement · Cleanliness measurement · Leakage inspection · Illuminance inspection · Airflow inspection etc. |

