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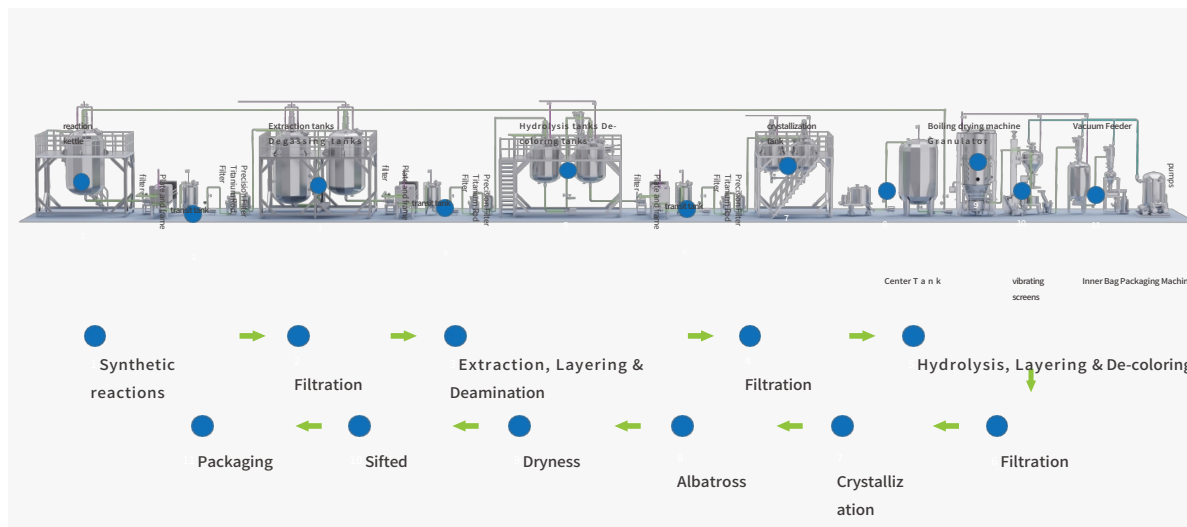
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# API Solution

## API solution

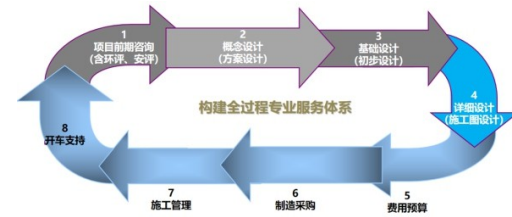
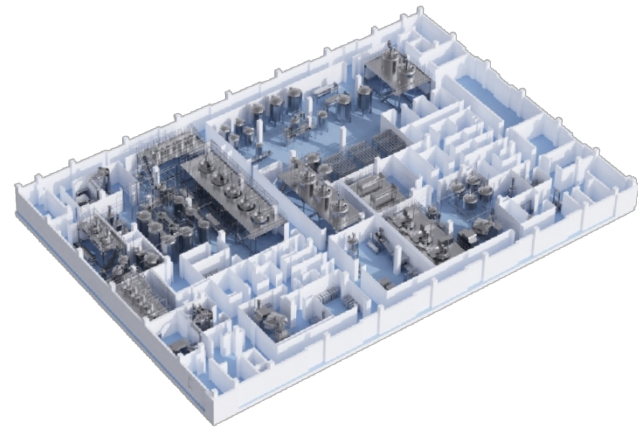
### Production





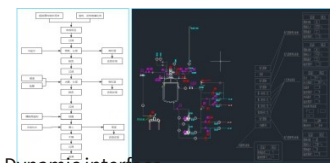
## Introduction of API Business Unit

Yichun Wanshen's API Division is dedicated to process design and implementation services for APIs, 生药, etc. We provide total information solutions for process optimization, process design, implementation, management and validation of work, MES, QMS, and so on. We combine automation, Web, Advanced technologies, such as artificial intelligence and data analytics, help to enhance the production efficiency and quality of API companies, and to realize digital transformation and smart manufacturing.



## Advantages

- High level of integration between self-control and workmanship
- Precise control of working parameters



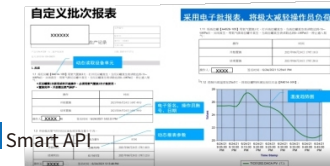
Dynamic interface



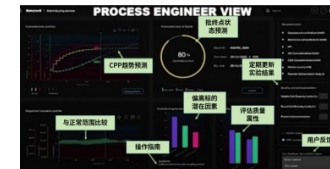
Custom Reports



Data Analysis and Traceability



Smart API



## Business Scope

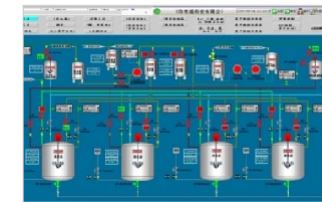
### 1 Automation of APIs

API automation

The automated production system for APIs comprises of technical equipment, DCS/PLC control system, SIS safety instrumentation system, instrumentation and valves, piping, cleaning, etc. We are able to carry out the implementation of each project from deeper design of P&ID drawings, selection, programming, installation, commissioning and validation from the client's point of view.

#### DCS/PLC automatic control system

- Construction design
- Autopilot System Functional
- Design EBR Electronic Batch
- Recording Batch Control
- Quarter Batch Analysis/Critical Work Data
- Contrast Analysis Abnormal and Exceeding Limits
- Data Report
- SIS Safety Instrumented System
- The alarm and interlock part of the control system is mainly used for the alarm action or regulation or shutdown control of the results detected in the control system.



### 2 Raw Material Drug Informatization

We provide services in the areas of manufacturing execution management systems (MES), laboratory information management systems (LIMS), and quality management systems (QMS).

#### Manufacturing Execution System (MES)

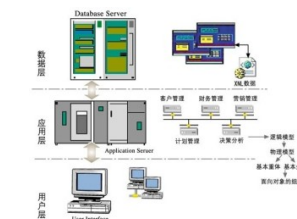
This includes management modules for manufacturing data management, planning and scheduling management, growth scheduling management, inventory management, human resource management, work center/equipment management, tools and equipment management, purchasing management, cost management, project kanban management, growth process control, underlying data integration and analysis, and upper level data integration and disaggregation.

#### Laboratory Information Management System (LIMS)

Including process management, test reports, resource management, data analysis, my machine, material, method and environment, etc., with the laboratory business as the core. The dynamic connection and closed-loop traceability of all management functions, testing processes and resources at the center of the service helps to enhance the overall operational efficiency of the laboratory.

#### Quality Management System (QMS)

This includes quality system management, product design quality management, supply control quality management, production process quality management, after-sales quality management, customer complaint quality management, and quality traceability and analysis management, all of which are intended to assist in the development of an effective quality assurance system.



### 3 Public Work

Utility

Provides systems engineering services for clean area air-conditioning control systems (BMS), clean environment monitoring systems (EMS), combustible/toxic gas detection and alarm systems (GDS), fire monitoring systems (FGS), intelligent weak electrical integration systems, and public utility piping systems.

#### Air conditioning control system (BMS)

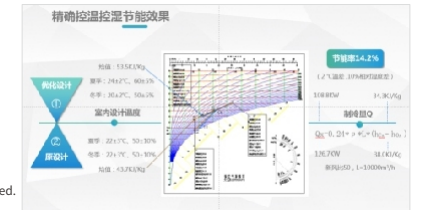
Automatic controls are used to ensure that the environmental state parameters of the air in a given space meet the desired values.

#### Clean Environment Monitoring System (EMS)

The key parameters of the clean area such as dust particles, plankton, temperature, humidity, differential pressure, speed, etc. are analyzed. Acquisition, recording, alarming, data query and traceability are performed.

#### Fire Monitoring System (FGS)

Through the acquisition of detection signals for fire buttons, smoke, fire, combustible and toxic gases at the site of the chemical plant, the software logic outputs control the alarm lights, alarm bells, shower valves, foam valves, and the fresh air conditioning system's new faucets, and so on.

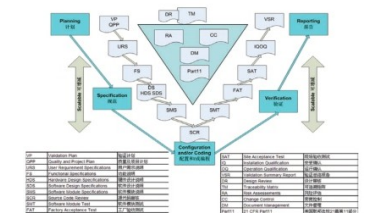


### 4 Computerized system validation

Working closely with equipment manufacturers, system suppliers or customers, we assist our customers to successfully pass GMP validation on schedule according to NMPA, FDA, EMEA, WHO in cGMP, GAMP5, 21CFR Part11 and other regulatory guidelines.

#### Computerized system validation master process

- Step1: Confirm computerized system category
- Step2: Initial risk assessment to determine system impacts and determine GxP critical systems
- Step3: Supplier Assessment to Determine Balance of Power and Engagement
- Step4: Hardware and software categorization assessment to determine complexity and novelty
- Step5: Develop an appropriate V-Model that takes into account the supplier's strength, complexity and novelty of the system, and the impact of GxP
- Step6: Perform validation in accordance with the established VModel.



Item	Item Name	Item Description	Item Status	Item Date	Item Version
1	Validation Plan	Validation Plan	Approved	2023-10-27	1.0
2	Validation Protocol	Validation Protocol	Approved	2023-10-27	1.0
3	Validation Report	Validation Report	Approved	2023-10-27	1.0
4	Validation Summary	Validation Summary	Approved	2023-10-27	1.0
5	Validation Certificate	Validation Certificate	Approved	2023-10-27	1.0