CONFIDENTIAL CLIENT

CHINA

2 YEARS | $895,000

GREENFIELD PRODUCT PORTFOLIO TRANSFER & PROCESS VALIDATION

- Commissioning & Qualification
- Building Commissioning
- Asset Management & Reliability
- Quality, Compliance, & Regulatory
- Human Performance
- **Process & Manufacturing Technology**
- Program & Project Management
- Automation & Information Technology
- The Chemistry of Full-Scale Operations™
- Data Centers

WHEN YOU NEED TO MEET A HIGHER STANDARD™

PROJECT OVERVIEW

This client has an existing plant in China which was established more than 30 years ago. It is the 1st joint venture pharmaceutical plant in China. Now, the client has built a new facility with 266,666m2 of land property and about 40,000m2 of construction area in a high-tech zone. The existing plant will be closed after products are transferred to this new site.

CAI's scope was to support technical transfer/validation documents generation related with 11 OSD products (Tablets, Capsules, Powder), 8 NSD products (Cream, Suppository, Lotions) and more than 33 packaging products. Document preparation includes PPQ master plans, Technical Assessment, Criticality Analysis, Characterization Protocols and reports, Process Performance Qualification protocols and reports, Cleaning Validation Protocols and Reports, Packaging line validation protocols and reports, Master Batch Records, etc. All documents must comply with CFDA's regulations and client's guidelines/procedures.

CHALLENGES

- Authority License schedule versus Inventory: In order to switch the products to the new plant, the client needed to get a manufacturing license, GMP licenses application, and product licenses in sequence according to Chinese regulatory requirement. Each milestone could affect the forecast of the inventory establishing, shutdown schedule, staff plan, etc.
- Client adapted new guideline/procedure/template combined with the product transfer opportunity.
- New type and/or size of equipment was introduced on new site, so process flow may have needed to be adjusted based on trail results. So, the equipment information used for cleaning validation kept getting updating which required extra effort and a need assessment with every change.

SOLUTIONS

- Communicated with the client to understand their requirements for the document quality and the delivery time, allocated proper resources for different tasks, and managed progress and cost as expected to meet client target schedule.
- Prepared cases for each document category for all relevant departments to review. Then the remaining product followed the aligned case to reduce repeat correction. Delivered documents efficiently.

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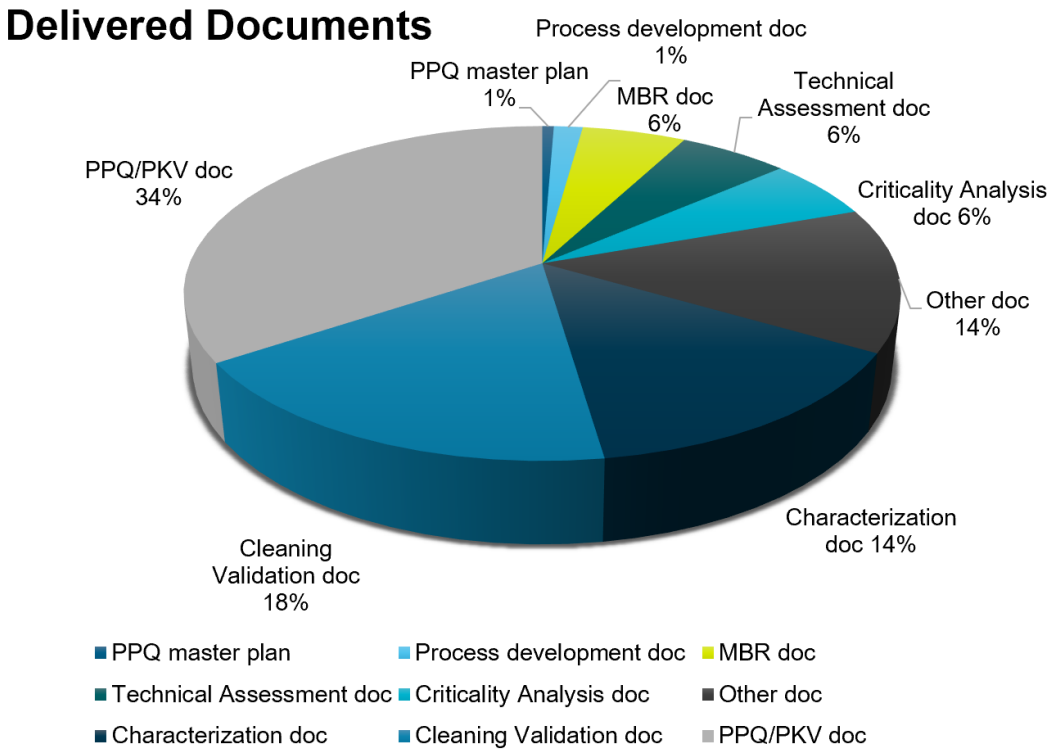
SOLUTIONS CONTINUED

- As a support role, shared knowledge/opinion for cleaning validation.

VALUE DELIVERED

Delivered about 320 documents altogether within the required quality level and timeline. Breakout of these documents is illustrated below.



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