

## **Driving the Pharmaceutical and Biotech Industries towards Excellence in Manufacturing, Supply and Quality**

### **EQUIPMENT SELECTION, PROCUREMENT, INSTALLATION & QUALIFICATION**

NDA consultants have helped pharmaceutical companies select, procure, install and qualify pharmaceutical and biotech manufacturing equipment world-wide.

We have experience in all dosage forms including sterile's and lyophilisation and understand the equipment needs to manufacture and package drug products.

We do this by creating with our clients, a comprehensive user requirement specification (URS). This URS acts as the core for the procurement and qualification process. We identify suitable vendors, and ask them to propose against the URS. Bids are scored against the URS and with the client team we select the most appropriate vendors.

Using experiences gained over many years, we work with the vendors to ensure the equipment is built and tested according to the URS and the purchase contract before it is shipped to the clients chosen manufacturing site.

Following delivery of the equipment at the clients chosen manufacturing site, we work with the client's team to install the equipment, commission and qualify the equipment against the URS.

Based on our experience we can assist you to layout new facilities. We work with your architect to ensure the correct room sizing, spatial needs and material & people flow for your process, We work with mechanical and electrical designers to ensure your facility is built to the standards you and your products require,

We support you in training your production staff, writing SOP's and validating the facility/equipment, including environmental monitoring and smoke test studies to ensure your facility meets the intent.

### **EQUIPMENT CASE STUDY – SELECTION AND PROCUREMENT**

#### **ISSUE:**

A pharmaceutical development organization with a drug loaded device needed to select and procure specialist equipment to manufacture phase III clinical trials materials.

#### **OBJECTIVE:**

Specify and procure suitable manufacturing equipment for Phase III and possible launch.

#### **DELIVERABLE:**

Based on the projected demand for clinical trials materials and possible launch scenarios specialist manufacturing equipment was sized and a User Requirement Specification was written and issued to specialist pre-screened vendors.

The drug loaded device called for very tight control of drug content uniformity. So trials were undertaken at vendor's facilities using similar equipment to demonstrate level of control, and to short list vendors.

Short listed vendors were asked to submit comprehensive proposals, and the successful vendor was selected following review of proposals and results of the trials..

An order placed with successful vendor and a project team was established to work with vendor to monitor equipment delivery and to ensure compliance with URS.

A successful Factory Acceptance Test (FAT) was conducted at vendor's facility prior to shipping the equipment to the manufacturing site.

The equipment was installed at the manufacturing site. A successful Site Acceptance Test (SAT) was completed and the equipment was qualified.

## Contact Us

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To learn more about how Nick Davies & Associates LLC (NDA) can help you, please contact us:

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