

Dave Malpas Consulting Client History



Dave Malpas Consulting Ltd

August 2021

Clients include:

Sanofi
Accord Healthcare
Piramal
Arcinova
Hall Analytical
MedPharm
Northern Balance
Solo Containment
Rockshaw

Assistance provided includes:

Preparation of Validation Master Plan and training in Qualification and Validation.

Gap analysis and assistance with audit preparation.
Preparation of Qualification protocols for clean room HVAC system.

Preparation of complete Quality Management System, policies and SOPs. Qualification of manufacturing and laboratory equipment. Temperature mapping of warehouse and stability cabinets.

Process validation.

Preparation of retrospective Design Review for new facility.

Upgrade of Quality Management Systems including preparation of Validation Master Plan, Qualification protocol and report templates, Quality Event and Change Control SOPs.

Assistance with upgrade project to commence commercial Drug Substance manufacture in compliance with GMP.

Preparation and validation of spreadsheets for monitoring Quality Events, Change Control and CAPAs.

Upgrade of data integrity policies and procedures, assistance with risk assessments, self-inspections and periodic review of computerised systems.

Upgrade of Quality Management Systems including Quality Events, Change Control, Data Integrity and Validation Master Plan.

Preparation of qualification protocol and report templates for laboratory equipment.
Review and upgrade of all SOPs.