



VALIDAPHARM



Meeting All Your Validation Needs

We Can Help You With...

VALIDATION PROJECTS

- The Validation Gap Analysis™
- Validation Master Plans
- Validation Project Plans

EQUIPMENT VALIDATION (IQ, OQ, PQ)

- Manufacturing
- Analytical
- Filling, Labelling & Packaging
- Autoclave sterilization studies
- Stability chamber studies (temperature, humidity)
- Temperature mapping studies (refrigerators, freezers, etc)

FACILITY VALIDATION

- Utilities (air, steam, vacuum, nitrogen)
- Water (USP purified water, USP WFI)
- HVAC

ANALYTICAL METHOD VALIDATION

- Assays (HPLC, GC, IR, UV, etc)
- Microbiology Testing
- Compendial
- Non-compendial

REFRIGERATOR/FREEZER QUALIFICATION AND WAREHOUSE QUALIFICATION

- Temperature mapping studies
- Temperature monitoring
- Temperature alarm/excursion process/procedures

PROCESS VALIDATION

- Solid dosage
- Liquid dosage
- Parenterals

ValidaPharm™, a division of Quality & Compliance Services Inc. (Q&C®), is a full-service company, providing expertise and assistance through every phase of your validation project. In addition to writing/revising your Validation Master Plan, and developing and executing protocols, we can help you with The Validation Gap Analysis™, periodic review of your validation status, large project management, technical writing, and training. Let us develop your detailed implementation plan with priorities, timelines, etc.

CLEANING VALIDATION

- Cleaning process review
- Grouping and worst case selection
- Calculation of residue acceptance limits
- Selection of sampling and analytical methods
- Sampling procedures
- Sampling recovery studies
- Characterization studies

SHIPPING VALIDATION

- Transportation validation (point A to point B)
- Packing configuration validation
- Qualification of single-use monitoring devices / data loggers

COMPUTER VALIDATION

- Spreadsheet
- Software
- Hardware
- URS, FRS, validation plans, IQ/OQ/PQ, configuration documents

STANDARD OPERATING PROCEDURES (SOPS) AND DOCUMENTATION

- Equipment / Production Lines
- Operation
- Start-up / Shut-down
- Changeover
- Cleaning
- Maintenance
- Temperature monitoring/excursions
- Calibration of monitoring devices
- Alarm incident/alarm testing

MEETING ALL YOUR VALIDATION NEEDS

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