PERFORMANCE VALIDATION

CQV SERVICES FOR cGMP MANUFACTURING

Since 1988, Performance Validation (PV) has focused on ensuring the quality and safety of pharmaceutical drugs and medical devices in cGMP manufacturing through Commissioning, Qualification, Validation (CQV), and related services.

YOUR CQV PARTNER FROM SUPPLY CHAIN TO DISTRIBUTION

- Critical suppliers, e.g., precursors, excipients, packaging
- Building Management Systems, Facilities, and Utilities
- API manufacturing, sterile preparation, and drug product formulation
- Parenteral fill-finish lines and OSD product manufacturing
- Automated, semi-automated, and manual inspection
- Device assembly, primary, secondary, and tertiary packaging
- Warehouses, Automated Storage and Retrieval systems (ASRS), and Automated Guided Vehicles (AGV)
- Logistics – road, rail, air
- Method Development, scale-up, and QA/QC laboratories

WHO WE SERVE

- API, parenteral, and OSD manufacturing
- Medical device and IVD manufacturing
- Drug/device combinations
- CDMOs and CMOs
- Late-stage clinical startups
- 3PL logistics companies
- Airlines & Airports
- 503A and 503B compounders
- Architectural, Engineering, and Construction companies
- Precursor, excipient, and packaging vendors
- Green field sites, new buildings, manufacturing line expansions, and upgrades
- Industry equipment and instrument vendors

SERVICES OFFERED

Comprehensive services for manufacturing and lab equipment, automation, facilities, and utilities.

- Audit preparation and mock audits
- VMP development and project planning
- QMS development and support
- Regulatory framework transitions
- Risk assessments
- CQV, C&Q, and Verification document authoring
- IT-CSV, OT-CSV, Robotics
- Temperature and humidity mapping
- Critical Airflow Visualization
- On-site and remote test execution
- Shutdown support
- Digital Validation as a Service (dVaaS)
- Digital validation systems support
- Record review including drawing walkdown
- Change controls
- Program/project management
- Project scheduling
- Engineering turnover packages
- PPAP
- Green building support – LEED credits, energy management

EXPERTISE ACROSS THE MANUFACTURING WORKFLOW

PV is a partner YOU CAN TRUST to get it done.

WHAT MAKES PV SPECIAL

We've spent many years optimizing our skills, tools, processes, and client-centric culture and have prioritized retaining our talent.

- In-house technical resources and long-tenured cGMP SME's
- Technical depth chart
- Recruitment, training, skills development
- Employee and client-centric culture
- Efficient back office systems and reporting
- Tracking and reporting tools
- Easy to do business with
- Financial strength

WHAT YOU CAN EXPECT

- Done your way
- Accountability
- Rapid staff onboarding and time to effectiveness
- Right first time and on schedule
- Never the one you are waiting for
- Flexible and adaptable
- Top-tier quality and safety
- Transparency of data and communications
- Accurate billing
- Flexibility, focus, intensity, rapid resolution

BUSINESS MODELS

- Deliverables-based statement of work
- T&MNTE or fixed-price
- Functional Service Provider (FSP)
- On-site, project-based, or remote workers
- Full-time employees or contract workers

KEY PHARMA INITIATIVES SUPPORTED

- Pharma 4.0, FDA digital transformation
- Digital fluency
- Continuous manufacturing
- Lights out automation
- Personalized medicine

REGULATORY FRAMEWORKS SUPPORTED

PV works with all the major frameworks and can guide your regulatory evolution.

Pharma: 21 CFR Part 210/211, 21 CFR Part 11, EMA, MHRA, ASTM e2500, ISPE GAMP5, ICH, WHO, ICA

Medical Device: 21 CFR Part 820, ISO 130485, MDR, IMDRF, MHRA, WHO

EMPLOYEE-OWNED SINCE 2018

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