

# "DRIVING PHARMA EXCELLENCE THROUGH GMP AND ENGINEERING COMPLIANCE"

In Collaboration With
VTS Consultants, Inc. (USA) &
AmpleLogic (India)

#### WHO WE ARE

Micron HVAC Private Ltd. is a trusted partner for the Pharmaceutical & Life Sciences industry.

We deliver end-to-end solutions in:

- GMP Compliance
- Regulatory Support
- Cleanroom & HVAC Systems
- CSV & Digital Quality Solutions
- Medical Devices & Biopharma

#### **Our Mission:**

"We aim to establish long lasting client relationships by offering exceptional services in an environment of trust & respect".



# GLOBAL COMPLIANCE & REGULATORY SERVICES

- Proactive FDA Inspection Readiness & Support during the Audit.
- Remediation of FDA 483 Observations.
- GMP Training.
- Global GMP Compliance & Gap Assessments.

"Helping you stay inspection-ready at all times".

# CLEANROOM & HVAC EXCELLENCE

- HVAC System Design for SMT & Semiconductor facilities.
- Cleanroom Qualification & Certification
- AHU & Critical Utility Validation
- HEPA Filter Testing
- Airflow Visualization Studies
- Process, MEP Designing & HVAC
- Procurement assistant, Conceptual & detailed engineering.

"Delivering controlled environments for quality manufacturing".



# MEDICAL DEVICE REGULATORY SOLUTIONS

- 510(k) Submissions & FDA Communication
- EU MDR Compliance & Technical Documentation
- ISO 13485 QMS Implementation & Audits
- Risk Management as per ISO 14971
- CE Marking & Post-Market Surveillance

### **SETTING UP FACILITIES**

- Setting-Up Quality Control, Quality Assurance department, Microbiology Laboratory & Injectable facility.
- Review of Validation Documentation and Facility Layout for Finished Dosage Manufacturing.
- Development of Pharmaceutical Quality System.



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## DIGITAL QUALITY & COMPLIANCE SOLUTIONS

- Computer System Validation (CSV)
- eQMS | DMS | LMS | e-Logbook | EMS
- MES + eBMR (Electronic Batch Records)
- Cleaning Validation Software (CVS) & Process Validation Software (PVS)
- Calibration & Preventive Maintenance Systems (CAPS)
- Risk-Based Validation & Data Integrity
   (21 CFR Part 11, GAMP 5)

"Driving digital transformation in compliance".



# POWERING PARTNERSHIPS, EXPANDING POSSIBILITIES

#### VTS Consultants, Inc. (USA)

- FDA Audit Preparedness & 483 Remediation
- Global GMP Compliance Support
- Specialized Regulatory Training
- · Warning letters & consent decrees

#### AmpleLogic (India)

- eQMS, DMS, LMS, eLogs, EMS
- MES + eBMR for paperless manufacturing
- Stability & Complaint Management Systems

"Together, delivering a 360° Global Portfolio — Compliance + Engineering + Digital Transformation — creating new benchmarks in Pharma Excellence".



#### WHY CHOOSE US?

- 200+ years of combined industry expertise
- Trusted by leading pharmaceutical companies.
- Global presence (India, Middle East, Africa, USA, Europe, Asia)
- 100+ Clients
- 100+ Project completed successfully
- One stop solution for GMP, CSV, Medical Devices, HVAC & Digital Quality Systems.



### **Get In Touch**

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