MICRON
PHARMA CONSULTANTS

WHAT WE OFFER

- FDA & GMP Regulatory Compliance
- CSV & Digital Quality Compliance
- Medical Device Regulatory Services
- Training & Capacity Building
- Turnkey Project Consultancy
- Aseptic Process Simulation

www.micronconsultants.com

ABOUT US

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Micron Pharma Consultants is a specialized pharmaceutical consulting subsidiary of Micron HVAC Pvt. Ltd., providing strategic consulting solutions to pharmaceutical, biotechnology, healthcare, and medical device organizations.

Built on Micron HVAC's legacy of serving regulated industries since **2009**, we support organizations in achieving regulatory compliance, inspection readiness, and operational excellence through practical, risk-based consulting.

Our services are aligned with global regulatory standards, including **USFDA, EU GMP, WHO, MHRA, and ISO**, helping clients strengthen quality systems, enhance compliance, and successfully navigate today's evolving regulatory environment.

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OUR STORY

2009
The Beginning
Micron Cleanroom Services was established, providing validation and cleanroom support services to pharmaceutical manufacturing industries.

2016
Expansion & Incorporation
Validation services expanded across major pharmaceutical manufacturing sites.
Micron HVAC Pvt. Ltd. was incorporated, strengthening technical, validation, and compliance capabilities.

2022
Accreditation
Achieved NABL Accreditation as per ISO/IEC 17025:2017 for Thermal Calibration Services, reinforcing our commitment to quality and technical excellence.

2023
New Capability Unlocked
Introduced GMP Consultancy and Regulatory Compliance Services to support pharmaceutical, biotechnology, and healthcare organizations.

2024
Consulting Vertical Launch
Established a dedicated pharmaceutical consulting practice focused on GMP Compliance, Validation, Quality Systems, Regulatory Affairs, Training, and Risk Management.

2025
Global Collaborations
Entered strategic collaborations with VTS Consultants Inc. (USA) and AmpleLogic (India), expanding expertise in REMS, CSV, CQV, Digital Compliance, and Process Automation.

2026
Independent Identity
Formation of Micron Pharma Consultants, a dedicated pharmaceutical consulting subsidiary.

The Journey Continues...

OUR VISION

To be the preferred global consulting partner for the pharmaceutical industry, recognized for transforming compliance into a catalyst for quality, innovation, and sustainable success.

OUR MISSION

To partner with organizations in delivering world-class pharmaceutical consulting that enables regulatory confidence, operational excellence, quality leadership, and sustainable business growth.

VISIONARY LEADERSHIP

ARUN WANGEKAR
FOUNDER

Mr. Arun Wangekar, Founder of Micron Pharma Consultants, is a seasoned industry professional with over 25 years of experience in pharmaceutical engineering, validation, regulatory compliance, quality systems, and project management. His extensive expertise spans the development and implementation of compliance-driven solutions for pharmaceutical, biotechnology, healthcare, and medical device industries.

Under his leadership, Micron has expanded its capabilities beyond engineering and validation into specialized consulting services including GMP Consultancy, Regulatory Affairs, Computerized System Validation (CSV), Risk Management, Medical Device Regulatory Services, Training & Capability Building, and Aseptic Process Simulation.

Arun's vision is centered on building a globally respected consulting organization that delivers practical and sustainable solutions aligned with international regulatory standards. His commitment to innovation, quality, and client success continues to drive Micron Pharma Consultants' growth and reputation as a trusted partner for pharmaceutical industries.

LEADERSHIP HIGHLIGHTS

- 25+ Years of Pharmaceutical Industry Experience
- Pharmaceutical Engineering, HVAC & Utility Systems Specialist
- Cleanroom Commissioning & Qualification (CQV)
- Greenfield & Brownfield Project Leadership
- Technical Trainer & Capability Development Leader
- Professional Affiliations – CCSI | ISPE | ASHRAE | ISHRAE

> *“Compliance is not just a regulatory requirement; it is the foundation of quality, trust, and sustainable growth.”*

THE LEADERSHIP TEAM

Mr. Vikas Hari Sathe - M. Pharm, MAM.
Associate Director

Mr. Vikas Hari Sathe, brings unique experience in management of formulation manufacturing operations and project management for new manufacturing facilities with over 35 Years.

He has core experience in Designing & qualification of formulation manufacturing facilities, manufacturing operations of wide spectrum formulations, GMP compliance and regulatory audits.

He is Subject Matter Expert (SME) in Designing and Operations of Isolator based manufacturing facility for Cytotoxic / high potency injectable formulations, including Lyophilized formulations, Manufacturing facility for Aseptic & terminally sterilized Injectable formulations, Manufacturing facility for Oral Solid dosage forms - Tablets and capsules, Manufacturing facility for External Preparations (Ointments and Creams).

He worked as Plant Head with reputed Indian Pharmaceutical Organizations.

Dr. Nand Kishore Khandelwal - Ph.D.
Associate Director

Dr. Nand Kishor Khandelwal, has comes with a strong Quality Assurance, Quality Control, Microbiology, Technology Transfer, Audit & Compliance, Qualification & Validations background with over 35+ Years of experience across the Parenterals, Cytotoxic, Oral Solid, API (Active Pharmaceutical Ingredient), and Medical Devices industries.

He is Subject Matter Expert (SME) in aseptic processing, sterility assurance, microbiology, Quality Management Systems (QMS), risk assessment, investigations & having vast experience in responding to inspectional observations of regulatory agencies.

He worked as Head Quality with reputed Indian Pharmaceutical Organizations such as, Lupin Limited, Orchid Chemicals & Pharmaceuticals Ltd., Wockhardt Limited, Emcure Pharmaceuticals Ltd., Sri Krishna Pharmaceuticals Ltd, he has faced several health authority inspections, US FDA, UK-MHRA, Health Canada, European Union (EU), TGA, SHAPRA, GCC, ANVISA, etc.

THE LEADERSHIP TEAM

Mr. Bipin Patil - Bsc (Engineering Science)
Associate Director

Mr. Bipin Patil, having 40 Years of experience in HVAC & contamination controls. He is running a Aerience (Institute of Air science & contamination Control) a unique Training Institutes located in Pune (India).

He is Subject Matter Expert (SME) in Designing HVAC, design of cleanroom, special purpose laboratories, BSL -1, BSL-2, BSL-3, BSL-4, Electronics, Semiconductor & Surface Mount Technology Industry, He has core experience in HVAC, Cleanroom performance, Optimization and Indoor Air Quality.

He has successfully handled MEP, CFD Analysis, Cleanroom designing, Building modelling projects & Cleanroom performance audits.

He has Designed & Successfully Commissioning & completed many Pharmaceuticals, Automobiles, Semiconductor & Engineering Projects in India as well as abroad.

Mr. Dnyanesh Motewar - B.E. Mechanical
Associate Director

Mr. Dnyanesh Motewar brings 28 years of extensive experience and technological expertise in Cleanroom HVAC, Lab Air Conditioning, Precision Air Conditioning, and Comfort HVAC Systems. As the Founder of Sagra HVAC Pvt. Ltd. (established in 2018), he has successfully led numerous turnkey projects across pharmaceutical, industrial, commercial, and hospital sectors.

With strong technical acumen and unwavering commitment, he plays a vital role at Micron HVAC Pvt. Ltd., driving excellence in design, engineering, installation, and project execution. His deep understanding of manufacturing, engineering, FMCG, and construction industries continues to enhance Micron's capabilities, innovation, and customer-centric approach.

THE LEADERSHIP TEAM

Mr. Kumar Kurle – MSc Microbiology
Associate Director

Mr. Kumar Kurle having 25 years of experience in pharmaceuticals and biopharmaceuticals API and finished products.

He has core experience in research and development, technology transfer and scale up, facility design, Recombinant cell line development & characterization, Toxicological GLP studies. Process validation, cleaning validation, Analytical method development and validation and Quality management in the areas of Biosimilars, Recombinant vaccines, monoclonal antibodies and plasma proteins.

He has worked with reputed pharma/biopharmaceutical companies such as Cipla, Wockhardt, Gennova, Piramal and Dr. Reddy's.

He has headed quality assurance department over 15 years. He is adept in statistical process controls, GMP trainings, investigations, Risk assessment and CAPA management.

Mr. Yogesh P. Gokhale
B.E. (Electronics & Telecommunication)
Manager - CSV & Automation

Mr. Yogesh P. Gokhale is an experienced engineering professional with over 17 years of expertise in plant maintenance, instrumentation, automation, and validation within the pharmaceutical industry. Where he has handled plant instrumentation, preventive maintenance, equipment qualification, HVAC, PLC/SCADA systems, and computerized system validation.

He has successfully led several digitalization and automation projects, including centralized SCADA implementation, SAP–PPM and MES integration, and automation of critical equipment. He is well verse with GAMP and 21 CFR Part 11 guidelines.

He holds a Bachelor's Degree in Electronics & Telecommunication, and completed specialized training in Thermal Validation, CSV, Data Integrity, and PLC Systems.

OUR SERVICES

DIGITAL QUALITY COMPLIANCE

Quality & Compliance Solutions

- **eQMS** – Electronic Quality Management System
- **APQR** – Annual Product Quality Review Software
- **CAPS** – Calibration and Preventive Maintenance Software
- **UAM** – User Access Management Software

Document & Learning Systems

- **DMS** – Document Management Software
- **LMS** – Learning Management System

Production & Laboratory Solutions

- **LIMS** – Laboratory Information Management System
- **MES** – Manufacturing Execution System
- **eLog** – Electronic Logbook Software

Validation & Monitoring

- CVS
- PVS
- EMS

Regulatory & Process Excellence

- **RIMS** – Regulatory Information Management System
- QC Planning and Method Validation Tools
- Business Process Automation (BPA) and Excellence (BPE)

OUR SERVICES

MEDICAL DEVICE REGULATORY SERVICES

Regulatory Strategy & Global Market Approvals

- ✔ Pre-market Notification (510k) Consulting
- ✔ India CDSCO Regulatory Approval Services
- ✔ CDSCO Import Authorization Services
- ✔ CDSCO Factory License Assistance
- ✔ CE Certification under EU MDR
- ✔ UK Market Access via UKCA Certification
- ✔ Russian Market Approval for Devices
- ✔ SFDA Certification for Medical Devices (KSA)

ISO 13485-Based Quality Management Solutions

- ✔ FDA 21 CFR PART 820 QUALITY SYSTEM REGULATION
- ✔ MEDICAL DEVICE
- ✔ QMS SOFTWARE (EQMS)
- ✔ ISO 15378:2017 CERTIFICATION

  PRIMARY PACKAGING

  REGULATORY CONSULTING
- ✔ MDSAP
- ✔ Medical Device QMS Setup & Compliance
- ✔ Technical Feasibility & Strategic Project Reports
- ✔ Turnkey Manufacturing Facility Solutions
- ✔ Regulatory Validation Protocols & Reports
- ✔ Controlled Environment Setup & ISO Guidance

Medical Device Design Control & Regulatory Documentation

- ✔ Drug–Device Integrated Product Services
- ✔ FDA Design Control Compliance (21 CFR 820.30)

OUR SERVICES

AUDITING / GMP CONSULTANCY / MICROBIOLOGY / TRAINING

GMP AUDITING

- ✔ Conduct the mock audit of client's site to determine readiness for FDA inspection.
- ✔ Due diligence audit.
- ✔ Third Party Audit on behalf of procurement companies.
- ✔ GAP assessment audit.
- ✔ Schedule M implementation

ASEPTIC PROCESSING

- ✔ Provide support in development of Aseptic Process Simulation.
- ✔ Qualification of Equipment.
- ✔ Process Validation (Terminal Sterilization & Aseptic Processing)
- ✔ Equipment Procurement.
- ✔ Qualification of Utilities.

GMP TRAINING

- ✔ We can develop & deliver a comprehensive & meaningful in-house training program that is tailored to, & appropriate for client specific needs.
- ✔ Inhouse training is the most cost effective means to improve the skills & capabilities of employees.
- ✔ It is helpful because of convenience & less disruption, value for the money, save time, provide freedom of expression & maintain the confidentiality, provide freedom to discuss client's own case, studies, better interaction, and effective learning.

MICROBIOLOGY

- ✔ Review of Microbial testing methods/procedures viz. Growth Promotion testing, Microbial Limit Test, Sterility testing, Bacterial Endotoxins testing,water testing, antimicrobial and preservative effectiveness.
- ✔ Development of Environmental Monitoring Program (EM).
- ✔ Development of Contamination Control Program (CCP).
- ✔ Development of admixture studies.
- ✔ Development of Microbiology method validation protocols.

OUR SERVICES

AUDITING / GMP CONSULTANCY /MICROBIOLOGY / TRAINING

FACED NATIONAL & INTERNATIONAL REGULATORY INSPECTIONS

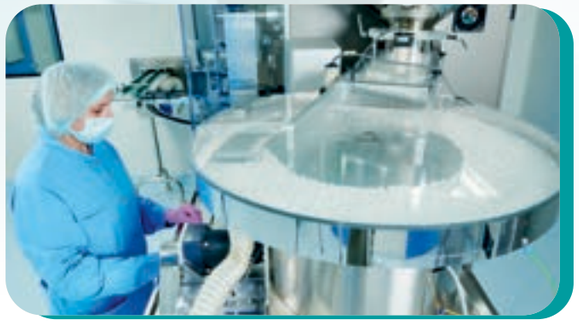
- ✔ Central Drugs Standard Control Org. (CDSCO)
- ✔ Indian FDA Inspections.
- ✔ U.S. Food & Drug Administration (USFDA)
- ✔ U.K Medicines & Healthcare Product Regulatory Agency (UK-MHRA)
- ✔ Agency for Medical Products & Medical Devices of the republic of Slovenia.
- ✔ Malta Medicines Authority, Malta and so on...

SETTING UP FACILITIES

- ✔ Setting-Up Quality Control and Quality Assurance department.
- ✔ Setting-Up the Microbiology Laboratory.
- ✔ Setting-Up the Injectable Facility.
- ✔ Review of Layout for Finished dosage form manufacturing facility.
- ✔ Review of Validation protocols and reports.
- ✔ Development of QMS & Pharmaceutical Quality System.

REGULATORY SERVICES

- ✔ Review of Abbreviated New Drug Application (ANDA) submissions.
- ✔ eCTD authoring and compilation for CEP, DMF, ANDA, GCC submissions.
- ✔ Guidance for preparation of ANDA and DMFs.
- ✔ Support in preparation of Remedial Action Plan (RAP) post FDA inspection.
- ✔ Provide support in drafting response to regulatory audit observations.



OUR SERVICES

BIO PHARMACEUTICAL • AUDITING / CONSULTANCY / BIO PROCESS CONTROLS

DESIGN & IMPLEMENTATION OF BIO-PHARMACEUTICALS R&D LAB & MANUFACTURING PLANT

- ✔ R&D Laboratories – Molecular biology, Biosafety, Fermentation, Protein purification, formulation development, Microbiology, Biochemistry, Cell based bioassays, Chemistry, and plasma fractionation.
- ✔ Large scale commercial plants – Seed development, fermentation, Protein purification, Sterile injectable formulation plants, warehouse and quality control laboratory.

CELL LINE DEVELOPMENT & VALIDATION

- ✔ Recombinant cell line development
- ✔ GMP Cell bank manufacturing
- ✔ Cell Bank characterization and biosafety assessment.

ELECTRONIC DOCUMENT MANAGEMENT & PROCESS DIGITALIZATION

- ✔ Development and implementation digital solutions for R&D labs, and commercial manufacturing plants
- ✔ Process flow mapping, digitalization for R&D, Manufacturing process, quality control, material management, information management, dashboard creation, instrument integration, data trending and analysis, batch manufacturing records, SOPs, protocols and report management.

ANALYTICAL METHODS

- ✔ Analytical method development,
- ✔ Analytical method validation
- ✔ Continuous method performance verification
- ✔ Life cycle management of analytical methods, critical quality attributes and critical process parameters
- ✔ Chemical, Biochemical, Microbiology, cell-based bioassays

BIOPROCESS CONTROLS

- ✔ Identification of CTP and CQAs. Process capabilities studies, control charting
- ✔ Viral validation studies
- ✔ Process assessment, Assessment of critical quality attributes and critical process parameters
- ✔ Cleaning Validation in Biopharmaceutical process
- ✔ Technology transfer, Process validation and Continuous process performance verification
- ✔ FDA, EU, ICH compliance

BIOPROCESS EQUIPMENT QUALIFICATION

- ✔ URS, DQ, IQ, OQ, PQ and life cycle management
- ✔ Risk assessment
- ✔ Identification of System boundaries

CHARACTERIZATION OF DRUG SUBSTANCE AND DRUG PRODUCT

- ✔ Charactrization of drug substance and drug products
- ✔ Risk assessment and structure-function relationships
- ✔ Impurity profiling and stability studies
- ✔ Protocol preparation and report review

QUALITY MANAGEMENT SYSTEM

- ✔ Implementation of QMS in developmental phases of products viz. research and development, technology studies, pre-clinical, clinical phases and commercial manufacturing as per regulatory expectations.
- ✔ Risk Assessment and evaluation of effectiveness of CAPA

OUR SERVICES

VALIDATION & TECHNICAL DOCUMENTATION, INTEGRATED CQV, CSV, CSA & PROCESS AUTOMATION

FDA 21 CFR PART 11 REGULATION, FDA 21 CFR PART 11,EU GMP ANNEX 1 & GAMP – 5

Computer System Validation (CSV) Services

R&D Lab & Manufacturing Plant

System Scope: Validation includes ERP Systems, DMS, Network & PC-based Systems, Facility / Utility / Barcode / Warehouse Systems, Building Automation, Maintenance Management Systems, SCADA / PLC / DCS / MES / EBRS systems, and process equipment.

Clinical Systems: Validation of eCRF, eSD, eTMF, Patient Databases, IV/WRS systems, data migration plans, and data quality control.

Deliverables

- ✔ **Validation Master Plan (VMP)**
- ✔ **SOPs for CSV**
- ✔ **URS/SRS – Requirement Specifications**
- ✔ **Design & Configuration Specs (DCS)**
- ✔ **Risk Assessments (QRM/RA, FRA)**
- ✔ **IQ/OQ/IOQ (Installation & Operational Qualifications)**
- ✔ **RTM (Requirement Traceability Matrix)**
- ✔ **Validation Summary Report (VSR)**
- ✔ **Audit trails, logical security, access control, data Integrity assessments (DIRA Audit)**
- ✔ **Spreadsheet (Excel) validation**

Infrastructure Support

- ✔ **Workforce augmentation**
- ✔ **IT Infrastructure validation**
- ✔ **Execution & Approval support**
- ✔ **Data Management Systems**

Computerized Equipment & Software Validation

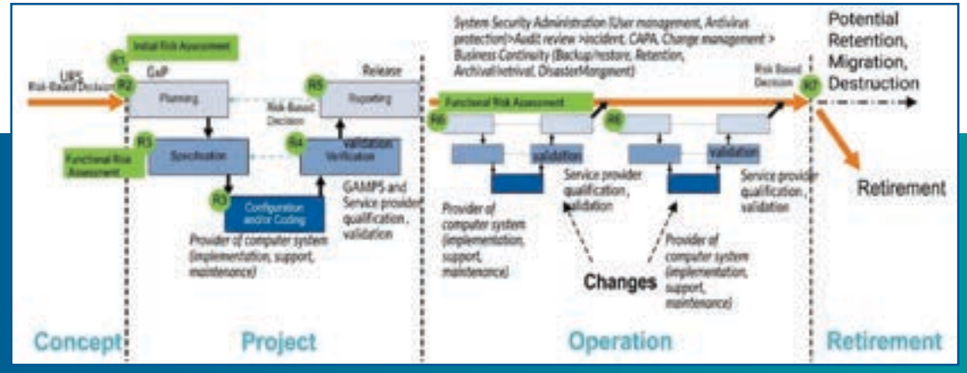
Application Categories (GAMP 5)

Category 1: Infrastructure Software

Category 3: Non-configured (firmware, instruments)

Category 4: Configured Software (SCADA, ERP, BMS, LIMS)

Category 5: Custom Software (internal/external IT apps, macros, PLC logic)



OUR SERVICES

ENGINEERING, TURNKEY'S AND GREEN FILED SOLUTIONS

Offers services compliant to ISO & ISPE Guidelines in Pharmaceutical industries

DESIGN & DEVELOPMENT

- ✔ Feasibility Study
- ✔ Conceptual Design
- ✔ GMP Risk Assessment
- ✔ Master Planning
- ✔ Technology Selection
- ✔ Equipment Study
- ✔ Expansion

CONCEPTUAL ENGINEERING

- ✔ Detailed Building
- ✔ Architectural
- ✔ Water System
- ✔ MEP Designing
- ✔ Electrical Load Sanctioning
- ✔ Plumbing & Utilities
- ✔ Civil
- ✔ Structural
- ✔ Process
- ✔ HVAC
- ✔ Mechanical & Piping

PROCUREMENT ASSISTANT

- ✔ Preparation of Detailed Vendor List
- ✔ Floating of Equipment Enquiry
- ✔ Follow up for Offers
- ✔ Techno Commercial Evaluation of Offers
- ✔ Approval of GA Drawings

OUR SERVICES

ENGINEERING, TURNKEY'S AND GREEN FILED SOLUTIONS

Offers services compliant to ISO & ISPE Guidelines in Pharmaceutical industries

DETAIL ENGINEERING

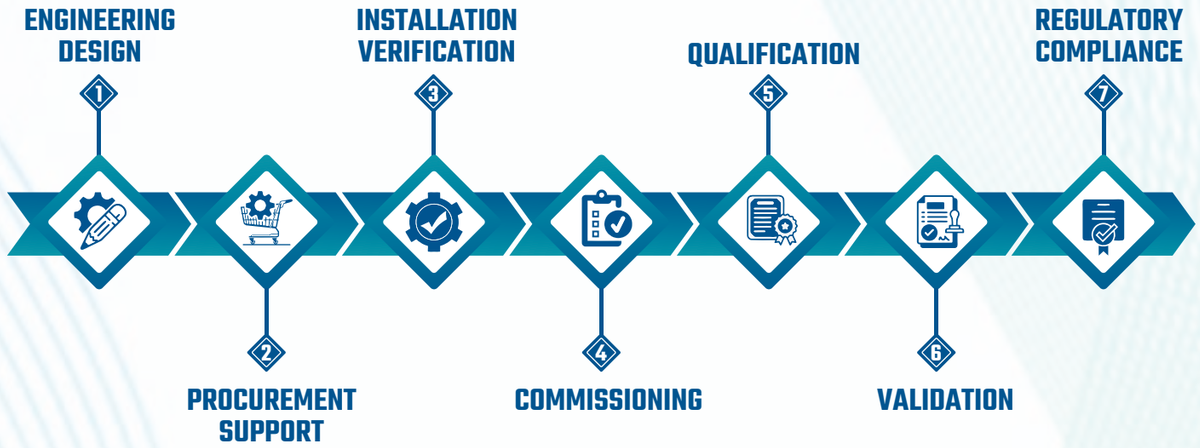
- ✔ Process Engineering
- ✔ Mechanical Engineering
- ✔ HVAC Engineering
- ✔ Electrical Engineering
- ✔ Instrumentation & Automation
- ✔ Utility System Design
- ✔ Piping & Layout Engineering
- ✔ Engineering Documentation

COMMISSIONING

- ✔ Equipment Commissioning
- ✔ Utility Commissioning
- ✔ HVAC Commissioning
- ✔ Process System Commissioning
- ✔ FAT & SAT Support
- ✔ Integrated System Testing

QUALIFICATION

- ✔ Design Qualification (DQ)
- ✔ Installation Qualification (IQ)
- ✔ Operational Qualification (OQ)
- ✔ Performance Qualification (PQ)
- ✔ Utility Qualification
- ✔ Cleanroom Qualification
- ✔ Equipment Qualification
- ✔ Process Qualification



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VISIT US