MMR CONSULTING

ENGINEERING - PROJECT MANAGEMENT - VALIDATION - COMPLIANCE

PASSIONATE ABOUT PEOPLE, EXPERIENCED IN ENGINEERING

- Engineering and Automation Services
- Commissioning, Qualification and Validation (CQV)
- Project Management & Project Controls
- Computer Systems Validation (CSV)
- Compliance

We're a dedicated team delivering robust solutions for the Pharmaceutical and Biotechnology industries

Engineering and Automation Services

MMR offers an extensive wealth of both knowledge and experience in automation and engineering services. Our engineering and automation expertise cover:

- Process engineering
  - Biologics, MCC, vaccines, Plasma Processing
  - Oral solid dose
  - Semi-solids
  - Liquid dose
  - Disposables process design
- Equipment design
  - Washer & autoclaves
  - Fill finish, packaging, serialization
  - Chromatography, TFF, UF, centrifuges
  - CO2 extraction, rotary evaporation
  - Compounding / formulation, buffer prep/hold
  - Chemical storage & dilution skids
  - Waste handling, neutralization, and bio-kill systems.
- Site master planning, front-end design (feasibility studies, conceptual design)
- Critical utilities design
  - WFI/PW, clean steam, CIP systems, process & lab gasses
- cGMP facility design
- GPP processes and facilities
- Automation specification development, integration, automation owner's rep/project management and automation validation including:
  - PLCs (Siemens, Allen Bradley)
  - DCS (Emerson DeltaV, Siemens PCS7, Honeywell Experion)
  - OSI-Pi, GE Unicorn software integration
  - BAS Systems (Siemens, Johnson Controls, Honeywell)
- Engineering software:
  - Process modelling (SuperPro / SchedulePro)
  - Hydraulic analysis (PipeFlo)
  - 2D & 3D CAD design

Commissioning Qualification and Validation Services

MMR offers our clients CQV expertise following conventional and risk-based approached (ASTM E2500 and ICQ). Our expertise covers:

- Paperless Validation software
- Validation Master Plan and Validation Project Plan development
- Analytical Lab equipment
- Performance qualification
- Cleaning validation
- Process validation
- Tech transfers
- Process scale-up
- Thermal & sterilization validation
- Packaging & Serialization Validation
- Equipment C&Q
  - Process and packaging equipment
  - Clean utilities, CIP, SIP, Fill/Finish
  - Facility C&Q
- Cleanrooms
  - Critical utilities
  - HVAC systems

Computer System Validation Services

MMR offers a custom risk-based approach to computer system validation (CSV). Our CSV experts have experience in creating and executing CSV deliverables for various systems, including ERP, LIMS, eQMS, MES, Process Automation Validation, Building Automation Validation, expertise includes:

Outsourcing experience includes Validation of Cloud-based, COTS, SaaS and Custom Applications:

- Cloud-based application: (SaaS, PaaS, IaaS)
- Configured Off the Shelf (COTS) packages
- Custom build systems and applications

Implementation of CSV program:

- Provide CSV SOP development such as Risk-based Validation, Change Control, Incident Management, Periodic Review, GxP assessment, including appropriate staff training.
- CSV templates such as Validation Plan, User Requirement, Test Protocols and Validation Report
- Implementation of paperless validation software
- Evaluate and assess current procedures and practices vs regulations and industry best practices
- Address compliance gaps by updating current procedure
- Implement risk-based methodologies and address inefficiencies

Project Management & Project Controls

Our Project Management services include developing or implementing:

- Stage-gate processes
- Project management office
- Project controls including cost control, estimation, schedule controls, and scope management
- Engineering document and drawing controls
- Project inception and business case development
- Risk/procurement/construction management and risk mitigation planning

Compliance

Our compliance expertise includes:

- Data integrity audits and assessments
- GMP audit readiness, inspections and remediation
- GMP gap assessments
- Quality system reviews
- SOP creation
- Training
- Calibration program audit & remediation
- Process scale-up

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LEADERSHIP TEAM

Michael Rodionov, P.Eng, PMP
Principal Engineer
Diversified experience in Process Engineering, Clean Utilities, Equipment Engineering, Capital Project Management and C&Q

Vaibhav Parekh, M.Sc
Validation Manager
Industry professional with over 15 years of industry experience in Qualification & Validation, Sterility Assurance/ Microbiology, and Lab Operations

Trevor Seelert, P.Eng
Engineering Manager
More than 9 years of process engineering expertise focused in bioprocessing, protein purification and disposable process design.

Igor Katz
Automation & CSV Manager
More than 15 years of expertise in Process and Building Automation, CQV and CSV

Roshily Mathulla
Chicago Area Manager
More than 8 years of engineering and project management experience in Clean Utilities, HVAC, BAS and Cleanrooms. Responsible for leading the Chicago region

Phil Hyland, P.Eng
SME - Compliance & Validation
Industry Veteran with over 35 years of experience in Engineering, Validation, Compliance and Operations.

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