

BOUNDARYLESS PROCESSING SYSTEMS

PHARMACEUTICALS

BIO-PHARMACEUTICALS





MANUFACTURING FACILITY | NASHIK, MAHARASHTRA, INDIA

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# PHARMA | BIOPHARMA

DESIGN

ENGINEERING

MANUFACTURING

ASSEMBLY

AUTOMATION

FAT

INSTALLATION

COMMISSIONING

VALIDATION

TRAINING

SUPPORT



# ABOUT US

## WE DELIVER VALUE ENGINEERED SOLUTIONS

For over 35 years Adam Fabriwerk has specialized in customized process system solutions for Pharmaceutical and Bio-pharmaceutical industries. We deliver customized turnkey solutions for;

- Aseptic mixing and blending
- Ointment and Cream manufacturing
- Liquid Oral manufacturing

Experience gained over the years help us to understand your requirement and deliver customized solutions that are optimized to suit your requirements. With Adam Fabriwerk, you are backed up by our fully equipped world class manufacturing facility supported by over 200 employees who are an ideal mix of process experts, trained technicians and skilled fabricators and project managers.

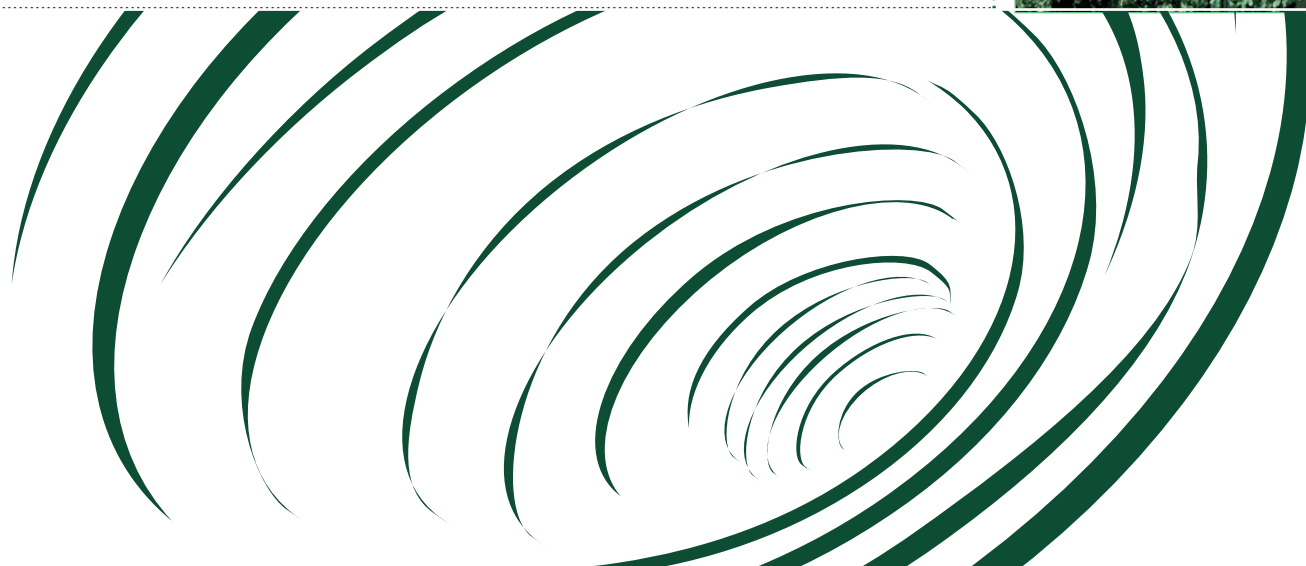


ESTABLISHED IN 1982

VESSEL MANUFACTURING AND INTEGRATION

MANUFACTURING FACILITY AT NASHIK

DEDICATED FAT FACILITY







# ADVANTAGE DELIVERED

- SYSTEM ENGINEERING
- SYSTEM MANUFACTURING
- QUALITY CONTROL SYSTEMS
- OUR INFRASTRUCTURE
- PROJECT EXPERTISE
- TECHNICAL SUPPORT
- VALIDATION SUPPORT
- TRAINING & GUIDANCE
- SERVICE SUPPORT



# THE ADAM FABRIWERK EDGE

## CUSTOMIZED SOLUTIONS

Every project comes with its own challenges and is unique. Trying to fit in standardized solutions to every project is a compromised option. We understand that every project is different and so are the solutions. Our ability to deliver customized process engineering solutions in a dynamic environment differentiates us from others.

## WORLD-CLASS QUALITY OF SYSTEM & EQUIPMENTS

Our equipments are designed to perform consistently, easy to operate, designed to be compact and reliable with low operational life-cycle cost. They are designed and engineered to be in compliance to international standards and guidelines such as ASME-BPE, US FDA, EU GMP etc.

## PROCESS CONTROL

With over 35 years of experience, our process automation methods enable a high level of reliability coupled with operational flexibility. We closely co-ordinate mechanical designs of customized equipment and processes with instrumentation and control systems. This is done in the initial design stage itself resulting in highly optimized design with reliability and flexibility in the system operation.

## MANUFACTURING INFRASTRUCTURE

Spread over an area of over 8000m<sup>2</sup>, we have one of the largest manufacturing facility in the field of our activity, at Nashik, India. Our plant at Nashik is a fully integrated, fabrication, assembly and testing facility managed by skilled technicians and engineers.

A dedicated area for Factory Acceptance Testing (FAT) enables all our systems to be tested under varying process conditions before shipment to site.

## EXPERIENCED PROJECT MANAGEMENT

We understand that efficiency in project management begins at the design stages. Our skilled project management team with considerable experience has keen focus to foresee issues and work to nullify most of the problems without allowing it to manifest. For the ones that manifests dynamically, we dig deep into our years of experience, leverage on our creativity and innovative ability to find lasting solutions. This ensures timely delivery of projects and savings of valuable resources.

## TRAINING & SERVICE SUPPORT

Our experienced training team provides operational training and works with your team to help operate the system efficiently. Our warehouse stocks most of the spare parts for timely delivery. Our Service engineers ensure timely support consistently.



EXPERTISE IN CUSTOMIZING SYSTEMS AND SOLUTIONS

OVER 8000 M<sup>2</sup> OF MANUFACTURING, ASSEMBLY AND TESTING AREA

OVER 200 COMMITTED AND TRAINED EMPLOYEES

OVER 35 YEARS OF PROJECT MANAGEMENT EXPERTISE

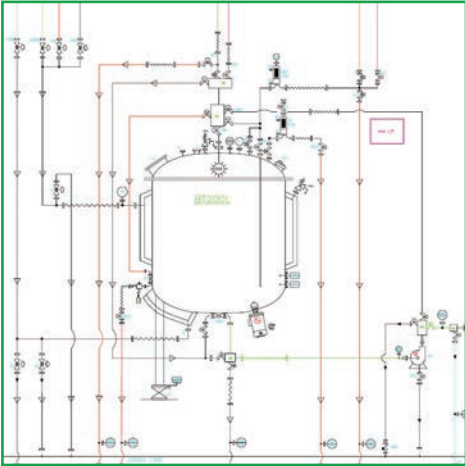






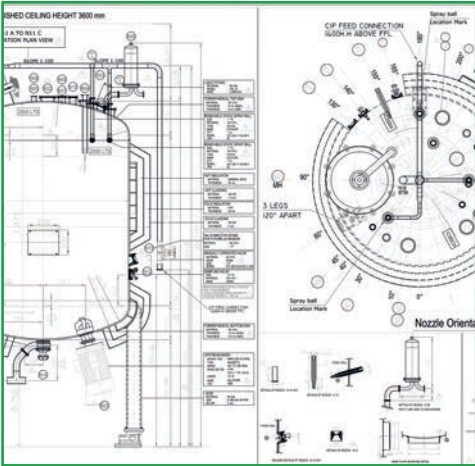
# MANUFACTURING WORKFLOW

## P&ID



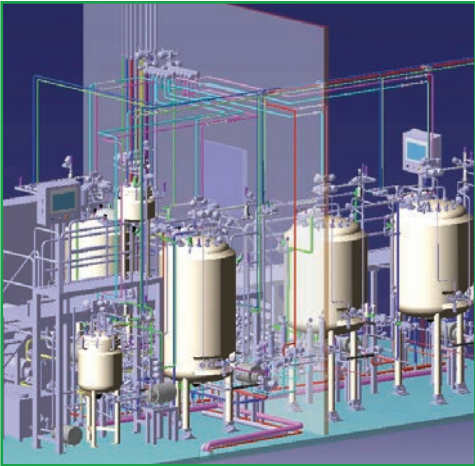
**01** The system manufacturing process is initiated with the preparation and approval of P&ID drawings. The P&ID accurately captures the arrangement of all instruments, equipments and component like the vessels, pumps, valves and instruments. Once the P&ID is approved, the process of creation of General Assembly (GA) drawings is initiated.

## GENERAL ASSEMBLY DRAWING



**02** The General Assembly drawings deliver information like the dimensional details, design parameters, quality of surface finish (Ra values), BO specs etc. On approval of this, we proceed to the next stage i.e. 3D design of the system.

## 3D MODEL



**03** We use the latest state of art 3D visualization and simulation software like CATIA & SIEMENS NX. These are great tools for engineering, visualization and simulation. They are also of great help in understanding the integration, size, scale and issues that might arise at the site during the installation and integration with other systems.

## SYSTEM BUILD



**04** On the basis of the 3D model, the systems are manufactured, assembled and tested. The use of 3D softwares ensures that minimal time is taken to assemble and integrate the system without any delays. The system is then checked for compliance and deviations with the P&ID, GA and the 3D models.

ACCURATE DRAWINGS AND 3D MODELS

HIGH END 3D CAD SOFTWARE DRIVEN MANUFACTURING

FASTER MANUFACTURING TURN AROUND TIME





# KEY APPLICATIONS

STERILE SOLUTIONS

IV FLUIDS

AEROSOLS

SVP SOLUTIONS

VACCINES

HUMAN INSULIN

SERUM

PLASMA FRACTIONS

BACTERIA & CELL CULTURES

mAb



# MOBILE SKIDS

## PORTABILITY, CONVENIENCE, COST EFFECTIVENESS WITH UNCOMPROMISED DESIGN SPECIFICATION

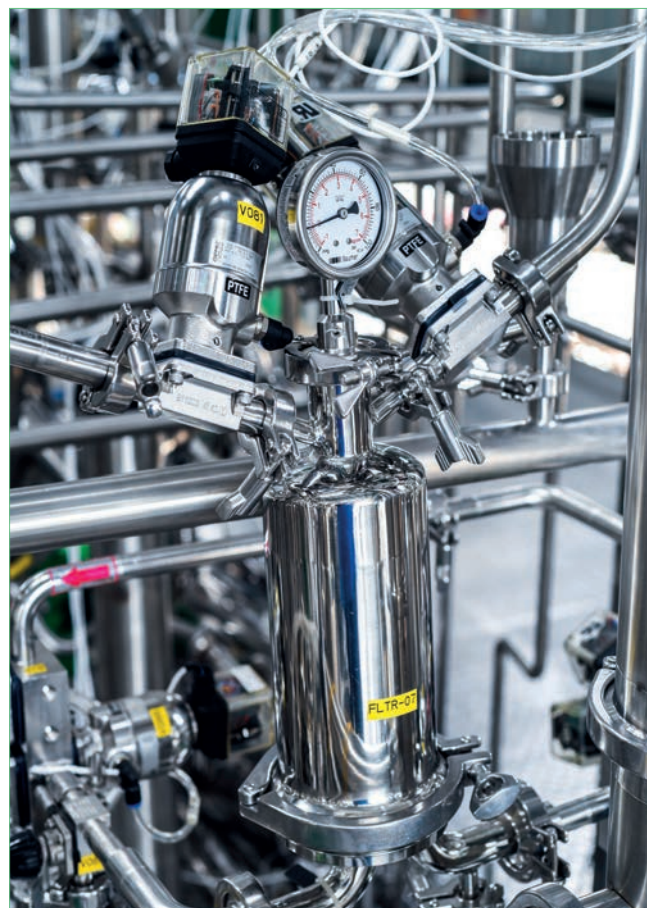
Our mobile skids are engineered, designed for efficient mixing and blending operations and can be moved around from one area to another. They can be custom optimized to suit your specific requirement of mixing and blending. They are compact, skid mounted and portable. They are cost-effective and ideal for mixing and blending of aseptic liquids of smaller capacities.

### ADVANTAGES

- Fast and easy installation
- Portable and compact
- Heating / Cooling options
- SIP / CIP / DIP options
- Full / Semi automated operation
- Capacities : 5 to 500 Litres

### KEY FEATURES

- Bottom mounted magnetic mixers with options for low / medium / high shear applications
- Flush bottom outlet valve with sampling / sterilization configurations
- Sterile flange connections of top dish / side ports to enhance CIP / SIP operations
- pH, temperature, conductivity, DO sensing through sanitary port on the vessel shell
- Load cell for weight measurement / Level sensors for level measurements
- 21 CFR part 11 compliant automated system



EASE OF PORTABILITY, COMPACT AND VALIDATABLE SYSTEMS

EASY TO INSTALL AND COST EFFECTIVE SOLUTIONS

OPTIONS FOR HEATING, COOLING, SIP, CIP AND DIP







# INTEGRATED SKIDS

Our integrated skids are a fully integrated end to end solutions, seamlessly integrating to cater to your aseptic process fluid handling applications. They are ideal for handling medium to high capacities. They can be customized and optimized to suit your requirements. The systems design ensures 100% cleanability.

## DESIGN, ENGINEERING, AUTOMATION

The systems are designed and engineered at our design centre with experienced and highly qualified design team. The systems are built in the latest simulation and CAD software and visualized in 3D before being approved for manufacturing. All the equipments are fully integrated to perform as a single system with high quality and reliable automation. They are programmed in accordance with S88 and automated in accordance with GAMP 5 standards and are 21 CFR part 11 compliant.

## TESTING & FACTORY ACCEPTANCE TEST (FAT)

All systems are tested at our dedicated FAT testing area that are fully equipped with all required utilities. High quality testing instruments ensure the systems work fine under the designed conditions. Our QA team ensures complete documentation that are required before and during the FAT.

## KEY FEATURES

- Designed as per US FDA / cGMP / ASME/ PED/ compliance with ASME - BPE norms
- 21 CFR part 11 compliant, fully automated PLC controlled touch screen HMI
- Bottom mounted magnetic mixers with options for low / medium / high shear applications

- Flush bottom outlet valve with sampling / sterilization configurations
- Sterile flange connections of top dish / side ports to enhance CIP / SIP operations
- pH, temperature, conductivity, DO sensing through sanitary port on vessel shell
- Load cell for weight measurement / Level sensors for level measurements
- Block valves for dead leg compliance and compactness
- Components and instruments from reputed international vendors
- Interconnected product piping through sampling systems and pumps with filtration skids

## CAPACITY

5 - 30,000 Litres.



ENGINEERED FOR SEAMLESS INTEGRATION AND PERFORMANCE

DESIGNED AS PER US FDA / cGMP / ASME / PED & ASME - BPE COMPLIANCE

21 CFR PART 11 COMPLIANT WITH PLC CONTROLLED TOUCH SCREEN MMI







# SUPER SKIDS

## WHY SUPER SKIDS?

The cost of bringing drugs to the market has gone up significantly. “High, Early” sales and marketing strategies are becoming a must considering the risks and the stakes involved. Advanced methods of facility creation have to be adopted. The time frame from ‘Permit to Qualification’ has become very critical. Modular construction is more a necessity than an option. When the rewards for setting up the validated production facility in very short time is big and the stakes of being late are high, Super skids is the answer.

Our professional and experienced engineers apply best practices and knowledge that is in sync with your plant design, implementation and commissioning strategies. This allows your project cost, project schedules and project performance outcomes to be more predictable and get the plant ready for production at the shortest possible time.

## WHAT ARE SUPER SKIDS?

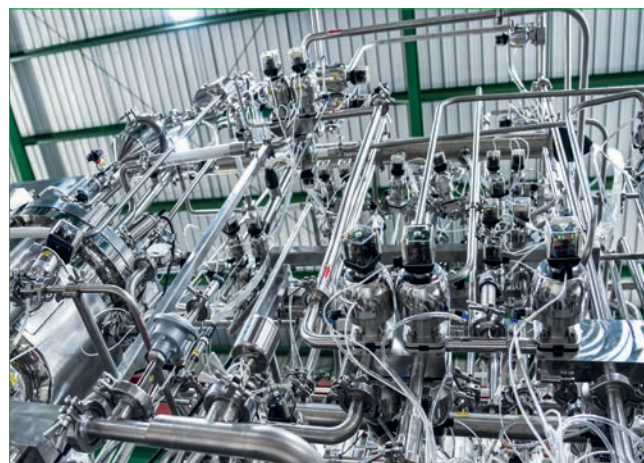
Super skids are fully integrated plant assembled and tested at our facility and shipped in assembled condition to your facility. This drastically reduces your project TAT ( Turn Around Time ), including the time for system validation. Our spacious manufacturing facility allows us to build fully integrated very large sized systems (Super skids) that are shipped directly to the project site and installed as fully integrated plant thereby reducing the overall project execution time.

## KEY ADVANTAGES

- Ship as single integrated plant without the need for dis-assembly and re-assembly at site
- Fully skid mounted, compact
- Modular construction
- Faster delivery
- Faster installation and validation
- Fully tested at our factory (FAT)
- Reduced project turn around time (TAT)

## CAPACITY

5 - 30,000 Litres.



SHIP AS FULLY INTEGRATED PLANT AND INSTALL

FASTER INSTALLATION AND VALIDATION

REDUCES THE PROJECT TURN AROUND TIME DRASTICALLY







# OINTMENT & CREAM PROCESSING SYSTEMS

We have been a leader for over 35 years with considerable expertise in designing and engineering systems for the manufacture of Ointment and Creams. Our systems are fully optimized for delivering the best performance with reduced life-cycle cost. Our systems are designed for optimization of key resources and designed with features that include;

- Flexible process parameters setting
- Variable shear force adjustment
- Fully contained processing system

## KEY FEATURES

- The easy-to-use mixer control package can incorporate process parameters storage for simple and fast set-up
- Heating / cooling and insulated jackets with temperature control and safety equipment
- Semi Contra Rotary agitator with open slot scraper design
- Short loop product re-circulation for smaller batch sizes
- Hydraulic lifting on manufacturing vessel top dish to facilitate product recovery
- Separate pre-mix vessels for wax and water phase
- Process piping with transfer panel design for automated plants
- Cleaning-in-place cycles with dosing systems
- In-line high shear mixer options

## VESSEL DESIGN

- Extensive research & development has produced the best combination of vessel and agitation system, offering high productivity, quality and yield

- Low relative batch size
- Conical design and proven geometric ratios ensure optimum product flow
- All surfaces angled to ensure ease of cleaning during CIP operations

## INTEGRATED VACUUM SYSTEMS

- Fully controllable to permit variation of vacuum levels according to the process phase
- Vacuum line can be fully flushed for sanitation purposes

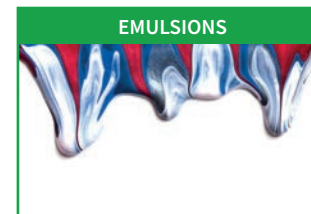
## USER FRIENDLY INTERFACE

- The easy-to-use mixer control package can incorporate process parameters storage for simple and fast set-up
- PLC based, with touch screen MMI and SCADA packages
- Choice of packages to suit application requirements
- Flexible configuration

## CAPACITY

5 - 20,000 Kgs.

## KEY APPLICATIONS



**BEST COMBINATION OF VESSEL AND AGITATION SYSTEM**

**FLEXIBLE PROCESS PARAMETER SETTING**

**FULLY CONTAINED PROCESSING SYSTEM**







# LIQUID ORAL PROCESSING SYSTEMS

## PERFECTED, OPTIMIZED, CUSTOMIZED

We provide customized, end to end solutions for liquid oral plants that are fully automated with SCADA controls or semi-automated as required. Our plants are designed with the highest quality of fabrication standards using the best components and instruments. They are also fully optimized for delivering the best performance with reduced life-cycle cost.

## PROCESS EQUIPMENTS

- Material handling and transfer
- Sugar syrup preparation
- Sugar syrup pre-filtration
- Solution preparation
- Solution storage
- Platform structure
- Transfer panels
- CIP Systems
- Plant automation
- API mixing

## STORAGE SYSTEMS

- Raw material storage
- Inverted sugar storage
- Liquid glucose storage
- Glycerine storage

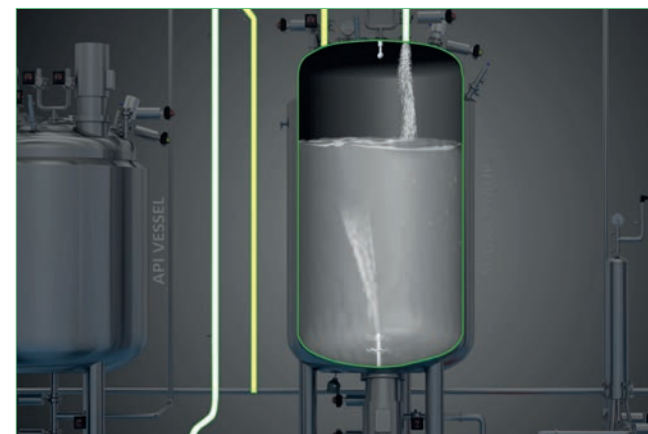
## KEY FEATURES, OUR PRODUCTS AND SERVICES

- Design of process, equipments and transfer piping
- Transfer systems for sugar through vacuum system
- Sugar preparation system with jacketed, insulated and cladded vessel with bottom entry propeller mixer for vigorous mixing
- In-line high shear mixer for suspensions

- Process vessels rated for vacuum
- EHEDG / 3A approved twin lobe pumps
- Electrically heat traced, insulated transfer lines of liquid glucose
- Back-washable stainless steel sintered filter for filtration
- Sanitary piping systems with butterfly valves
- Stainless steel operating platform with staircase and railing
- 21 CFR Part 11 compliant PLC / SCADA based automation system
- Automated CIP system
- Highly experienced team for installation and validation support

## CAPACITY

50 - 30,000 Litres.



CUSTOMIZED END TO END PROCESSING SYSTEMS

BEST PERFORMANCE, REDUCED LIFE CYCLE COSTS

21 CFR PART 11 COMPLIANT PLC / SCADA AUTOMATION



# PROJECT MANAGEMENT

## OUR TURNKEY APPROACH - 360° VISION, INTEGRATED AND SYNCHRONIZED

Over the past 35 years, our project management capabilities, workflow, training methods, project monitoring systems (software and measurable metrics) have been refined many times over.

Our highly skilled and experienced project management team has access to high end tools, training and project review mechanisms. This ensures timely project delivery and efficiency in dynamic resolution of project issues.

Our project team is always in sync with your requirement and site situations. Our established policies, business processes and guidelines are in sync to meet the rigorous FDA guidelines. Strong



internal quality processes and systems ensure all our systems are in compliance with the design documents and as per the agreed deliverables.

We have established standard methods and processes for project management. This serves as a guide in every project through all the phases of the project - from project planning, system design, system engineering, assembly, testing, installation and validation.

Adam Fabriwerk's project managers along with skilled, experienced and trained project engineers take complete charge of the project.



Our project team is reputed for;

- Responsible, with target-oriented attitude
- Having single point of contact with ownership attitude
- Assurance of agreed quality and deadlines
- Flexibility and transparent project change management
- Fast project execution
- Easy to understand, well organized project documentation delivery
- Support through the entire project lifecycle
- Quick decision making abilities
- Dynamism and responsiveness

**PROJECT MANAGEMENT METHODS REFINED MANY TIMES OVER THE LAST 35 YEARS**

**RESPONSIVE, EXPERIENCED, DYNAMIC PROJECT MANAGEMENT TEAM**

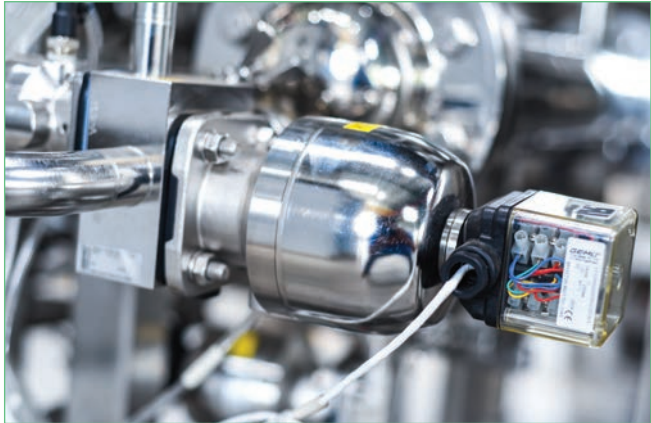
**ESTABLISHED METHODS AND PROCESS FOR PROJECT MANAGEMENT**



# OUR APPROACH TO QUALITY

Quality continues to be our identity. Every component that goes into our system passes through a stringent quality process by fully trained, committed and experienced quality experts. The team ensures dedicated focus on the **material, workmanship and documentation**. High quality and reliable *Orbital welding machine, Borescopy machines, Pipe Bending machines* and other key measuring instruments are integral to the quality of our systems. We rely on standard as well as project specific quality assurance and qualification procedures that ensure the conformity of the system to the designed specifications and GMP requirements.

Many bought out components like instruments, valves, pumps etc. are critical to the functioning of our systems. We have a stringent qualification standards for our partners. We buy from the most reliable and reputed international companies that are known for their quality and global service support. They are quality checked by our QC team to ensure they perform as designed and expected.



QUALITY CONTINUES TO BE OUR IDENTITY OVER THE LAST 35 YEARS

HIGH QUALITY TESTING AND MEASURING INSTRUMENTS

TRAINED, EXPERIENCED AND COMMITTED QA TEAM



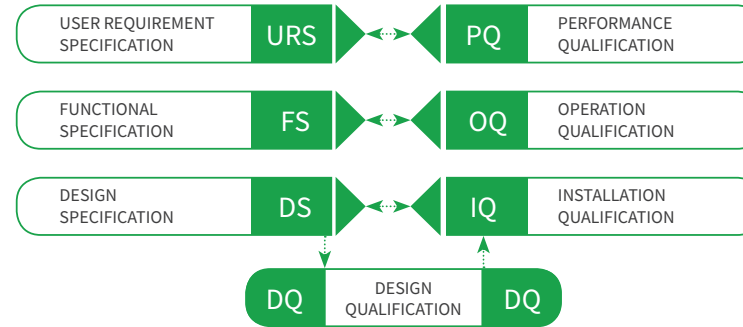
# VALIDATION & DOCUMENTATION

At Adam Fabriwerk, we understand the importance of validation. Our Quality Assurance team provides close assistance to our customers, throughout their validation cycle.

We have a dedicated, in-house Factory Acceptance Test (FAT) facility that is fully equipped with all the required utilities to ensure the systems that are ready are thoroughly tested and documented. Our QA team works closely with our clients to understand the validation and documentation needs and ensures the requisite support. Deviations are documented, attended to and cleared for inspection and shipment on approval.

Our Quality Assurance team ensures delivery of all the required documents like test certificates, MOC, drawings, P&ID, Weld certificates, Mill certificates, calibration certificates etc., are compiled and organized in an easy to retrieve format and handed over to our customers.

The QA team ensures full support for validation at the site and assist to qualify the system during installation as well as during the operation of the system. This is done in accordance with the functional and design specification and ensure the system is installed and operates as per the design approved.



**TRAINED AND COMMITTED QA TEAM FOR DOCUMENTATION SUPPORT**

**CLEAN, ORGANIZED, EASY TO RETRIEVE DOCUMENTATIONS**



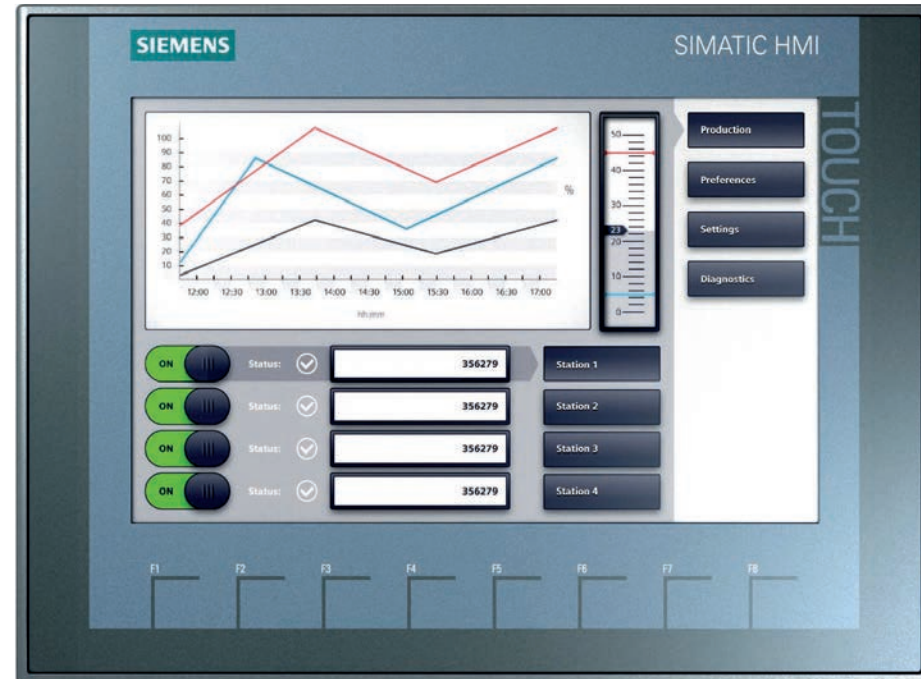
# INTELLIGENT AUTOMATION

We design comprehensive automation system that is reliable, easy to operate, connects, streamlines and sequences the processes seamlessly. Our system design ensures different equipments work together in harmonious sequence. Our ability to understand the process requirements in-dept, ensures robust, optimized, safe and user friendly system automation.

Automation that is driven by highly reliable and accurate instruments and controls deliver consistency and repeatability. A highly skilled, experienced and well trained electrical & automation team works together with process specialists to design automation sequences that are implemented and rigorously tested.

## KEY FEATURES

- 21 CFR part 11 compliant
- PLC-SCADA open solution
- As per GAMP 5 guidelines.
- Programming in accordance with S88
- HMI / IPC controls for localized control.
- Electronic Batch Records (EBR)



RELIABLE, EASY TO OPERATE  
AUTOMATION

AUTOMATION DRIVEN BY RELIABLE,  
WORLD CLASS INSTRUMENTS

SYSTEMS DESIGNED WITH  
21 CFR PART 11 COMPLIANCE





DELIVERING VALUE BY CUSTOMIZING SOLUTIONS  
PHARMA | BIOPHARMA PROCESSING SYSTEMS

HEAD OFFICE:

Adam Fabriwerk Pvt. Ltd.  
702, Tanishka, Akurli Road,  
Kandivali East, Mumbai - 400101,  
Maharashtra, India  
T : + 91-22-61776700  
E : info@adamfabriwerk.com  
W: www.adamfabriwerk.com

WORKS:

Survey No. 81, Plot No. A & B,  
Ambad, Nashik  
Maharashtra - 422010  
India

