

INTRODUCTION

- □ Established in 1975 by technocrats experienced in the field for Window Air-conditioner manufacturing and maintenance, and later on Airmax (Gujarat) Pvt. Ltd. has gradually grown to be preeminent designer, supplier, installer, servicer and repairer of Heating, Ventilation and Air Conditioning Systems (HVAC) Systems, Specially in Pharmaceuticals as per WHO.USFDA.MHRA.TGA norms.
- □ Airmax has 20 years plus experience for offering comprehensive solutions in Clean Room HVAC (Heating, Ventilation and Air Conditioning), Validation and Building Management systems(BMS).
- □ Doing Projects in Western, Northern & Eastern Part of India & Also Outside Indian Countries like Lebanon, Uzbekistan, Srilanka, Ghana etc...
- □ Our staff is experienced working with architects, engineers, owners and developers, plant managers, and other contractors to deliver the highest quality product within specifications and on schedule. This experience has found manifestation with repeat orders from all the Pharmaceutical majors.

ABOUT US

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 FOR WINDOW AIR-CONDITIONER MANUFACTURING AND
 MAINTENANCE. AIRMAX (GUJARAT) PVT. LTD. HAS GRADUALLY
 GROWN TO BE A PROMINENT DESIGNER, SUPPLIER, AND INSTALLER
 OF HEATING, VENTILATION AND AIR CONDITIONING SYSTEMS (HVAC)
 SYSTEMS WITH PRIMARY FOCUS IN THE PHARMACEUTICAL SECTOR
 WITH A THOROUGH KNOWLEDGE AND UNDERSTANDING OF THE
 USFDA, MHRA, TGA, EU, WHO GUIDELINES AND ISO STANDARDS USED
 WORLDWIDE, WORKING MAJORLY IN THE INDIAN SUBCONTINENT,
 AFRICAN SUBCONTINENT, CIS COUNTRIES, AND SO ON.
- AIRMAX HAS MORE THAN 29 YEARS OF EXPERIENCE, PROVIDING YOU
 WITH COMPREHENSIVE AND EFFECTIVE SOLUTIONS IN CLEAN ROOM
 HVAC (HEATING, VENTILATION AND AIR CONDITIONING),
 VALIDATION, AND BUILDING MANAGEMENT SYSTEMS (BMS), WHICH
 ARE SUITED TO YOUR NEEDS AND WHICH PERFECTLY FALL IN LINE
 WITH THE CONCERNED REGULATORY AUTHORITIES...

TYPE OF HVAC PROJECTS INVOLVED (PHARMACEUTICALS)

□ OSD - Oral Solid Dosage
 (Tablet, Capsule)
 □ OralLiquid
 □ ORS
 □ DPI
 □ SVP (Small Volume Parental)
 & LVP (Large Volume
 Parental)
 □ R & D Lab, QC Lab

Working with HVAC Consultant

□ SoftGelatin

- □ IPS Mehtalia consultants Pvt. Ltd.
 □ CGMP Pharmaplan
 □ Doshi consultants Pvt. ltd.
 □ MottMacDonald
 □ NNE Pharmaplan
 □ RIM Consultancy/ RIM Quality
 □ System
- ☐ Adept Consultant and Engineers ☐ DIBIS UtilitySolutions

COMPETENT FACILITY DESIGN AND EXECUTION IN ALL HVAC PROJECTS

- □ The pharmaceutical industry is undergoing rapid changes, competition will increase continuously, while pressure of costs on individual companies will continue to rise. This requires the development of more efficient solutions, with new paths being trod in the process.
- □ Current projects have to be executed <u>within ever shorter time limits</u> and are <u>subject to strictly predetermined</u> <u>budgets</u>. Meanwhile, The technology thereby employed has become <u>increasingly complex and demanding</u>.
- □ The regulatory requirements within the pharmaceutical industry are becoming increasingly wide-ranging. The GMP regulations are subject to constant development, although clear instructions are rarely issued. Nevertheless, your investment has to be fit for future. This requires a careful analysis of the demands made by authorities and a reliable interpretation of the GMP regulations.
- ☐ If you manufacture for foreign markets, the demands made by their national authorities such as, for example, the <u>US</u> <u>FDA</u>, the <u>Australian TGA or the British MHRA</u> exercise a significant influence.
- To achieve above, Client require a partner to propose optimum solutions which are both based on the regulatory environment and tailored to your objectives and to subsequently implement these efficiently. This partner must be familiar with all the elements necessary to a project and have the advantage of many years' professional experience in the GMP regulated industry. Moreover, it makes sense to engage the partner for the project's entire duration, from the initial design stages to the execution, commissioning and qualification and, if necessary, beyond this.

PROJECT PLANNING AND EXECUTION (HVAC)

- We employ tried and tested project planning and execution techniques which have proved during innumerable projects implemented on different scales. Quality and efficiency are always our top priority.
- Our project teams draw up an individual project schedule plan which is tailored to your specific requirements, based on proven standards and supplemented as the project advances. Deviations from the planned schedule are recognized in time allowing for the subsequent implementation of the necessary corrective measures.

Feasibility Study	Concept Design Second Opinion/ Value Engineering	Basic Design Revised Design after Value Engineering	Procurement evised Design after Installation			
	Client Decision/ Start	Ultimate Client Decision about Investment	Qualification Handover Support Validatio n		Production Start	Maintenance/ Customer Service
Consultancy		Design	Execution	Qualification/ Validation		Operation

OUR SERVICES

- □ We predominantly tend to view project work as the realization of interlinking thought processes. Each element makes its own contribution to the project's success. Here, the key factor is coordination.
- □ <u>An optimum flow of information</u> between the disciplines is crucial to a project's success or failure. A team of specialists with interdisciplinary knowledge is required in order to work together to interlink these elements.
- * We have these specialists at our disposal and have succeeded in implementing a tried and test project sequence model. We incorporate our knowledge of the overall context into your project, even if you entrust us only with partial services.

Our Strengths

- **■** Energy Efficient and Economical Design
- □ Commitment to Quality
- ☐ Strong Technical Set up
- ☐ Innovative Approach
- **■** Adhering to Time Schedule
- **■** Material Management
- Customer Satisfaction
- **Excellent Services during and after Completion of the Job**

CLEAN ROOM TECHNOLOGY

- ☐ Clean room technology plays a decisive role in respect of pharmaceutical industry processes. A safe process
 - environment is an important guarantee in terms of fully functioning production.
- Elements within clean room technology begin to play a crucial role during the conception development of new plants and revamps. Defined hygienic zones, air lock concepts and air pressure cascades defined from process requirements are just as important as optimum air flow within critical areas. These concepts have to be realized and technically optimized during the design phases. Our knowledge in respect of the installation of clean rooms is of particular significance. The components are handled under strict cleanliness requirements, even on construction site conditions.
- If required, we can also develop and install specific designs to meet your needs, tailored to your objectives. After installation and cleaning, the clean room will be subject to extensive tests. Our qualification team will provide you with the necessary information on complying with the room's conditions in terms of ventilation. differential pressure, temperature, humidity, particles and microorganisms, smoke studies during qualification.

QUALIFICATION

<u>Design Phase</u>	Exect	<u>Validation Phase</u>	
Design Qualification (DO)	Installation Oualificat ion (IO)	Operational Qualification (OQ)	Performance Oualification (PO)
Basic & Detail Engineering	Detail Engineering	SOP Design	SOP Design
GMP Review & Value Addition	Material Order/ Delivery	Personnel Trainng	Personnel Trainng
Risk Analysis (RA)	FAT	Testing to evaluate Operation of HVAC System	System Wise Testing to evaluate Performance of HVAC System
Technical Submittals	Supervision & Installation	Operational Qualification Reports	Validation Reports
Final Drawings for Execution	SAT		
	Material Certificates/ Instruments Calibration		

- □ The good old days, when a qualification team used to visit the site and qualify the facilities after commissioning was complete, are long gone. Nowadays, the early integration of all elements of the qualification process is the key to success. Important decisions are now made during the development of the validation master plan and the initial risk analyses, which may have a significant effect on project.
- □ Concrete decisions concerning the design of individual systems and the scope of the qualification process. The above ensures compliance with current FDA regulations at the very beginning.
- □ The efficient coordination of acceptance tests, commissioning activities and qualification is our top priority. This integrated process helps us to avoid double work and allows us to qualify the facilities quickly and efficiently. If any discrepancies arise, these are documented and dealt with "change control system".
- □ We are able to offer you an extensive consultancy and support service as regards performance qualification, cleaning validation and computer system validation, in addition to the IQ and OQ.

MAINTENANCE AND TECHNICAL FACILITY MANAGEMENT

- □ Nobody can maintain your facilities as good as those responsible for their design and construction!
- This is precisely why we have made maintenance and technical facility management one of our top priorities over recent years. At Airmax, the emphasis is on rapid fault repairs and preventive maintenance.
- □ It goes without saying that we remain on call 24-7, all year through, at your disposal to solve those tricky problem cases. And, in the process, we don't solely contribute to secure facility operations, but also ensure that your facilities are equipped with a longerlife-span.
- Additionally, regular requalification safeguard and document the GMP compliant status of your quality critical systems.

WHY AIRMAX?

Our professional experience

Our origins lie in pharmaceutical technology and clean room technology. We are, meanwhile, far more than merely experienced specialists in these fields. We have built on our core competencies and developed into comprehensive, professional service provider and general contractor.

Our employees

Our employees represent our strongest potential. Many of these have longstanding experience in pharmaceutical facility design and construction. Others spent many years on your side, as facility operators, operational engineers in pharmaceutical facilities or were even active in the maintenance sector. You can be sure that we know your needs and understand your wishes.

Our working methodology

Our strategies are both tried and tested and flexible. We tailor our project execution to your standards, requirements and specifications. We are in a position to provide you with comprehensive services during all project phases. And, as we employ all the specialists necessary to the various project phases in house, your interfaces to us are minimized.

PROJECT GALLERY











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