



Align your production seamlessly with your Business Strategy

We combine engineering and management expertise to deliver operational excellence, by optimising your productivity, quality and yield.

Led by Umesh Kapre, Training Inc. endeavours to fulfil all your training needs at a single source. Acting as Technology Liaison between talent and Top Management, we align production activity seamlessly with your Business Strategy.

Our passion is to help develop a culture of keen observation and precision engineering in your organisation. Training Inc. excels at training and consulting for Cost Containment, Technology Upgrades, Effectiveness of Safety Systems, Manufacturing Efficiency and cGMP.



## Umesh Kapre

Mr. Kapre has more than 35 years of rich experience in the API Industry. He believes that both the transfer of knowledge and continuous education are critical elements to business success. Having served as an engineer and valued Operational Head, he has complete insight into Quality Systems Implementation, cGMP and Regulatory Compliance, Engineering, all Technical, Statutory, Regulatory Audits and Process Management.

His forte is developing and instilling customized success metrics that help organizations achieve their business objectives.



## Our Expertise

Strategic Management	Pharmaceutical Manufacturing	cGMP Audit / Six Sigma / GEP
Project Management	Chemical Engineering	Safety Audit / SOP
Profit Centre Operation	Quality Assurance	Energy Management
Training and Development	Regulatory Affairs	Waste Management
Team Leadership	Crisis Management	Energy Saving / MIS

## Our Knowledge Share

Are you prepared for your overseas regulatory Audits (US FDA, MHRA, TGA, WHO Geneva)?

We help you get there by training your talent and establishing seamless systems

Are your critical process parameters accurate?

We audit, test and fine-tune for precision

Have you re-engineered your processes for optimum profitability?

Our job is to ensure optimum usage of resources

Is your technical and engineering talent fully motivated and aligned with business strategy?

We upskill and educate talent, instilling a sense of ownership and confidence



# Our Offering, Your Advantage

We facilitate execution of Business Strategy at the grass root level in your plant, offering you several benefits -

- ➔ Cost Cutting
- ➔ Improved Production Quality
- ➔ Good Audit Reports
- ➔ Enhanced Productivity and Yield
- ➔ Reduced Incidents Empowered and
- ➔ Motivated Operational Talent

## Our Process

### Stage 1 Identifying Training Needs

We brainstorm with Senior Management, HR and Plant Heads, and observe your production processes to identify training needs.



### Stage 2 Training on-site and off-site

We offer classroom lectures, and develop on-site cost reduction projects with your talent.



### Stage 3 Follow Up and Soft Skills Training

We follow up with monthly checks and reports, or as per your organization's needs. We impart soft skills training to motivate and build confidence in answering audit questions, communicating with Management and developing interpersonal skills and awareness.



### Stage 4 Feed Back and Sustainability

We invite feedback from Top Management and Operations on improvements in performance, cost savings, compliance and return on the training investment. Processes and checks are put in place to sustain the level of performance, quality and productivity.



# Training Programs

Our training programs are specifically designed to create operational excellence in the API / Chemical Industry.

Empower your people to improve business outcomes and efficiency by implementing best practices. Our integrated approach embraces functional and technical expertise through Master Classes, On-Site Demonstrations and Cost Reduction Projects. We believe that good audit reports, cost containment and reduced incidents are a measure of effective training.

## Master Classes and Cost Reduction Projects

The Master Class is conducted after verifying your training needs and evaluating the depth of understanding of the staff. Class room training by industry experts includes lectures with practical and real-time examples, discussion or group work. Labs may be set up for demonstrations, experiments and simulations while Cost Reduction Projects are reviewed periodically. The objective is to inculcate safety, cGMP and energy conservation as values in your organization.



### Focus Areas:

1. Technical Training
2. cGMP Training
3. Safety Training
4. Energy Savings
5. Soft Skills Training



# 1. Technical Training

The course focuses on basic theory, practices and integrated solutions, with an emphasis on problem solving. Control of critical quality attributes is emphasized across key areas and multiple approaches are evaluated. The design of processes to yield optimal products will be a key aspect. Our Technical Training Program covers the following processes:

1. Filtration Science
2. Drying Science
3. Crystallization Science
4. Distillation Science

- Theory
- Types of equipment
- Selection Criteria
- Selection of Equipment and MOC
- Safety related to unit operation and equipment
- cGMP Requirements and Validation
- Energy Savings



## 2. cGMP Training

Our comprehensive curriculum of GMP training includes discussions, case studies, and group exercises which are taught in an enthusiastic, interactive manner. Course Covers:

- a. How to write SOPs and Master BPRs
  - Identification of CPP
  - How to Review BPR
  - Overview of ICH Guidelines
- b. Water System
  - Design
  - URS and FRS
  - Generation
  - Distribution
  - Validation
  - Audit Preparation
- c. HVAC and Classification
  - Classification
  - Different Types of Filters
  - Various Types of Standard
  - Clean Room Requirements
  - Air Changes and Differential Pressure
  - Elements of AHU and Validation
- d. Preventive / Shut-Down Maintenance
  - What is PM / SM?
  - Importance of PM / SM
  - Scheduling PM / SM
  - Organizing PM / SM
  - cGMP Requirements
  - Documentation
- e. Calibration
  - What is Calibration?
  - Need for Calibration
  - Standard Calibration Procedures
  - How do you fix frequencies?
  - cGMP Requirements
  - Documentation
- f. Validations
  - Process Validation
  - Blender Validation
  - Microniser Validation
  - Nitrogen Generation
  - System Suitability
  - Cleaning Validation
- g. Qualifications
  - Equipment Qualification
  - Facility Qualification
  - System Qualification
  - System Qualification
- h. Facing a Regulatory Inspection
- i. Data integrity
  - Regulatory view on data management
  - ALCOA model for data management
  - Breach of data integrity (BDI)
  - Examples of Improper practice
  - Data integrity & cGMP violations
  - Detection & prevention BDI
- j. Market complaints



## 3. Safety

We consistently ensure that you are manufacturing in line with compliance guidelines. By planning for and reducing risk, you will reduce cost and regulatory burden of changes in the future. The Safety course covers:

a. Near Miss

- What is a Near Miss?
- Why is Near Miss not reported?
- Significance of reporting a Near Miss
- How to report a Near Miss
- Root Cause Analysis
- Action Plan
- Case Study

b. Static Electricity

- Theory of Static Electricity
- Generation of SE
- Dissipation of SE
- Prevention of SE
- Case Study

c. Behavioural Safety

- How Safe are you?
- One Minute Safety
- Unsafe act and unsafe conditions
- Safety and Behaviour
- Paradigm Shift
- Case Study





## 4. Energy Savings

We help you create Energy Efficiency by implementing financially attractive and technically viable improvements of Thermal, Electrical and Process Savings in you power plant. The Energy Savings course covers:

a. Thermal Savings

- Boiler Efficiency
- Insulation Losses
- Use of alternate source of heating
- Waste Heat Recovery

b. Electrical Savings

- Motor Efficiency
- Transmission Losses
- Pumps and Blowers Efficiency
- Compressor Losses
- Savings in Lighting

c. Process Savings

- Unit Operation Savings
- Savings by Optimum Capacity Utilization
- Savings through Time Cycle Reduction
- Savings through Increased Throughput



## 5. Soft Skills Training

The mere presence of technical abilities does not guarantee success. Soft skills are essential for winning the race. Depending on the style and the operations of your organization, the role and utility of soft skills may vary. We help your employees develop goal orientation and critical thinking skills through the following modules:

### a. Leadership

- Leader or Manager
- Types of Leadership
- Qualities of a Good Leader
- How to develop Leadership Qualities
- Identify: What Type of Leader am I?
- Case Study

### b. Communication

- What is Communication
- Elements of Communication
- Types of Communication
- Effective Communication
- Where am I?
- How to become an Effective Communicator
- Case Study

### c. Motivation

- What is Motivation?
- Theory of Motivation
- Self Motivation
- How to Motivate Others
- Case Study







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