

SMALL AUTOMATION – BIG IMPACT

The Automation Imperative for Hyderabad's Pharma Leaders

Presented to the Bulk Drugs Manufacturing Association
(BDMA)

INSTRUMENTS : PORTFOLIO

Process



Clean Room



Clocks



Lab



Zone 1 HMI



HEAT TRANSFER SYSTEMS : PORTFOLIO

Dedicated



Packaged Utility



Multiple Header



Chillers

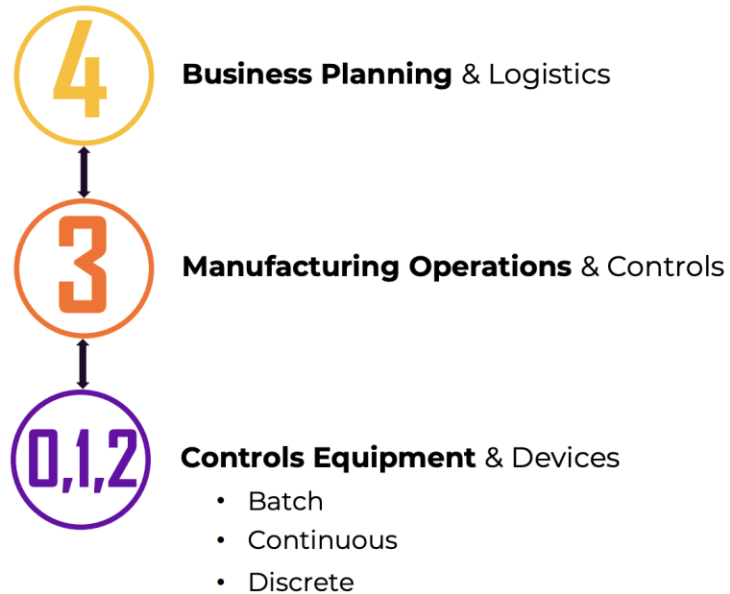


Parallel Synthesis



AUTOMATION: PORTFOLIO

S-95 Capabilities



Interface to ERP – Level 4

- Production Schedule
- Production from Plan, Inventory update
- Production capability, performance and cost

Information Solutions – Level 3

- Production Management
- Performance Analysis
- Quality Management
- AI/ML, Analytics
- Performance Analysis – OEE, KPIs, Downtime
- Alarm management
- Real-time quality systems SPC/SQC/LIMS
- Document control, Electronic Batch Records

Automation / Process Control – Level 0, 1, 2

- Automation planning and design
- Continuous & S88 batch control integration
- Electrical and Network Design
- Instrumentation specification
- Installation /cutover engineering & management
- Testing, Commissioning & Validation
- Training/Support

KEY NUMBERS

Revenue

300Cr

CUSTOMERS

1500

EMPLOYEES

600

EXPERIENCE

30+

GROWTH

30%

INSTALLED

2000

THE TRIPLE THREAT FACING OUR INDUSTRY



REGULATORY SCRUTINY

US FDA and EU GMP standards are evolving. "Data Integrity" is no longer optional; it is the primary focus of audits.

GLOBAL COMPETITION

The "China Plus One" strategy is an opportunity, but only if we match global standards in cost and consistency.



PROCESS SAFETY

Recent incidents highlight the urgent need to remove human intervention from hazardous reaction zones.

THE "DIGITAL FACTORY" COMPONENTS



SMART INSTRUMENTATION



ON/OFF + CONTROL VALVES



CONTROL SYSTEM

OVERCOMING BARRIERS

THE COST MYTH

The biggest hesitation is often Upfront CAPEX. However, when we factor in:

- Cost of a single rejected batch + Out of spec
- Cost of regulatory remediations
- Energy savings from optimized utilities

The ROI for full automation is typically realized within **18 to 24 months**.

THE TALENT SHIFT

Automation doesn't just replace manual labor; it upskills our workforce. We move from "operators turning valves" to "technicians managing systems."

Hyderabad has the engineering talent pool to support this transition better than any other city in India.

A ROADMAP FOR BDMA MEMBERS

A scalable pathway to digital maturity: From fundamental sensing to plant-wide intelligence.



1. MEASURE & LOG

The Foundation: Robust field instruments and simple 21 CFR Part 11 compliant Data Loggers.

We ensure every critical parameter is captured accurately at the source.



2. AUTOMATE & CONTROL

The Core: Integrated PLC & SCADA systems. We move from monitoring to active control of Reactors, Solvent Recovery Columns, and Utilities, eliminating manual variability.



3. DIGITIZE & COMPLY

The Future: Paperless manufacturing. Our Electronic Batch Manufacturing Records (EBMR) and MES solutions.

AUTOMATION SOLUTIONS

Simple Automation

1. Layer Separation
2. Addition Control
3. Alarm Management
4. Data Acquisition
5. HVAC Control/EMS
6. Vacuum Control System
7. Equipment Time Cycle Monitoring

Block Automation

1. Reactor Process Control
2. Solvent Dispensing
3. Solven Recovery
4. Reactor Utility Automation
5. Hydrogenation

Plant Automation

1. EBMR Solution

CASE STUDY : DATA ACQUISITION

THE CHALLENGE

- Manual logbooks are prone to transcription errors, illegible handwriting, or missing entries.
- In API synthesis, slight variations in temperature ramp rates or dosing speeds can drastically affect the impurity profile.
- When a batch fails quality testing (Out of Specification - OOS), the investigation often halts production.



CASE STUDY : DATA ACQUISITION

THE SOLUTION :

Parameter Monitoring

DAQ systems record values automatically (e.g., every second), creating an unalterable digital record.

SCADA Visualization

You pull up the historian graph. You might see that at 3:14 AM, the agitator RPM dropped by 10% for five minutes, or the cooling brine flow fluctuated.

Audit Trails

DAQ systems record not just the process data, but *who* changed a setpoint and *when*. If an operator changes a temperature limit from 50°C to 60°C, the system stamps the time and User ID, satisfying auditors' demand for traceability.

Predictive Maintenance (Asset Management)

DAQ systems monitor equipment health indicators, such as vibration on centrifuge motors or differential pressure across a scrubber.

CASE STUDY : DATA ACQUISITION

THE BENEFITS



Regulatory Compliance

ALCOA+ Compliance: Automated data is naturally **A**ttributable, **L**egible, **C**ontemporaneous, **O**riginal, and **A**ccurate.



"Golden Batch" Replication

Every batch produced matches the highest yield and purity standards, reducing the cost of goods sold (COGS).



Root Cause Analysis (RCA)

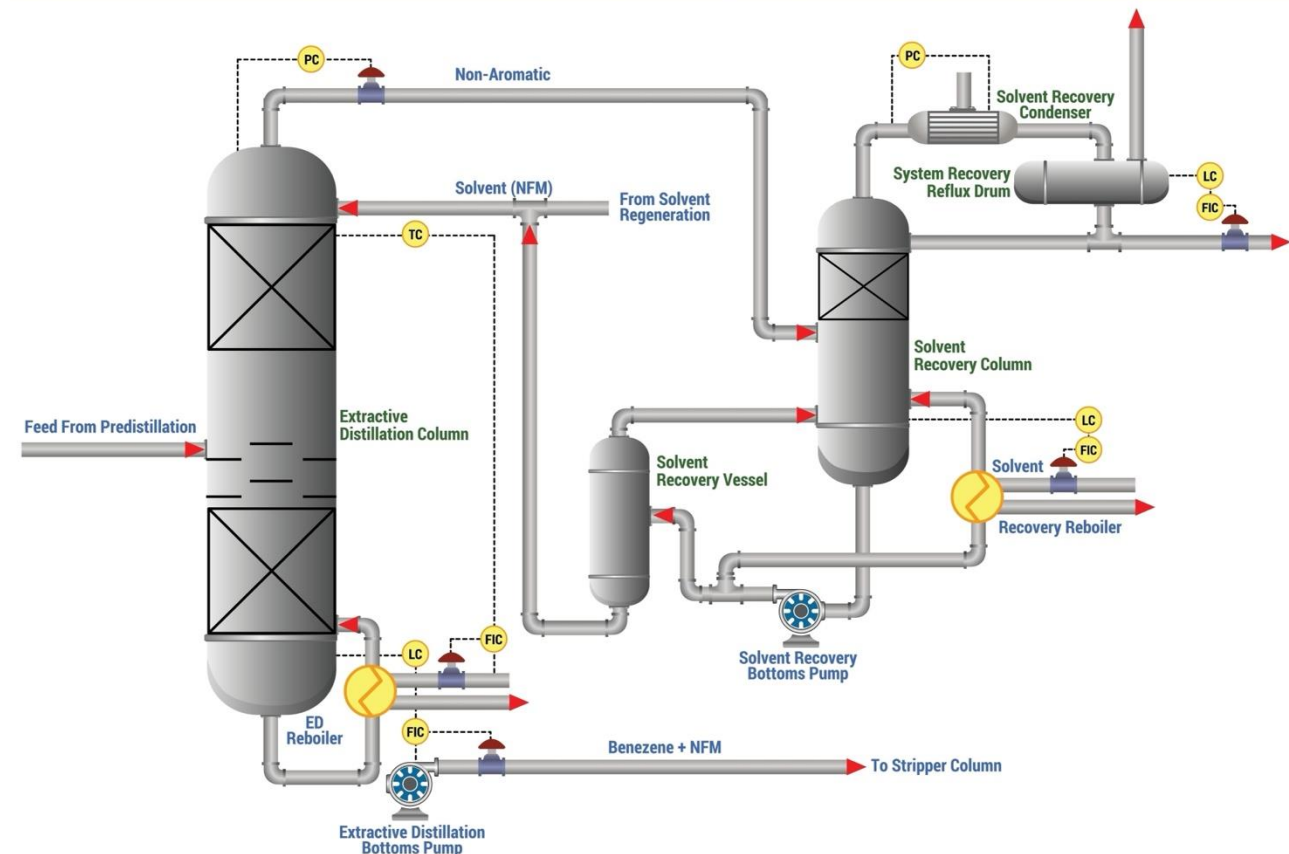
Pinpoint the exact cause of failure instantly, implement a Corrective Action (CAPA)

CASE STUDY : SOLVENT RECOVERY

THE CHALLENGE

- Operators often run the steam valve "wide open" or at a fixed percentage to play it safe, regardless of the feed rate. This leads to "over-boiling" and massive energy waste.
- Operators set a fixed reflux rate. If the feed composition changes (e.g., the waste solvent becomes more dilute), the fixed reflux isn't enough, and impure solvent slips into the product tank, ruining the recovery batch.

Process Flow Diagram



CASE STUDY : SOLVENT RECOVERY

THE SOLUTION :

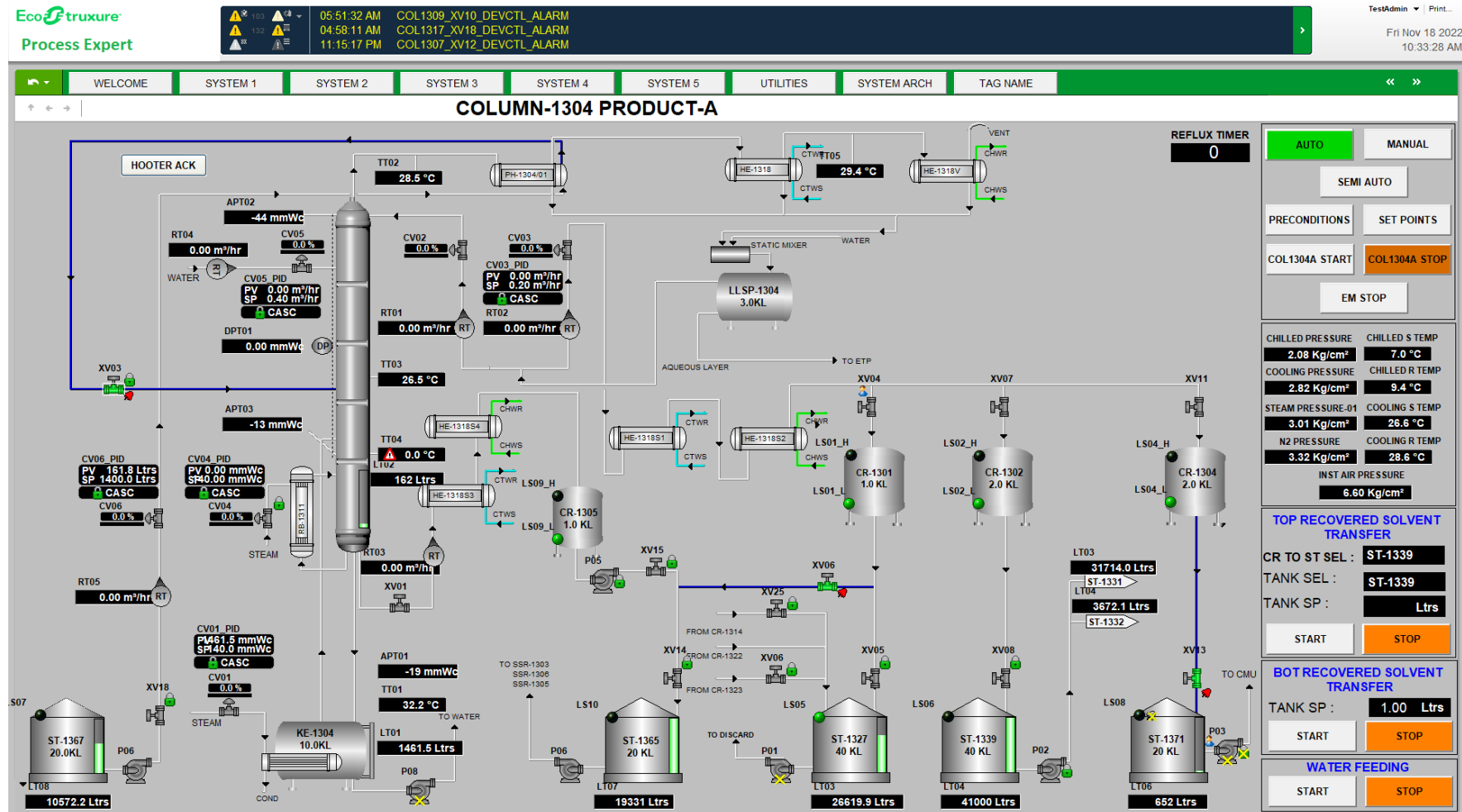
Feed-Forward Control Loop

Measures the incoming feed flow rate and temperature, and calculates exactly how much steam is needed to vaporize that specific mass and adjusts the steam control valve accordingly.

Precise Purity Control (Reflux Ratio Optimization)

Online temperature sensors (on specific trays) or inline analyzers (Near-Infrared/Refractometers) monitor the separation profile inside the column. The system dynamically adjusts the Reflux Valve to maintain the target purity, regardless of feed disturbances.

CASE STUDY : SOLVENT RECOVERY



CASE STUDY : SOLVENT RECOVERY

THE BENEFITS



Maximizing Hydraulic Capacity

You can process **10–15% more volume per hour** compared to manual operation, effectively increasing the plant's capacity without buying new hardware.



High Purity

Consistent "Spec-Quality" solvent, eliminating the need for re-distillation (re-work).



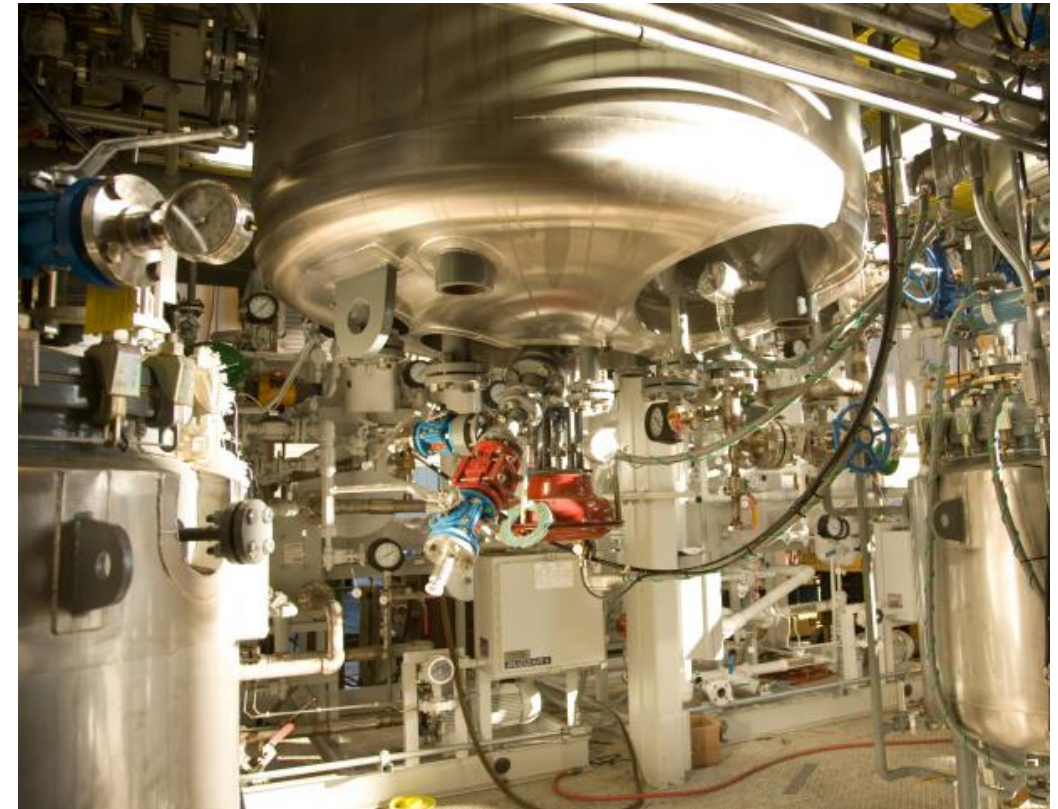
Cost Saving

This typically reduces steam consumption by **15–20%**, a massive saving for high-volume plants.

CASE STUDY : REACTOR UTILITY AUTOMATION

THE CHALLENGE

- Manual control often leads to "overshoot" (getting too hot) and "undershoot" (getting too cold), creating a zigzag temperature profile.
- Utility cross contamination is the biggest issue in manual temperature control. Massive amount of steam and refrigeration energy is lost
- Highly exothermic reactions (like Hydrogenation, or Nitration) can spiral out of control in seconds.



CASE STUDY : REACTOR UTILITY AUTOMATION

THE SOLUTION :

Cascade Control

Master Loop monitors the internal Batch Temperature.
Slave Loop monitors the Jacket/Utility Temperature.

Interlocks

The heating valve completely closes (and the jacket drains) before the cooling valve begins to open. This prevents the utilities from "fighting" each other, saving massive amounts of steam and refrigeration energy.

CASE STUDY : REACTOR UTILITY AUTOMATION

THE BENEFITS



Regulatory Compliance

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Precision Control

Every batch produced matches the highest yield and purity standards, reducing the cost of goods sold (COGS).



Root Cause Analysis (RCA)

Pinpoint the exact cause of failure instantly, implement a Corrective Action (CAPA)

CASE STUDY : LAYER SEPARATION

THE CHALLENGE

- ✓ **Reliance on Visuals:** Operators must physically watch the sight glass, often for hours, waiting for the phase change. This is inefficient and error-prone.
- ✓ **"Rag Layers":** Emulsions or cloudy interfaces can make the separation point nearly impossible to distinguish visually, leading to product loss.
- ✓ **Safety Hazards:** Manual operation often requires proximity to the process, increasing exposure risk to hazardous solvent fumes.



CASE STUDY : LAYER SEPARATION

THE SOLUTION : CONDUCTIVITY BASED CONTROL

The Principle of Detection

This method exploits the drastic difference in electrical conductivity between phases. Aqueous layers are typically highly conductive (>1 mS/cm), while organic solvents are non-conductive (~ 0 μ S/cm).

The "Step Change"

An inline conductivity sensor is installed at the vessel outlet. As the liquid drains, the system monitors the signal. When the interface passes the sensor, a massive "step change" in conductivity occurs instantly, signaling the PLC to act.

Rapid Response

Upon detecting the interface, the control loop triggers the Flow Control Valve (FCV). The valve must have a closure time of <1 second to prevent the wrong phase from entering the downstream tank.

Throttling Capabilities

Advanced strategies use the valve to "throttle" (slow down) the flow as the mass-balance calculation predicts the interface is near, ensuring the highest possible separation accuracy.

CASE STUDY : LAYER SEPARATION

THE BENEFITS



Maximized Yield

Precise, repeatable "cut" points minimize the loss of active pharmaceutical ingredients (API) into the waste solvent layer.



Enhanced Safety

Moves the operator away from the equipment. The closed-loop process reduces the risk of chemical exposure and spills.



24/7 Efficiency

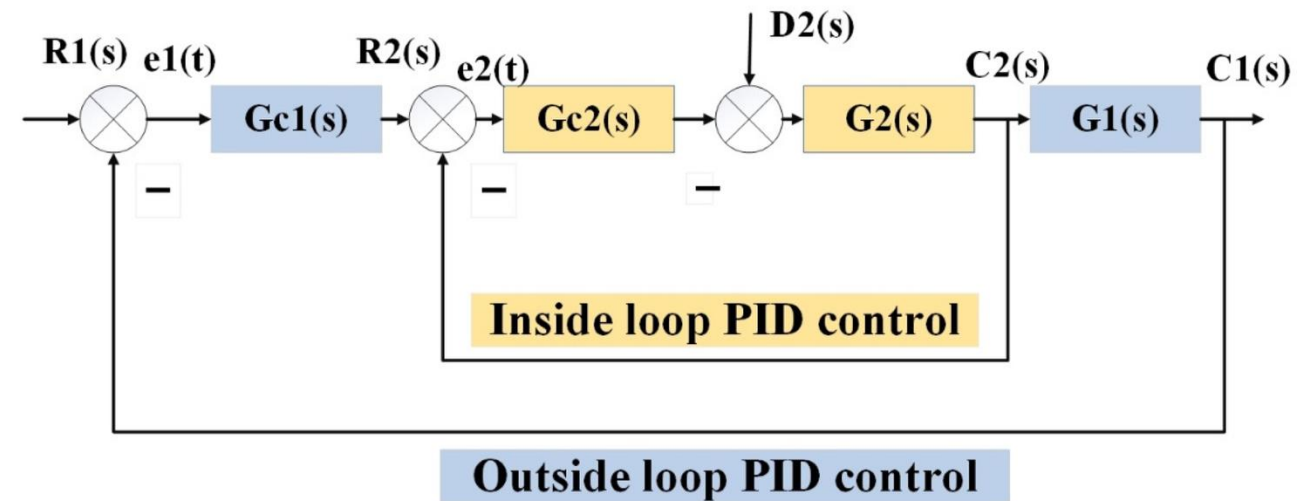
Automated sequences run consistently without fatigue, allowing operators to focus on higher-value tasks like sampling or batch setup.

CASE STUDY : ADDITION CONTROL

THE CHALLENGE

- Maintaining pH and temperature during addition is a tedious job and requires constant monitoring
- Failure of utility or agitator can cause catastrophic runaway reactions

Dual-loop PID control algorithm



CASE STUDY : ADDITION CONTROL

THE SOLUTION :

Parameter Monitoring

Monitor the pH, temperature and rate of addition using load cell. Additionally monitor agitator RPM, utility temperature

Redundant Instrumentation

Redundant instruments for critical process parameters removes single point of failure

Interlocks

Addition shutdown upon agitator or utility failure

Flow Control Valve

Flow control valve allows precise control on addition rate

CASE STUDY : ADDITION CONTROL

THE BENEFITS



Maximized Yield

Batch to batch consistency and higher yield



Enhanced Safety

Safe operating conditions under any adverse event



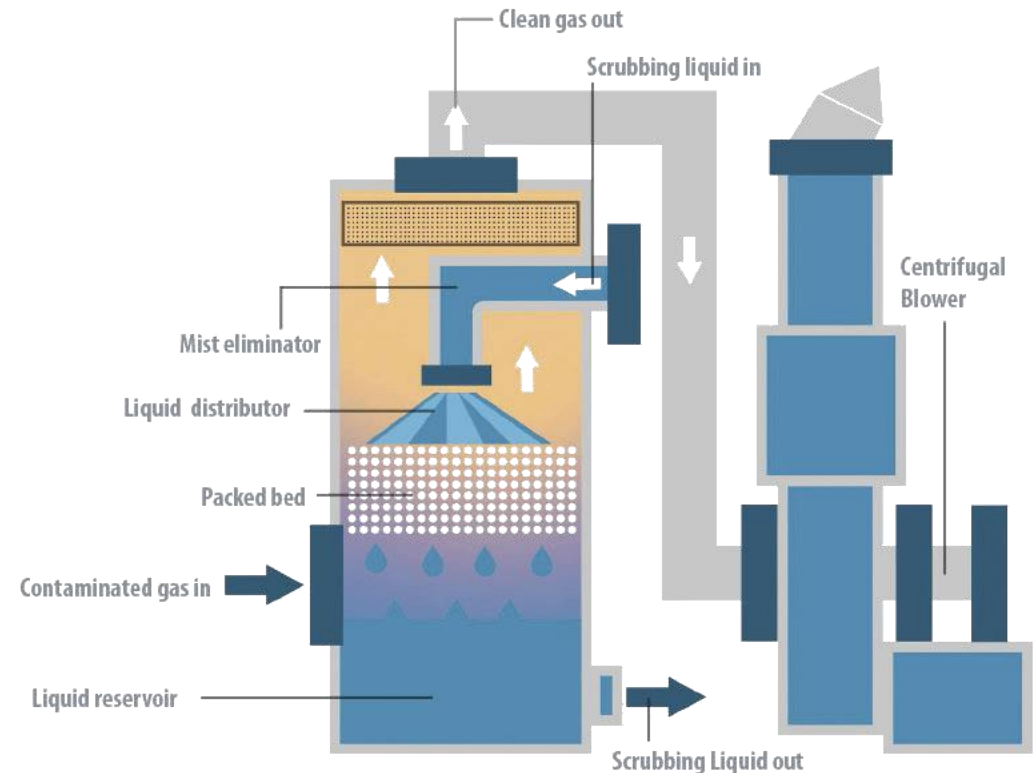
24/7 Efficiency

Automated sequences run consistently without fatigue, allowing operators to focus on higher-value tasks like sampling or batch setup.

CASE STUDY : SCRUBBER AUTOMATION

THE CHALLENGE

Industrial scrubber must ensure that Blower is running continuously, maintaining a blower draft, ensure circulation pump is running, and maintain the pH. Any failure in the above components can cause dangerous gasses to release into the atmosphere.



CASE STUDY : SCRUBBER AUTOMATION

THE SOLUTION :

Parameter Monitoring

Monitor the blower draft using differential pressure transmitter, circulation pump feedback, pH & ORP of the scrubbing solution

Dynamic Dosing control

Alkali solution is automatically added based on the pH.
Dosing is adjusted based on the load

Interlocks

Shutdown the reaction, if any component of the scrubber is malfunctioning

Automated Blowdown & Energy Optimization

Conductivity sensor monitor the concentration of the dissolved salts in the scrubbing liquid. VFD connected to the ID fan operates based on the reactor load

CASE STUDY : SCRUBBER AUTOMATION

THE BENEFITS



Regulatory Compliance

Adhere to PCB norms with no
breakthrough emissions



Enhanced Safety

Packing fouling can easily be detected and
prevent back pressure



24/7 Efficiency

Operating on VFD can reduce the energy
consumption by 50%

CASE STUDY : TANK LEVEL AUTOMATION

THE CHALLENGE

- Manual tank filling is the #1 cause of industrial spills (environmental disasters)
- Running a pump dry (cavitation) can destroy expensive mechanical seals and impellers in minutes.
- In Pharma, accounting for every litre of solvent is a regulatory requirement (to prevent diversion or theft) and a cost control measure



CASE STUDY : TANK LEVEL AUTOMATION

THE SOLUTION :

Parameter Monitoring

A Level Transmitter (Radar, Ultrasonic, or Differential Pressure) continuously sends the current level (Process Variable) to the PLC/DCS.

Dry Run Protection

The automation system monitors the low level. If the tank level drops below a critical point (e.g., 5%), the system triggers a **"Low-Low" alarm** and instantly trips the discharge pump.

Interlocks

The level transmitter tells the inlet valve to close when the tank reaches 90%.
An independent **High-Level Switch** (often a vibrating fork switch) acts as a fail-safe.

Inventory Management & Reconciliation

The Level Transmitter data is integrated with the plant's historian software. It calculates the volume based on the tank's geometry (strapping table) and the liquid's specific gravity.

CASE STUDY : TANK LEVEL AUTOMATION

THE BENEFITS



Regulatory Compliance

Adhere to PCB norms with no
breakthrough emissions



Enhanced Safety

Hazardous chemicals never overflow,
preventing fire risks

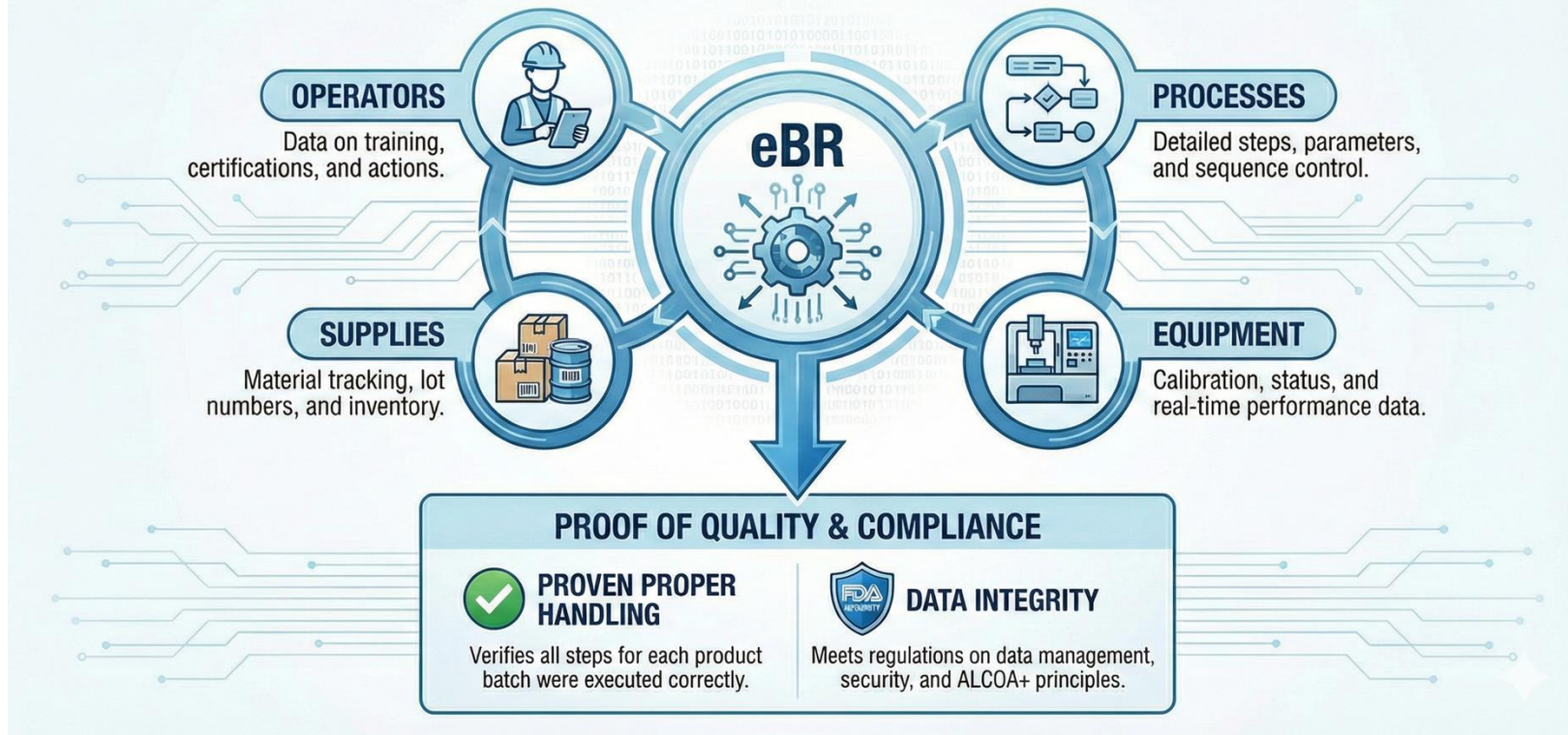


24/7 Efficiency

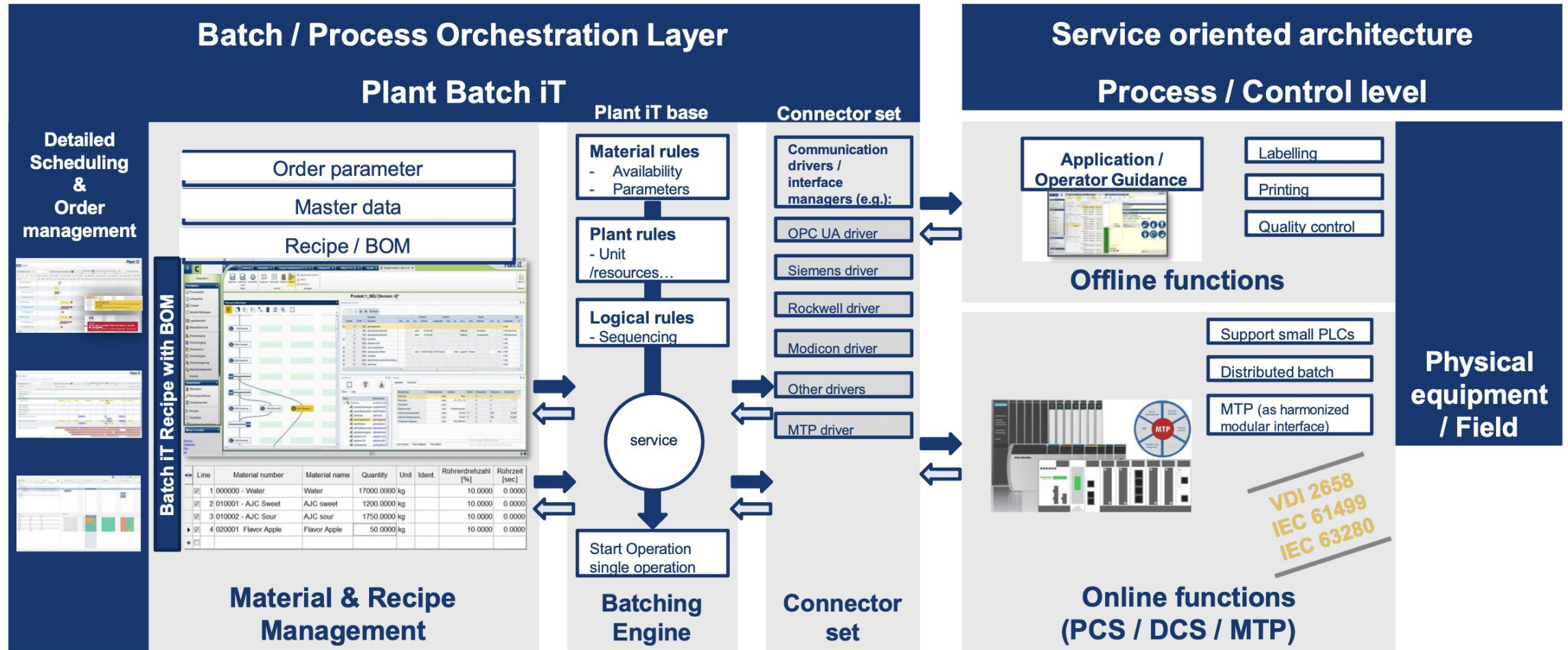
This extends the lifespan of your rotating
equipment and prevents maintenance
downtime

CASE STUDY : Electronic Batch Record

ELECTRONIC BATCH RECORD (eBR): THE LYNCHPIN OF DIGITAL TRANSFORMATION



CASE STUDY : Electronic Batch Record



CASE STUDY : Electronic Batch Record

THE BENEFITS

- Gives the manufacturer a complete digital documentation of all its production steps
- **Work flow automation**
- Remove manual entries from operators, ensuring data integrity, and simplifying the process
- Data transparency is crucial for quality control

"The factories of the future will not be measured by the number of people on the floor, but by the intelligence of the systems that run them."