

# **Process Automation System (PAS) – Simplified Sub Control Narrative**

## **1. Purpose and Scope**

The Process Automation System (PAS) is designed to control, monitor, and automate manufacturing processes involved in bulk drug substance production. The system supports multiple process modes including fed-batch, intensified fed-batch, hybrid perfusion, and continuous perfusion processes.

This sub-control narrative provides a high-level overview of key controls implemented within PAS to ensure process consistency, data integrity, product quality, and operational safety.

## **2. System Overview**

PAS functions as a centralized automation platform that:

- Controls process equipment and unit operations
- Interfaces with OEM skid systems
- Collects, monitors, and historizes process data
- Generates alarms and enforces control limits

OEM-controlled skids are treated as black-box systems, with PAS exchanging predefined commands and data through standardized interfaces.

## **3. Key Control Objectives**

The primary control objectives of PAS are:

- To ensure controlled and repeatable manufacturing operations
- To prevent out-of-specification (OOS) conditions
- To maintain proper sequencing of process steps
- To ensure safe operation of equipment
- To provide traceability through alarms and historical data

## **4. Surge Vessel Controls**

Surge vessels are used to manage material flow between unit operations.

**Key Controls:**

- Weight, pH, and conductivity are continuously monitored
- Automated addition control adjusts pH or conductivity when enabled
- Divert valves redirect flow when vessel weight exceeds defined limits
- Alarms are triggered when flow imbalance or abnormal conditions are detected

These controls prevent overfilling, incorrect material routing, and unstable process conditions.

## 5. Process Configuration Controls

PAS allows operators to configure the sequence of unit operations prior to each run.

### Key Controls:

- Operator-configurable process sequencing
- Assignment of surge vessels through system parameters
- Configuration changes permitted only before process execution

This ensures flexibility while preventing unauthorized or mid-run changes.

## 6. Unit Operation Controls

PAS manages and coordinates multiple unit operations including:

- Cell culture and perfusion
- Chromatography
- Depth filtration
- Viral inactivation
- Final filtration and formulation

### Common Control Features Across Unit Operations:

- Automated startup, feed, pause, shutdown, and abort states
- Flow and speed control based on vessel weight and process conditions
- Automatic pausing of operations during OOS conditions
- Controlled transitions between process phases

## 7. Alarm Management

PAS uses a structured alarm strategy to ensure meaningful alerts.

**Key Controls:**

- Alarms are enabled only during relevant process steps
- High-priority safety alarms remain active at all times
- Alarms are disabled when equipment or vessels are disconnected
- Alarm conditions include high/low limits for weight, pH, conductivity, pressure, and UV

This approach minimizes nuisance alarms while ensuring critical events are detected.

## **8. Data Monitoring and Historization**

PAS collects and stores critical process data from:

- Internal equipment
- External OEM skids
- Sensors and transmitters

Collected data supports:

- Batch traceability
- Process monitoring
- Investigation of deviations and alarms

## **9. Exception Handling and Safe States**

PAS includes defined responses for abnormal situations.

**Key Controls:**

- Automatic pausing or shutdown during unsafe conditions
- Abort sequences place equipment in a safe state
- Valves are closed and pumps are stopped during abort or hold states

These controls reduce the risk of equipment damage and product loss.

## **10. Conclusion**

The Process Automation System (PAS) implements standardized, automated controls to manage complex manufacturing operations. Through controlled sequencing, alarm management, and real-time monitoring, PAS supports consistent production, regulatory compliance, and operational safety.