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.