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4jMarte Industrial Automation Ltd

Statement of Work (SOW) Proposal: Digital Plant MES Automation Engineering Services

Project Title: Digital Plant MES Syncade Automation & Integration Services

Document Version: 1.0

Target Platform: Emerson Syncade MES

Target Facility: GxP / Digital Plant Manufacturing Facility

Prepared For:

Cognizant Technology Solutions

Prepared By:

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Version: 1.0

Date: November 2026

Confidentiality Notice

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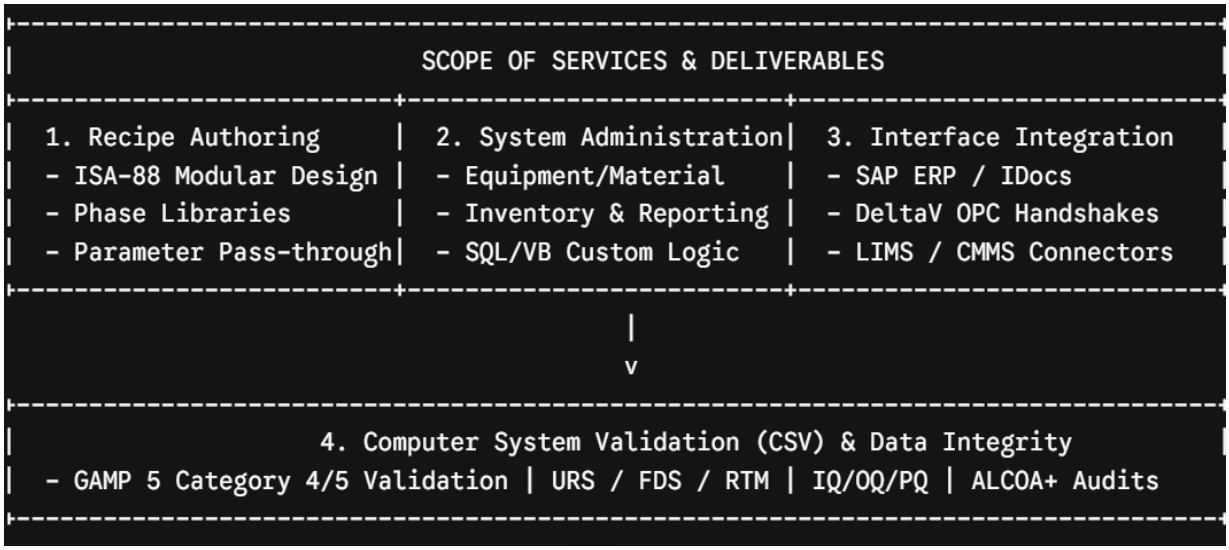
1. Executive Summary

This Statement of Work (SOW) defines the scope, deliverables, governance framework, and commercial terms for engaging a specialized **Digital Plant MES Automation Contractor/Consultant**.

The primary objective is to deliver robust, compliant, and validated MES master recipes, maintain third-party boundary system interfaces (SAP ERP, DeltaV DCS, LIMS, CMMS), and enforce corporate MES design standards to achieve High Product Quality and Lean Manufacturing objectives under strict GxP / 21 CFR Part 11 regulatory standards.

2. Scope of Work & Technical Deliverables

The Contractor will be responsible for executing technical capabilities across four key operational domains:



Domain A: MES Recipe Authoring & Standardisation

- ISA-88 Architecture: Author and maintain modular Syncade Master Recipes adhering to corporate design standards (Procedure, Unit Procedure, Operation, Phase).
- Standard Phase Libraries: Develop and re-use standardized phase templates to minimize custom scripting and streamline batch execution.
- Master Recipe Change Control: Execute technical updates, peer code reviews, and impact assessments for recipe modifications in GxP environments.

Domain B: Syncade System Administration & Module Configuration

- **Core Module Maintenance:** Configure and maintain Syncade modules including:
    - Equipment Management: Status tracking, clean/hold time enforcement, and calibration checks.
    - Material Management & Inventory: Container hierarchy, dispensing logic, tolerance enforcement, and real-time inventory reconciliation.
    - Reporting: Configured eEBR reports, audit logs, and exception handling summaries.
- **Custom Logic & Scripting:** Write, optimize, and troubleshoot T-SQL database queries/stored procedures and Visual Basic (VB/VBScript) action logic.

Domain C: Interface Delivery & Systems Integration

- **SAP ERP Integration:** Maintain bi-directional data flows for Process Order downloads, Material Master synchronization, and automated Goods Issue / Goods Receipt transactions.

- **DeltaV DCS Interface:** Configure and troubleshoot OPC UA / DA communication layers for automated phase handshakes, setpoint downloads, and parameter pass-through.
- **LIMS & CMMS Connections:** Ensure seamless analytical sample request creation, result reporting, and maintenance work order status sync.

Domain D: Computer System Validation (CSV) & Compliance

- Lifecycle Deliverables: Draft, execute, and maintain validation documentation per GAMP 5 guidelines (Category 4 Configured Software & Category 5 Custom Scripts):
    - Requirement Traceability Matrix (RTM) mapped to URS and FDS.
    - Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols.
- Data Integrity Governance: Ensure all electronic batch records (eEBRs) comply with **21 CFR Part 11, EU Annex 11**, and **ALCOA+** principles.

3. Key Milestones & Project Phases

Phase	Description	Key Deliverable / Exit Criteria	Estimated Duration
Phase 1: Mobilization & Assessment	Access provisioning, standards review, and baseline audit of existing Syncade build and interfaces	Approved Onboarding Checklist & Architectural Gap Analysis.	Weeks 1 – 2
Phase 2: Recipe Authoring & Configuration	Authoring of ISA-88 Master Recipes, Material/Equipment module build, and VB/SQL custom script updates.	Draft Recipes & FDS approved by Engineering & QA.	Weeks 3 – 8
Phase 3: Integration & Testing	Interface handshake verification (DeltaV/SAP/LIMS) and dry-run testing.	Integration Test Execution Logs & Interface Sign-off.	Weeks 9 – 12
Phase 4: CSV Execution	Execution of formal IQ/OQ/PQ protocols, deviation resolution, and RTM closure.	Executed Validation Summary Report (VSR) approved by QA.	Weeks 13 – 16
Phase 5: Go-Live & Hypercare	Commercial manufacturing support, shift handovers, and operational troubleshooting.	30-day stable operation with zero Critical site deviations.	Weeks 17 – 20

Phase 1: Mobilization & Assessment

Objective

Establish access, baseline existing Syncade configurations, and create the architectural gap analysis before active recipe build.

Step 1: Onboarding & Access Provisioning

1.) Obtain site credentials
2.) Gain read access to boundary system configurations
3.) Complete site GxP, Data Integrity, and Safety training

Step 2: Architecture & Artifact Audit

1.) Extract current Syncade object lists using Syncade Document Management and Configuration utilities.

2.) Review existing corporate Recipe Design Standards, Phase Libraries, and Naming Conventions.

3.) Inspect boundary integration interfaces:

- Verify OPC UA/DA node connections between Syncade OPC Server and DeltaV Application Stations.
- Review SAP IDoc / Web Service mappings for Process Order download and Goods Issue/Receipt transactions.

Step 3: Gap Analysis & Execution Plan Creation

1. Identify legacy paper workflows or custom scripts that lack standard ISA-88 modular alignment.
2. Document infrastructure gaps, boundary schema mismatches, or missing standard phases in a **Gap Analysis Report**.
3. Baseline the project schedule and obtain QA and Engineering sign-offs.

QA Gating Criteria (Exit Checklist)

- Approved Onboarding & Security Checklist.
- Signed-off Gap Analysis Report and Baseline Master Schedule.

Phase 1 Proof of Delivery (PoD) Acceptance Table (Sample)

Deliverable ID	Deliverable / Task Item	Acceptance & Verification Criteria	Responsible Party	Evidence / Artifact
PoD-1.1	System & Network Access Provisioning	Active credentials verified for Syncade (Dev/Test/Prod environments)	Contractor / IT Admin	Access Confirmation Ticket / Log

Phase 2: Recipe Authoring & Configuration

Objective

Develop ISA-88 compliant Syncade Master Recipes, configure material and equipment modules, and write required SQL/VB logic.

Step 1: Material & Equipment Module Setup

1. **Syncade Material Management:**
    - Configure **Material Master** records, container hierarchies, storage conditions, and unit of measure (UOM) conversions.
    - Define Dispensing logic rules, including scale tolerance bands (e.g., $\pm 0.5\%$) and dual-sign-off verification checks.
2. **Syncade Equipment Tracking:**
    - Build Equipment Master objects, setting up clean-hold time limit rules, sterilization tracking, and calibration expiry checks.
    - Establish equipment state transitions

Step 2: Modular ISA-88 Recipe Authoring

1. Open Syncade **Recipe Authoring Tool**.
2. Build Master Recipes hierarchically: **Procedure → Unit Procedure → Operation → Phase**.
3. Import standardized Phase templates from the Corporate Phase Library.
4. Configure phase parameters, electronic signature (e-sig) prompts, and instruction text for operators.
5. Embed automated validation checks for pre-step conditions (e.g., verifying equipment status is Clean prior to charging).

Step 3: Custom Database & Scripting Logic

1. **T-SQL Stored Procedures:** Write and optimize database queries for custom data retrieval, audit log extracts, or inventory reconciliation.
2. **Visual Basic (VB) Logic:** Implement custom VB/VBScript event handlers for specialized calculations or conditional branching within steps.
3. Conduct peer code reviews for all custom SQL and VB routines to ensure code maintainability.

QA Gating Criteria (Exit Checklist)

- Draft Master Recipes built to corporate design standards.
- Functional Design Specifications (FDS) updated and approved by QA.
- Code review completion record for all custom SQL/VB scripts.

Phase 2 Proof of Delivery (PoD) Acceptance Table (Sample)

Deliverable ID	Deliverable / Task Item	Acceptance & Verification Criteria	Responsible Party	Evidence / Artifact
PoD-2.1	Material Master & Inventory Setup	Material Master objects, container hierarchies, storage conditions, and scale tolerance limits ($\pm 0.5\%$) verified in Syncade.	Contractor / MES Lead	Syncade Material Master Export File

Phase 3: Interface Integration & Boundary Testing

Objective

Configure and verify bi-directional data flow across SAP ERP, DeltaV DCS, LIMS, and Syncade MES.

Step 1: DeltaV DCS Interface Setup (OPC Handshakes)

1. Map Syncade Phase parameters directly to DeltaV Control Module tags via the Syncade OPC interface.
2. Configure automation handshake logic:
    - **Syncade → DeltaV:** Send Setpoints, Recipe Parameters, and Start Phase commands.
    - **DeltaV → Syncade:** Receive Phase Complete, State Status, and continuous Process Parameter trends.
3. Simulate phase execution to verify edge-case handling (e.g., command timeout, communication link drop, emergency stop).

Step 2: SAP ERP Boundary Configuration

1. Configure SAP Web Service / IDoc interface definitions:
    - **Process Order Download:** Map SAP order header, line items, and batch numbers to Syncade Order Master.
    - **Goods Issue (GI):** Configure automated material consumption messages sent from Syncade to SAP upon container dispense.
    - **Goods Receipt (GR):** Configure final yield reporting and finished product posting back to SAP.

Step 3: LIMS & CMMS Connectors

1. Map analytical sample trigger points within Master Recipes to generate auto-requests in **LIMS**.
2. Configure result fetch mechanisms so Syncade holds execution until LIMS returns a Pass quality status.
3. Configure **CMMS** links for automated maintenance log entry creation upon equipment fault detection.

QA Gating Criteria (Exit Checklist)

- Dry-run Integration Test Execution Logs with 100% pass rate.
- Interface Functional Sign-off signed by Automation and IT lead teams.

Phase 3 Proof of Delivery (PoD) Acceptance Table (Sample)

Deliverable ID	Deliverable / Task Item	Acceptance & Verification Criteria	Responsible Party	Evidence / Artifact
PoD-3.1	DeltaV OPC Handshake Integration	Verified OPC UA/DA tag mappings between Syncade and DeltaV.	Contractor / Automation Engineer	OPC Channel Log & Phase Handshake Trace (Snapshots)

Phase 4: Computer System Validation (CSV) & Data Integrity

Objective

Execute formal GAMP 5 validation protocols (IQ/OQ/PQ) and ensure full compliance with 21 CFR Part 11 and ALCOA+ principles.

Work Instructions

Step 1: Traceability & Protocol Preparation

1. Construct the **Requirements Traceability Matrix (RTM)**, linking every User Requirement Specification (URS) clause to its FDS section and corresponding Test Protocol step.
2. Draft formal **Installation Qualification (IQ)**, **Operational Qualification (OQ)**, and **Performance Qualification (PQ)** protocols.

Step 2: IQ & OQ Execution

1. **IQ Execution:** Verify software version numbers, database schemas, network connections, security user roles, and installation parameter files in the Validation Environment.
2. **OQ Execution:**
    - Test electronic signatures, password expiration rules, and audit trail generation (21 CFR Part 11 / EU Annex 11).
    - Conduct positive and boundary testing on all Master Recipes, Material Dispense rules, and Equipment state logic.
    - Perform negative testing: disconnect network interfaces mid-step to prove zero data loss and appropriate exception logging.

Step 3: PQ Execution & Deviation Closure

1. Execute end-to-end simulated batch runs (PQ) reflecting real-world commercial manufacturing conditions.
2. Log any unexpected system behavior in the formal **Deviation Management System**.
3. Conduct root cause analysis, apply corrective updates via formal Change Control, re-test affected steps, and close all deviations.
4. Compile the **Validation Summary Report (VSR)**.

QA Gating Criteria (Exit Checklist)

- 100% execution of IQ/OQ/PQ test scripts with fully signed logs.
- Closed RTM and zero unresolved Critical or Major deviations.
- Approved Validation Summary Report (VSR) signed by Quality Assurance.

Phase 4 Proof of Delivery (PoD) Acceptance Table (Sample)

Deliverable ID	Deliverable / Task Item	Acceptance & Verification Criteria	Responsible Party	Evidence / Artifact
PoD-4.1	Requirements Traceability Matrix (RTM)	Fully populated RTM mapping 100% of URS requirements to FDS sections and executed IQ/OQ/PQ protocol test steps.	Contractor / Validation Lead	Approved RTM Document (.pdf)

Phase 5: Go-Live, Cutover & Hypercare

Objective

Safely deploy validated configurations to the Production environment, execute commercial cutover, and provide real-time operational support.

Step 1: Production Cutover

1. Execute approved **Change Control Record (CCR)** for Production deployment.
2. Migrate validated Master Recipes, Material Masters, Equipment configurations, and SQL/VB scripts into the Syncade Production instance.

3. Perform Production Readiness Checks (System Smoke Tests) to verify interface connectivity without altering active batch records.

Step 2: Commercial Batch Execution Support (Hypercare)

1. Provide 24/7 or shift-aligned **Hypercare floor support** for initial commercial manufacturing batches.
2. Monitor Syncade application logs, SQL execution queues, and OPC communication health during live operations.
3. Assist shop-floor operators with eEBR navigation, container scans, and electronic signature entries.

Step 3: Issue Resolution & Handover

1. Log and resolve any post-go-live operational incidents according to SLA targets:
    - **Critical (S1):** Immediate intervention (< 2-hour resolution target).
    - **Minor (S3):** Queue for next maintenance sprint.
2. Conduct standard operational knowledge transfer sessions with site administration personnel.
3. Hand over final system documentation to site maintenance teams.

QA Gating Criteria (Exit Checklist)

- Successful deployment under CCR approval with zero unapproved deviations.
- Completion of 30-day stable operation period with zero Critical site deviations.
- Signed Final Project Acceptance Certificate.

Phase 5 Proof of Delivery (PoD) Acceptance Table (Sample)

Deliverable ID	Deliverable / Task Item	Acceptance & Verification Criteria	Responsible Party	Evidence / Artifact
PoD-5.1	Production Migration Execution	Approved Change Control Record (CCR) executed; validated Master Recipes,	Contractor / Automation Lead	Approved CCR & Production Deployment Log

4. Governance, Quality & Change Management

- **Change Control Workflow:** No change to recipes, DB schema, or interface settings shall be deployed to Production without a pre-approved Change Control Record (CCR) and QA approval.
- **Progress Reporting:** Weekly status updates covering project milestones, risk registers, and interface performance metrics.
- **Defect Classification:**
    - **Critical (S1):** System down / batch execution halted - 2-hour response, continuous resolution work.
    - **Major (S2):** Functional workarounds available - 8-hour response.
    - **Minor (S3)**: Cosmetic/procedural queries - Resolved in standard sprint cycles.

5. Engagement Models & Rates

Choose from the following pricing structures depending on site requirements:

Option A: Time & Materials (T&M) Model ***(Recommended for Ongoing Support & Optimization)***

- **Billing Unit: 600/Day | 70/Hour** Rate based on logged hours.
- **Invoicing Schedule:** Monthly in arrears against approved timesheets.
- **Flexibility:** Allows rapid shifting of technical priorities across troubleshooting, recipe authoring, and validation as site needs change.

Option B: Milestone-Based / Fixed Price Model ***(Recommended for Discrete Recipe Build or System Upgrades)***

- **Billing Unit:** Fixed fee tied to formal acceptance of specific project deliverables (e.g., Completion of Phase 3 Integration Testing).
- Invoicing Schedule:
- Triggered upon QA approval of defined milestone outputs.

Acceptance Page

Proposal Acceptance

This proposal is accepted and approved by the duly authorized representatives of both parties.

Cognizant Technology Solutions

Company Name:

Representative Name:

Position:

Signature:

Date:

4jMarte Industrial Automation Ltd

Representative:

Dante Divinagracia

Director & Principal Consultant

Signature:

Date:
