



Ruben Calles Alonso

Senior IT/OT & MES Integration Specialist



KEY SKILLS

Professional

IT/OT Integration

- ◊ IT/OT network architecture, VLANs, routing, PSnet.
- ◊ Windows Server, Active Directory, virtualization.
- ◊ Industrial Cybersecurity.

Pharma MES

- ◊ PAS-X, LOM/LOC/Lion, SLC.
- ◊ Multi-vendor packaging line integration (Uhlmann, Pester, Dividella, WLS, Fargo, Robomat, B+S).

OT Systems

- ◊ Siemens TIA Portal, WinCC, PCS7, Rockwell, Mitsubishi, Omron, Schneider.
- ◊ Comms: OPC UA, Profinet, EtherNet/IP, Modbus.
- ◊ Vision: Cognex, Omron, VA.
- ◊ Robotics: ABB, KUKA.

Validation (GxP)

- ◊ FAT/SAT/IQ/OQ test execution & troubleshooting.
- ◊ GxP, GMP, GAMP5.
- ◊ eTIMS: test creation, execution, evidence collection, deviation handling
- ◊ SOP creation & documentation
- ◊ Training delivery

Infrastructure & DevOps

- ◊ VMware ESXi, VirtualBox
- ◊ Containerization: Docker
- ◊ Version control: Octoplant
- ◊ Linux & Windows OS

Industry 4.0, AI & Data

- ◊ Kafka, MQTT, IIoT integrations, Databases.
- ◊ AI agents, workflow automation, LLM integrations.

Project Delivery

- ◊ Project management
- ◊ Cross-functional coordination
- ◊ Vendor management
- ◊ Risk management
- ◊ Technical leadership



PROFILE

Senior IT/OT & MES Integration Specialist with **20 years of experience**, including **8 years supporting Novo Nordisk** across complex pharma packaging projects. Extensive experience in bridging the IT/OT gap, with focus on network architecture, line connectivity, PAS-X integration, virtualization, system interfaces and troubleshooting in GxP-regulated environments. Strong background across all communication layers, from corporate ERP and MES systems down to site infrastructure, production lines and shop-floor equipment, with extensive involvement in multi-vendor integration, FAT/SAT/IQ/OQ execution, and cross-functional alignment between IT, OT and MES teams.



KEY ACHIEVEMENTS

- IT/OT configuration for 15+ multi-vendor packaging lines, ensuring consistent IT setups, successful FATs and reducing integration issues.
- Responsible for Novo Nordisk's Multi-Vendor Program PSnet-in-a-Box (PIB), enabling vendors to simulate PSnet services and perform efficient FAT validation testing.
- Support full multi-vendor line integration as cross-functional technical responsible.
- Extensive hands-on experience executing the full validation cycle (FAT, SAT and IQ/OQ) across multiple pharma packaging and assembly lines internationally.
- Led rollout of Octoplant/VersionDog across 10+ Novo Nordisk sites worldwide.
- Global deployment of advanced WinCC SCADA tools across 14+ Rockwool sites, improving system consistency, reducing downtime and standardizing monitoring.
- Supported programming and commissioning of BMW automotive manufacturing lines.
- Full-scope involvement in design, programming, integration and commissioning of logistics machinery.



PROFESSIONAL EXPERIENCE

ProjectBinder, Worldwide, Aug 2018 - Present

Senior IT/OT & MES Integration Specialist

Working as a consultant across multiple projects:

- **Novo Nordisk A/S:** MES Consultant supporting multi-vendor packaging line integration at vendor sites through PAS-X configuration and FAT execution. Responsible for setting up and testing the communication between PAS-X, LionConnect (Line Optimizer), PLC and Track&Trace systems (SLC).
- **Novo Nordisk A/S:** Responsible for the Multi-vendor Program's PSnet in a Box (PIB), enabling virtualization of PSnet services to simulate the production network at vendor sites (Uhlmann, Pester, Dividella, Robomat, B+S, Fargo, WLS) for efficient unit FAT execution. Tasks include coordinating with cross-functional teams, executing project plans, managing stakeholders, and driving solution implementation, as well as network configuration, service virtualization, and server infrastructure management.
- **Novo Nordisk A/S:** Led teams of IT/OT engineers worldwide in successfully rolling out VersionDog/Octoplant across the corporation in 10+ sites. Tasks included project coordination with sites, solution deployment, configuration, and technical support.
- **Ferring A/S:** Supported network migration and installation of production lines.



Personal

- ◇ Communication
- ◇ Problem-solving
- ◇ Documentation & compliance
- ◇ Teamwork
- ◇ Adaptability



LANGUAGES

- ◇ **Spanish:**
Native proficiency
- ◇ **English:**
Full professional proficiency

- **Rockwool A/S:** Developed and deployed advanced WinCC SCADA tools to enhance control systems, leading to successful global rollout across 14+ sites, reducing downtime, and increasing productivity. Led the integration of Industry 4.0 IIoT tools, utilizing Kafka for real-time production data collection, processing, and visualization through interactive dashboards.
- **Novo Nordisk A/S:** Supported the on-site commissioning and validation of four Novo Nordisk FlexPen packaging lines in Iran and Algeria. Responsibilities included network configuration, FAT & SAT execution, documentation creation, employee training, and PLC code review.

BMW, Germany, Sep 2017 - Jun 2018

Senior Automation Specialist

Programmed robotic systems for new automotive manufacturing lines, optimizing productivity, product quality, and worker safety.

ROHACO Industrial Handling BV, The Netherlands, Mar 2016 - Feb 2017

Software Engineer - PLC & SCADA

Designed, developed, commissioned, and tested production lines across diverse industrial environments, working with PLCs and SCADAs of all brands.

TrioMachine SL (Gaitech), Spain, Oct 2015 – Mar 2016

Electrical Department Manager, Spain

Led the electrical department, handling design, installation, and improvement of automation systems, including electrical drawings and cabinet assembly.

Crown Packaging, United Kingdom & Spain, Jun 2006 – Aug 2014

Various positions:

- **Customer Service Electrical Engineer**, Crown Packaging UK, 2011 - 2014
- **Head of PLC & Artificial Vision Systems**, Crown Packaging Spain, 2006 - 2011



EDUCATION & CERTIFICATIONS

-  **PAS-X V3.3 Professional Certification, 2024**
Körber Pharma
-  **PAS-X V3.3 Basic & System Administration Certifications, 2023**
Körber Pharma
-  **Industrial Control Systems Cybersecurity Certification, 2022**
Cybersecurity and Infrastructure Security Agency (CISA)
-  **ThinManager Certified Integrator, 2020**
Rockwell Automation
-  **Advanced Industrial Robotics Course, 2016**
Nebrija University
-  **Higher Grade in Automatic Regulation & Control Systems, 2004 - 2006**
Hogar College

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