

Weston Guerra

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SUMMARY

Staff level **OT manufacturing** engineer with 12 years supporting regulated medical device and life sciences production. Leads controls, **automation**, validation, cybersecurity, and **OT IT integration** from requirements through commissioning, ramp, and sustained operations. Hands on work spans Rockwell, Siemens, FactoryTalk, Ignition, MES interfaces, ISA 95, OSIsoft PI, industrial networks, and **secure remote access**. Builds practical validation plans, protocols, trace matrices, and controlled records for IQ, OQ, and PQ. Uses pFMEA, DMAIC, SPC, Cpk, OEE, and Minitab analysis to improve reliability and production insight. Partners with Quality, IT, Production, R&D, Supply Chain, and Regulatory teams, while guiding integrators, vendors, and junior engineers. Brings steady judgment to production issues and can support safe, compliant OT delivery for complex manufacturing operations.

EXPERIENCE

Staff OT Manufacturing Engineer

January 2023 - Present

HelixPoint Medical Devices

San Jose, CA

Owns regulated OT architecture, controls delivery, validation, cybersecurity, vendor governance, and **production sustainment** across medical device operations. Guides cross functional decisions from requirements through release and mentors controls engineers.

- Architected **Rockwell** controls and **Ignition** interfaces for production expansion, improving commissioning readiness across manufacturing cells.
- Created IQ, OQ, and PQ **trace matrices** for **MES** releases, giving Quality clear evidence for approval.
- Segmented OT networks with VLANs and firewalls, reducing exposure during secure remote maintenance activities.
- Used PI historian data with **OEE** reviews, helping Production isolate recurring downtime patterns and corrective actions.
- Directed integrator reviews, FAT, SAT, and ramp support, keeping technical decisions visible across stakeholder teams

Senior Controls and Automation Engineer

July 2020 - December 2022

NovaCell Therapeutics

South San Francisco, CA

Led Siemens controls, GMP automation, MES integration, validation, and process capability work for life sciences production. Coordinated vendors and internal partners through factory testing, site acceptance, release, and support.

- Programmed Siemens **PLC** sequences using **IEC 61131 3** methods, supporting repeatable GMP equipment operation.
- Mapped **ISA 95** MES handshakes and recipes, clarifying batch data exchange during system acceptance testing.
- Built FAT and SAT protocols with controlled records, helping **validation** teams close findings before production release.
- Applied SPC, **Cpk**, and **Minitab** analysis to process data, guiding practical adjustments for stable output.
- Led vendor technical reviews and commissioning workshops, giving operators clearer training and support materials

Controls Engineer

June 2017 - June 2020

Precision Cardio Systems

Sunnyvale, CA

Delivered medical device controls, **HMI** applications, MES handshakes, risk assessments, and validated commissioning. Supported production teams with troubleshooting, corrective action, documentation, and process monitoring.

- Configured **FactoryTalk** HMI screens for assembly equipment, helping operators identify **alarms** and recover production faster.
- Performed pFMEA reviews for automated fixtures, turning failure modes into testable controls and documented actions.
- Applied DMAIC root cause analysis to communication faults, restoring dependable equipment behavior during **commissioning**.
- Verified **I O lists**, wiring diagrams, and **control narratives**, giving technicians reliable references during startup.
- Coordinated Quality and Production reviews for validated changes, preserving traceability through release and sustainment

Manufacturing Automation Engineer

June 2014 - May 2017

BayTech Life Sciences Automation

Fremont, CA

Supported regulated automation delivery, PLC and HMI change control, qualification, downtime analysis, and vendor coordination. Helped manufacturing teams move equipment from technical review through commissioning and reliable daily operation.

- Delivered **PLC** and **HMI** change packages for regulated equipment, supporting controlled commissioning and qualification.
- Analyzed downtime records with production leads, prioritizing practical fixes for recurring **automation** interruptions.
- Coordinated vendor scope and technical reviews, keeping drawings, specifications, and acceptance needs aligned.
- Prepared commissioning records and operator procedures, helping teams adopt new equipment with fewer startup questions.
- Supported risk assessments and corrective actions, linking equipment changes with quality and safety expectations

Junior Controls Engineer

October 2012 - May 2014

Vector Process Controls

Santa Clara, CA

Developed early controls engineering experience through Rockwell programming, HMI configuration, I O verification, FAT execution, and electrical documentation. Worked with senior engineers and technicians on equipment delivery and troubleshooting.

- Built Rockwell **Ladder** Logic updates under senior review, supporting dependable machine sequences during factory testing.
- Configured HMI tags and alarm screens, giving technicians clearer feedback during equipment troubleshooting.
- Verified I O points against electrical drawings, catching wiring discrepancies before FAT execution.
- Recorded **FAT** results and open issues, helping project teams track fixes through customer acceptance.
- Assisted controls troubleshooting at startup, building practical knowledge of safe commissioning and production support

PROJECTS

Secure OT Integration Program 📅 2026

Strong results start with clear control. Delivered a cross site OT integration framework connecting PLC, HMI, MES, historian, and secure network services for regulated production, with validation evidence and sustainment practices.

Validated Production Data Flow 📅 2025

Good engineering creates room for better decisions. Established controlled data flows between automation, MES, and OSIsoft PI, supporting alarms, events, OEE review, electronic records, and process capability analysis.

LEADERSHIP & AWARDS

- ISA/IEC 62443 Cybersecurity Fundamentals Specialist, recognized for regulated OT security preparation, 2025
- Project Management Professional, recognized for disciplined multi project leadership, 2024
- Lean Six Sigma Green Belt, recognized for practical process improvement and data analysis, 2023

EDUCATION

Bachelor of Science in Electrical Engineering

2012

San Jose State University GPA: 4.0

San Jose, CA

Coursework: Control systems, industrial automation, electrical circuits, computer engineering

CERTIFICATIONS

- ISA/IEC 62443 Cybersecurity Fundamentals Specialist 📅 2025
- Project Management Professional 📅 2024
- Lean Six Sigma Green Belt 📅 2023

TECHNICAL SKILLS

- **PLC and PAC Platforms:** Rockwell, Siemens, Schneider
- **HMI and SCADA:** FactoryTalk, Ignition, Wonderware
- **Control Programming:** Ladder Logic, Structured Text, Function Block
- **Manufacturing Systems:** MES, ERP, PLM
- **Data and Historians:** OSIsoft PI, alarms, events
- **Validation and Compliance:** IQ, OQ, PQ, 21 CFR Part 11
- **Industrial Networking:** Managed switches, VLANs, industrial firewalls
- **OT Cybersecurity:** IEC 62443, NIST, secure remote access
- **Process Analytics:** OEE, Cpk, SPC
- **Quality and Risk:** pFMEA, DMAIC, corrective action
- **Project Delivery:** FAT, SAT, commissioning
- **Regulated Manufacturing:** GMP, medical devices, audit support

SKILLS

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|-----------------------------|--------------------|-------------------------|---------------------------|
| • Operational Technology | • Siemens Controls | • Industrial Networking | • SPC and Cpk |
| • Manufacturing Engineering | • HMI and SCADA | • OT Cybersecurity | • Vendor Management |
| • PLC and PAC Controls | • IEC 61131 3 | • IQ OQ PQ Validation | • Technical Communication |
| • Rockwell Controls | • MES Integration | • pFMEA and DMAIC | |

PROFESSIONAL AFFILIATIONS

- International Society of Automation, member focused on controls, cybersecurity, and regulated manufacturing
- Project Management Institute, member supporting structured delivery, risk review, and stakeholder alignment

- Society of Manufacturing Engineers, participant in manufacturing automation and production improvement forums

LANGUAGES

- English (Native)
- Spanish (Proficient)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST