

# Christian Mathews

☎ (919) 555-1846 ✉ christian.mathews@example.com 💼 linkedin.com/example/christianmathews 📍 Raleigh, NC 27609

## SUMMARY

Senior Automation Engineer with 10 years of progressive controls experience in cGMP pharmaceutical and **biopharmaceutical manufacturing**. Leads Drug Product optical inspection, visual inspection, device assembly, **sterile fill finish**, packaging, and automated equipment initiatives. Hands on work spans PLC, DCS, SCADA and HMI, machine vision, robotics, servo and motion control, industrial networks, OT infrastructure, and ISA 95 Level 1 through Level 3 integration. Owns automation delivery from concept and detailed design through controls development, FAT, SAT, commissioning, qualification, start up, troubleshooting, and lifecycle support. Partners with Process Engineering, Manufacturing, Quality, CSV, OT, MES, Digital, OEM, and system integrator teams. Applies ISA 88, ISA 95, GAMP 5, **21 CFR Part 11**, **EU GMP Annex 11**, data integrity, cybersecurity, and risk based validation practices. Brings clear technical judgment and practical support for reliable, compliant manufacturing operations.

## EXPERIENCE

### Senior Automation Engineer, Optical Inspection and Device Assembly

July 2023 to Present

Helixor Therapeutics

*Durham, North Carolina*

Owns automation and controls delivery for Drug Product **visual inspection** and **device assembly** cells in a cGMP facility. Leads technical coordination across manufacturing, quality, CSV, OT, MES, OEM, and system integrator teams while protecting validated operation and reliable production data.

- Owned PLC, HMI, vision, robotics, servo, alarms, and interlocks for inspection cells
- Resolved OEM sequence issues before FAT, reducing late commissioning rework across two inspection lines
- Developed Rockwell PLC and HMI changes under controlled validation and traceable testing
- Directed FAT, SAT, commissioning, qualification, and start up issue resolution through handover
- Integrated inspection data with **Werum PAS X** and OSI PI for **electronic traceability**
- Applied **GAMP 5**, Part 11, Annex 11, **data integrity**, and cybersecurity controls

### Automation Engineer III, Sterile Fill Finish and Packaging

March 2021 to June 2023

Meridian Sterile Products

*Research Triangle Park, North Carolina*

Delivered automation for **sterile fill finish** and **packaging** equipment across a capital expansion. Coordinated integrators, suppliers, Process Engineering, Quality, and site support teams from functional design through start up and operational readiness.

- Delivered Siemens **PLC**, SCADA, **motion**, vision, and Ethernet controls for sterile equipment
- Converted approved requirements into sequences, alarms, interlocks, interfaces, and qualification tests
- Coordinated integrators through design reviews, FAT, SAT, commissioning, and **start up**
- Restored stable operation during control failures using structured root cause analysis
- Verified MES, **historian**, recipe, tag mapping, event sequencing, and auditability interfaces
- Created recovery procedures, training materials, maintenance records, and spare parts recommendations

### Automation Engineer II, Drug Product Manufacturing

June 2018 to February 2021

Northstar Biopharma Manufacturing

*Clayton, North Carolina*

Supported validated automation assets for Drug Product filling, inspection, and secondary packaging operations. Combined PLC and DCS configuration, batch control, commissioning, qualification, troubleshooting, and **lifecycle support** within regulated manufacturing systems.

- Supported PLC, **DCS**, SCADA, batch, and sequence controls for **Drug Product** operations
- Implemented **Emerson DeltaV** changes using **ISA 88** concepts and risk based verification
- Reviewed OEM machine and vision designs for interfaces, alarms, integrity, and supportability
- Executed **commissioning** and qualification tests for equipment and industrial network interfaces
- Investigated recurring faults with manufacturing and maintenance teams to improve availability
- Maintained validated releases, backups, periodic reviews, deviations, and inspection readiness

### Controls Engineer, Packaging and Automated Inspection

June 2016 to May 2018

Piedmont Pharmaceutical Services

*Greensboro, North Carolina*

Configured and supported controls for **cGMP** packaging and automated inspection equipment. Built foundational capability in PLC diagnostics, HMI support, industrial networks, historian interfaces, documentation, testing, commissioning, and regulated maintenance.

- Configured PLC, HMI, machine controls, and **industrial networks** for packaging equipment
- Created I O definitions, sequences, alarm lists, interfaces, and software test records
- Supported bench testing, **FAT**, field checkout, and commissioning with **OEM** technicians
- Diagnosed sensor, actuator, communication, and sequence issues using PLC diagnostics
- Supported historian tags and manufacturing interfaces by checking timestamps and data quality
- Built experience with **change control**, validation records, **data integrity**, and maintenance

PROJECTS

Optical Inspection Data Integration 📅 2024

Connected inspection equipment data with MES and historian services, improving traceability, recipe context, event visibility, and support for validated Drug Product operations.

Sterile Packaging Capital Expansion 📅 2022

Coordinated controls design, supplier testing, commissioning, and start up for automated packaging assets within a regulated manufacturing expansion.

Validated Automation Recovery Program 📅 2020

Strengthened backup, recovery, troubleshooting, and lifecycle practices for PLC, DCS, SCADA, and network assets supporting continuous manufacturing operations.

LEADERSHIP & AWARDS

- ISA Certified Automation Professional, earned 2024 for demonstrated automation engineering capability
- Recognized by project leadership for resolving inspection controls issues before commissioning
- Selected to coordinate cross functional automation readiness across suppliers and site teams

EDUCATION

Bachelor of Science in Electrical Engineering

2016

North Carolina State University GPA: 3.5

Raleigh, North Carolina

*Coursework: Control systems, electrical circuits, industrial automation, computer programming, engineering design*

CERTIFICATIONS

- ISA Certified Automation Professional 📅 2024
- GAMP 5 and Computerized System Validation Certificate 📅 2022

TECHNICAL SKILLS

- **PLC Platforms:** Rockwell Automation, Siemens PLC, PLC programming
- **DCS Platforms:** Emerson DeltaV, DCS configuration, batch control
- **SCADA and HMI:** SCADA, HMI, alarm management
- **Vision and Robotics:** Machine vision, optical inspection, robotics
- **Motion Systems:** Servo control, motion control, machine control
- **Manufacturing Systems:** Werum PAS X, MES, recipe management
- **Historian Systems:** OSI PI, historian tags, event history
- **Automation Standards:** ISA 88, ISA 95, Industry 4.0
- **Validation Standards:** GAMP 5, 21 CFR Part 11, EU GMP Annex 11
- **Quality Practices:** cGMP, CSV, risk based validation
- **Project Testing:** FAT, SAT, commissioning, qualification
- **Industrial Connectivity:** Industrial Ethernet, industrial networks, communication protocols
- **Data Governance:** Data integrity, electronic traceability, audit trails
- **Lifecycle Support:** Change control, CAPA, disaster recovery
- **Operational Support:** Maintenance strategy, spare parts, business continuity

SKILLS

- |                  |                            |                      |                 |
|------------------|----------------------------|----------------------|-----------------|
| • PLC            | • Robotics                 | • ISA 88             | • FAT and SAT   |
| • DCS            | • Servo and Motion Control | • ISA 95             | • Commissioning |
| • SCADA and HMI  | • Optical Inspection       | • GAMP 5             | • Qualification |
| • Machine Vision | • Device Assembly          | • cGMP Manufacturing |                 |

PROFESSIONAL AFFILIATIONS

- ISA member, automation and controls engineering community
- ISPE participant, pharmaceutical engineering and manufacturing practice

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST