

Aleksandar Henderson

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SUMMARY

Senior digital manufacturing professional with 8 years supporting **computerized systems**, **smart manufacturing technologies**, and GMP production across biotechnology and pharmaceutical operations. Leads MES, ERP, SCADA, Systech, Serialization, and shop floor initiatives spanning requirements, configuration, integration, qualification, validation, lifecycle management, troubleshooting, and continuous improvement. Translates operator, supervisor, QA, and technical team needs into reliable system capabilities that support commercial manufacturing. Creates clear GMP documentation, including SOPs, forms, FMEAs, deviations, CAPA records, change controls, **master batch records**, and technical reports. Applies root cause analysis, data analytics, lean manufacturing, and Kaizen methods during investigations and production improvement work. Brings practical **technical leadership**, user training, schedule coordination, and cross functional communication that strengthen compliant operations and dependable manufacturing performance.

EXPERIENCE

Senior Digital Manufacturing Associate

January 2024 - Present

Cardinal Bioprocess Systems

Columbus, OH

Leads **digital manufacturing initiatives** for a GMP biologics operation, owning MES and shop floor system requirements, configuration, testing, validation, deployment, lifecycle support, documentation, and user readiness. Serves as a first line technical resource for production, QA, and support teams.

- Led MES configuration testing and validation for GMP biologics workflows, supporting controlled production deployment.
- Resolved SCADA interface and Serialization issues through structured troubleshooting, restoring dependable **shop floor** execution.
- Converted operator feedback into master batch record requirements, improving alignment with approved **manufacturing processes**.
- Directed upgrade impact assessments, change controls, validation plans, test evidence, and implementation schedules.
- Authored SOPs, FMEAs, deviations, CAPA records, and **technical reports** supporting compliant investigations and corrective actions.
- Delivered role based training for **operators**, **supervisors**, QA, and technical teams before controlled workflow changes.

Digital Manufacturing Engineer

January 2022 - December 2023

Scioto Therapeutics Manufacturing

Newark, OH

Supported commercial manufacturing applications across MES, ERP, SCADA, and Systech environments. Coordinated system changes, investigations, analytics, maintenance windows, validation evidence, and Kaizen improvement work with manufacturing, automation, IT, and QA stakeholders.

- Configured **MES** and **ERP** changes from approved requirements, documenting traceability before GMP deployment.
- Investigated recurring system exceptions with event data and user observations, advancing practical CAPA actions.
- Analyzed downtime and workflow exceptions, giving manufacturing leaders clearer views of schedule risks.
- Coordinated maintenance windows with manufacturing, automation, IT, and QA teams during controlled operations.
- Facilitated Kaizen reviews that converted **shop floor** feedback into prioritized digital workflow **improvements**.
- Documented validation evidence for **Systech** updates, supporting reliable **serialization** activities across commercial production areas.

Manufacturing Systems Specialist

July 2020 - December 2021

Riverbend Pharmaceutical Operations

Dayton, OH

Provided production floor support for **computerized systems** used in batch execution, equipment monitoring, material transactions, and electronic production records. Combined user support, controlled testing, documentation, **investigations**, training updates, and improvement workshops across active pharmaceutical operations.

- Supported batch execution systems during production, resolving electronic record and equipment monitoring questions.
- Triaged MES and ERP issues with reproducible details, accelerating escalation of integration defects.
- Reconstructed deviation timelines from system records and user interviews, strengthening investigation documentation.
- Executed approved **configuration** test scripts, recording expected and actual results for **validation** packages.
- Updated work instructions and training materials, giving operators practical guidance for revised digital processes.
- Supported improvement workshops that reduced transaction errors across production and support handoffs.

Manufacturing Technology Associate

October 2018 - June 2020

Buckeye Life Sciences

Cincinnati, OH

Supported GMP manufacturing teams using electronic production and business systems while building practical knowledge of batch processes, controlled records, ERP transactions, validation evidence, and **shop floor** technology. Contributed documented troubleshooting, testing, quality review, and lean improvement activities.

- Supported electronic production records by checking data completeness with manufacturing personnel.
- Applied documented **troubleshooting** steps before routing complex system defects to **engineering** or IT specialists.

- Resolved ERP transaction questions through timely review of controlled **manufacturing** records.
- Prepared controlled **forms**, work instructions, and technical notes under document management procedures.
- Executed tests for minor system changes, recording evidence and discrepancies for quality review.
- Contributed lean problem solving activities focused on production workflows and digital handoffs.

PROJECTS

Commercial Serialization Integration 📅 2024

Supported integration work connecting Systech Serialization workflows with manufacturing systems. The effort strengthened transaction visibility, troubleshooting, and controlled production support.

Digital Workflow Improvement Program 📅 2023

Used downtime analysis, user observations, and Kaizen reviews to prioritize practical improvements across MES workflows and production schedule support.

LEADERSHIP & AWARDS

- Recognized by manufacturing leadership for dependable MES production support and clear technical problem solving during controlled operations.
- Received professional recognition for completing Lean Six Sigma Green Belt development and applying structured improvement methods.

EDUCATION

Bachelor's Degree in Computer Science

2018

University of Cincinnati GPA: 3.5

Cincinnati, OH

Coursework: Computer systems, database management, software engineering, systems analysis

CERTIFICATIONS

- Lean Six Sigma Green Belt 📅 2023
- GMP Computerized Systems Validation Certificate 📅 2022

TECHNICAL SKILLS

- **Manufacturing Systems:** MES, ERP, SCADA
- **Serialization Platforms:** Systech, Serialization, Track and Trace
- **Validation Practices:** IQ, OQ, PQ
- **GMP Documentation:** SOPs, FMEAs, Technical Reports
- **Quality Processes:** Deviations, CAPA, Change Controls
- **Batch Records:** Master Batch Records, Electronic Records, Batch Execution
- **Integration Technologies:** System Integration, Interfaces, Data Exchange
- **Analytics Tools:** Downtime Analysis, Event Data, Schedule Analysis
- **Improvement Methods:** Lean Manufacturing, Kaizen, Root Cause Analysis
- **Training Materials:** Work Instructions, User Training, Forms
- **Digital Technologies:** AR, VR, Smart Manufacturing
- **Testing Methods:** Test Scripts, Traceability, Validation Evidence

SKILLS

- | | | | |
|-------------------------|--------------------|----------------------|-----------------------|
| • Digital Manufacturing | • SCADA | • System Integration | • CAPA |
| • Smart Manufacturing | • Systech | • GMP | • Root Cause Analysis |
| • MES | • Serialization | • Validation | • Data Analytics |
| • ERP | • AR/VR Technology | • Qualification | |

PROFESSIONAL AFFILIATIONS

- GMP manufacturing technology community participant, sharing practical lessons on computerized systems, documentation, and user support.
- Lean improvement practitioner, contributing Kaizen discussions focused on reliable workflows and stronger production handoffs.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST