

Jasen Carroll

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Former ASQ Certified Software Quality Engineer
MBA Graduate and current MSSE candidate

phone: 484.318.2164

location: Philadelphia, PA

Summary

Full stack developer with a decade of engineering experience in regulated software environments. Background spans UAT ownership, SDLC participation, Agile delivery, and AI/ML model validation at Philips under FDA consent decree. Now building full-time – current project is [pyr](#), an open-source Python runtime manager built in TypeScript on Deno with cross-platform CI/CD. Stack includes React, JavaScript/TypeScript, Python, PostgreSQL, and Node.js. BS Mechanical Engineering (Drexel), EMBA (Quantic), MSSE candidate 2026.

Skills

Polyglot developer – academically trained in Java and C++, originally bootcamped in Python and JS with formal study in JavaScript including Eloquent JavaScript, solidified with graduate level studies, self-taught TypeScript, Bun, Deno, and some Go.

- Frontend: React, CSS, JavaScript, ES6+
- Backend: Node.js, Python
- Database: PostgreSQL, MySQL, SQLite
- APIs: RESTful API design and integration
- Tooling: Git, CI/CD, Deno
- AI: Early adopter – built tooling around frontier models, including a [chat-responses-proxy](#) to route between Mistral, Claude, and others.

Education

Quantic University

Master of Science in Software Engineering
Executive Master of Business Administration

Remote
Aug 2026 (anticipated)
Oct 2023

Drexel University

Bachelor of Sciences in Mechanical Engineering

Philadelphia, PA
June 2012

Certifications

- Certified Software Quality Engineer (CSQE) – ASQ (2020–2023)
- Six Sigma Green Belt – DVIRC
- Data Science Foundations – Quantic (2025)
- Intermediate JavaScript – Udacity (2024)
- Full Stack Developer Nanodegree – Udacity (2015, 2024)

Projects

- **QMS Assistant** – qms.jasencarroll.com – A publicly queryable AI assistant over a Software as a Medical Device (SaMD) Quality Management System corpus. Built on a RAG architecture – Flask API, Mistral embeddings, Chroma vector DB, top-k retrieval with citation injection. Domain expertise (12+ years FDA-regulated QMS) converted directly into a working AI product. Bootstrapped with pyr. Deployed to Railway.
- **Cafe Fausse** – cafe-fausse.jasencarroll.com – Full stack restaurant reservation system. React + Vite frontend, Flask + SQLAlchemy backend, PostgreSQL, deployed to Railway with GitHub Actions CI/CD. CORS-controlled API, table availability logic, newsletter signup, production-grade endpoint with gunicorn.
- **Goodware** – goodware.jasencarroll.com – Anomaly detection toolkit trained on 50,000+ labeled executable samples – applicable to fleet telemetry, risk, and insurance domains. Python, scikit-learn, PyTorch MLP, XGBoost, LightGBM. Flask web app with CSV upload, /predict API endpoint, AUC/accuracy reporting, and confusion matrix. Full CI/CD with gated deployment on Railway.
- **Recipe Recommender** – recipe-recommender.jasencarroll.com – Full stack ML recommendation engine trained on 41,932 Food.com recipes using K-means clustering. React + Vite + Tailwind + shadcn/ui frontend, FastAPI + Uvicorn backend, scikit-learn pipeline with serialized joblib model artifacts for instant inference. Multi-stage Docker build, GitHub Actions CI/CD with lint/test/build gates, deployed to Railway.

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Experience

PCI, Philadelphia, PA - Hybrid

Senior Quality Engineer | Quality Engineer

Sep 2023 – Mar 2026

- Designed source code review and software backup processes to strengthen GAMP5 compliance and data integrity controls
- Designed User Access Management evaluation tools consolidating 21 CFR 211, 21 CFR 820, Part 11, and Data Integrity guidance into a single baseline assessment framework
- Led LEAN/Six Sigma cleaning optimization project – \$0.5M in labor savings, 3,600 hours of production time recovered

Dexcom, Remote

Staff Software QA Engineer (Beacon Hill)

Aug 2022 – October 2022

- Released redlined procedures addressing documentation gaps for FDA and ISO compliance; supported automation of field action and recall processes.
- Provided governance to Change Control Boards to maintain compliance over quality-impacting systems.

Acumed LLC, Hillsboro, OR - Hybrid

Quality Engineer – Software, Sterilization, and Sustaining.

Dec 2021 – July 2022

- Developed 21 CFR Part 11 compliance checklist for software validation using phased implementation approach
- Harmonized software validation SOPs across multiple QMS platforms through LEAN methodology
- Defended BSI tech file audit for EU MDR submission solo – zero additional non-conformities

Philips North America, Remote

Software Validation Engineer | Quality Engineer – CAPA

Jul 2019 – Sept 2021

- Owned UAT and acceptance protocols for regulated software systems under FDA consent decree
- Validated two AI/ML models – an aggregator and a recommendation engine – human-in-the-loop, before FDA had a formal framework for it
- Managed Non-Product System Software validation lifecycle end to end
- Worked within Agile delivery cycles on global QMS software teams supporting NPSS solutions
- Reduced active CAPA load 50% – from 150 to 75 open worldwide – through data analysis and KPI reporting to SteerCo

Acumed LLC, Hillsboro, OR

Validation Engineer (Quality Assurance)

Oct 2017 – Jun 2019

- Co-owned risk-based Master Validation Plan covering all software validation packages including IQ/OQ/PQ
- Owned UAT and acceptance protocols for QMS software systems supporting Class II/III orthopedic medical device manufacturing
- Managed CAPA Review Board ensuring timeliness and effectiveness of site-wide corrective actions

Johnson & Johnson Consumer, Los Angeles, CA

Process Validation Engineer | Lead R&D Pilot Plant Scientist

Sep 2012 – Nov 2014