

Kyle Henderson

// Validation Engineer

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> SUMMARY

Validation engineer with 5 years in sterile injectables and pharmaceutical packaging under cGMP. Writes and runs IQ/OQ/PQ protocols for equipment, utilities and computer systems, leads risk assessment before each change, and closes validation packages that have passed 4 FDA and client audits.

> SKILLS

• Validation • cGMP • IQ/OQ/PQ • Risk Assessment • Technical Writing • Root Cause Analysis • Troubleshooting
• Minitab • Python • Excel

> EXPERIENCE

Validation Engineer

03/2023 - Present

Crossroads Biologics

Indianapolis, IN

Contract manufacturer of sterile injectable drugs with 3 fill-finish lines.

- Write and execute IQ/OQ/PQ protocols for 35 pieces of fill-finish equipment, all approved by QA on first review.
- Lead risk assessment workshops for 20 change controls a year, setting test scope with QA and engineering.
- Investigate validation deviations with root cause analysis and troubleshooting, closing **95%** within 30 days.
- Analyze temperature mapping data in Minitab and Python for 12 cold rooms and autoclaves.

Associate Validation Engineer

06/2021 - 02/2023

White River Pharma Services

Lebanon, IN

Pharmaceutical packaging and labeling services provider for 40 drug makers.

- Executed cleaning validation on **8** packaging lines, collecting 600 swab samples with zero sampling errors.
- Rewrote 40 SOPs and validation reports, applying technical writing standards that cut QA comments by half.
- Tracked revalidation dates for 150 systems in Excel, so no validated state lapsed in 2 years.
- Verified 12 label printing and vision systems under computer system validation rules.

> EDUCATION

Bachelor of Science

05/2021

Purdue University

West Lafayette, IN

Chemical Engineering

> CERTIFICATES

Certified Pharmaceutical GMP Professional (CPGP)

2024

ASQ