OLIVIA SMITH

Validation Specialist

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PROFESSIONAL SUMMARY

Validation Specialist with 2 years of experience in validating pharmaceutical processes and equipment. Skilled in developing and executing validation protocols in compliance with GxP standards. Adept at conducting risk assessments and generating detailed reports to enhance quality assurance. Seeking to contribute my expertise to a dynamic team focused on regulatory compliance and operational excellence.

WORK EXPERIENCE

Validation Specialist/Director

Jan / 2024-Ongoing

WidgetWorks Inc.

Denver, CO

1. Participated in validation projects for new and existing packaging equipment.
2. Developed and executed IQOQPQ protocols and engineering studies for various processes.
3. Created summary reports for completed validation studies to ensure compliance.
4. Conducted Factory Acceptance Tests (FAT) to qualify equipment pre-delivery.
5. Executed Site Acceptance Tests (SAT) after equipment installation.
6. Collaborated with engineering teams to support equipment validation initiatives.
7. Ensured compliance with FDA regulations by obtaining and analyzing samples as per validation protocols.

VALIDATION SPECIALIST

Jan / 2023-Jan / 2024

Cactus Creek Solutions

Phoenix, AZ

1. Led the development and execution of qualification protocols for automated packaging systems.
2. Validated PLC software and HVAC systems using detailed engineering drawings.
3. Oversaw the qualification of Air Handling Units (AHUs) and other automated equipment.
4. Managed validation processes for equipment including Capper, Induction Sealer, and Electronic Label Verification Systems.
5. Documented validation deliverables in accordance with cGMP standards.
6. Coordinated project tasks and reported progress to stakeholders and management.

EDUCATION

Bachelor of Science in Biology

Jan / 2022-Jan / 2023

State University

Denver, CO

Focused on biological sciences with coursework in quality control and regulatory compliance.

SKILLS

Quality Assurance Auditing

Software Validation

Training Development

Technical Documentation

ACHIEVEMENTS

- Increased validation throughput by 15% through optimized documentation practices.
- Successfully executed over 10 validation protocols for critical packaging equipment.
- Reduced validation cycle time by 20% by implementing streamlined processes.