

Kerry Hernandez

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Twenty one years experience in production, of which fourteen years are within an FDA regulated medical device company. Three years experience as a supervisor over production and quality.

Skills

- ISO 90001 and 13485
- Project Management
- CAPA Management
- Employee Evaluations
- GMP (Good Manufacturing Practices)
- ISO audits
- Writing SOPs and Work Instructions
- Document Control

Experience

08/2015 TO CURRENT

Supervisor / Carestream Health Inc.-Windsor, CO

- Ensured that production met safety guidelines and performed all activities with the ultimate goal of producing safe and legal products in full compliance with good manufacturing practices and FDA regulations, ensured production met department matrix goals
- Conducted daily good manufacturing practice audits ensuring compliance with procedures and policies resulting in passing ISO audits that have failed in the past
- Setup, implemented, and maintains employee training record for entire department saving the company \$10,000
- Supervised and developed 15 employees, 3 of which have received promotions
- Setup, implemented and maintains training for document authors for the department reducing mistakes by 65%
- Responsible for performing ISO audits in the building
- Investigated and completed Corrective and Preventative Action plans
- Developed and presented training to all department personnel on good manufacturing practices regarding documentation control within the department, ensuring strict compliance to all procedures and policies, leading to an 88% reduction in documentation errors.
- Hired production personnel when needed
- Implemented quality control coordinator meetings for better communication of job expectations and any training needed, reducing mistakes made in documentation and containment issues by 30%
- Setup and completed all training plans for operations team
- Supervisor for 15 employees, coaching them on their development, 3 have received promotions

- Resolved any personnel conflicts to the satisfaction of all parties involved
- Approved vacation requests while staffing the team appropriately

07/1999 TO 08/2015

Production Operator / Kodak/Carestream Health Inc.- Windsor, CO

- Machine operator working with computer programs and utilizing knowledge to monitor quality of running machine and produce detailed paper work for each product roll, responsible for making adjustments to machine when necessary
- LDR (Leadership Development Roll) responsible for final disposition of all products, assist with training other operators, lead team and quality meetings, effectively communicating with them what needs to be done and why, write detailed reports on daily machine activity
- Directed team on high activity events
- Chosen operations representative for design, build and installation of new auto bagger machine, wrote work instructions and trained all employees within the department, including maintenance, once installed and running

Education

05/1995

Diploma / Windsor High School-Windsor, CO