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Recommendation for Technician Strategies: Report Prepared for Orchid Orthopedic Solutions

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Abstract

When running a medical production facility, proper documentation is crucial with every process. The current system is so tedious and inefficient some are opting to ignore regulations completely, leaving Orchid Orthopedic Solutions liable in audits. As we cannot change the intricacy of the system itself, we are left to allocate a larger investment of resources to the system. With a greater knowledge and training on how to complete change records correctly, more specified employees for revising these actions, or a selected representative from each department could benefit everyone within the process. To both decrease the risk and increase efficiently, a change must be made.

Keywords
Manufacturing, Systems, Engineering, Medical, and Device.

Background

Orchid Orthopedic Solutions is a global leader for medical device outsourcing services in development and design to the manufacturing of finished goods. Worldwide production stands at over 2 million parts a year, with a small percentage coming from Chelsea MI, USA. Our customer return rate is low, and the audit findings from the suppliers and the Food and Drug Administration (FDA) remains low. Production depends heavily on accuracy and efficiency in usage of materials. Without this operation efficiency, profit margins greatly decrease and some operations may prove to no longer be financially viable. All optimization stands to increase productivity and profit margins.

Orchid currently outputs over 100,000 parts per month. Within our Chelsea Michigan facility we produce only plastic products through injection molding, milling, and lathe machining. Each part is produced within the clean room requirements of the customer, along with the FDA Code of Federal Regulations Title 21 (FDA CFR 21) standards. Furthermore, parts are also inspected to a predetermined ratio dependent on batch size using statistical reasoning. The parts endure a cleaning and trimming process as instructed before moving to packaging. Each of these steps are meticulously documented for accountability and accuracy. Any lapse in this documentation could leave Orchid liable in the event of audits by the customer or the FDA. With that in mind, the documentation is vast, complex, but integral to the accurate completion of production. The last thing we would want to compromise as a medical device production company is quality and if we lose sight of that the entire operation could crumble from a preventable mishap. While striving for continuous improvements, we not only improve quality for our consumers but cost effectiveness for ourselves.

Purpose of Recommendation

Over the summer, the hardest mechanism to understand was the documentation process that accompanies every operation completed on the floor and by the operation technicians. It is not easy to follow and error prone, but crucial to the functionality of the records. The people knowledgeable about the inner workings of documentation standards are those who perform these tasks every day, but those people are few in number. I have observed how frustrating it can be for the entire staff to be dependent on one person in order to move on to the next step of a project. This scarcity of expertise creates unnecessary tensions along with roadblocks in projects, and a waste of resources when one employee cannot complete further work because of this same dependency.

Recommendation

Below includes three possible new approaches to resolve this issue. Each varies in cost, time, and effectiveness. All together the options could greatly improve the current system and should be taken into consideration.

First, we could hire an employee to specialize in document approval, similar to a Quality Assurance engineering technician. This simply adds more manpower to handle the current workload involved in keeping operations flowing. This would prevent the current bottleneck that accompanies obtaining Engineer Change Request (ECR) approval. A greater number of experts on the new system would mean utilizing less time from operator technicians and quicker production throughput. This could also allow for more experts to teach others and create a higher level of base competence among the workforce. The time to train a new hire on the system would be extensive, but having an employee focus solely on document approval could effectively double productivity. It would have the largest initial investment of the three options and does not effectively change the current documentation setup, but would increase proper usage. Integrating this new employee into the existing system would not require any training of the rest of the team at Orchid Orthopedic Solutions, making it more time efficient.

As a second approach, we could address the lack of general knowledge on ECR completion by holding training sessions for the workforce. This would entail the current ECR approvers to take note of the most common problem areas that force them to reject or fix for approval, and then set up refresher sessions for all needed personnel. If everyone had a refresher course, we could help minimize potential for mistakes and speed up the approval process. This option addresses part of the issue at the source of documentation errors, and would only take an investment of time with the current personnel. With the baseline of documentation knowhow stronger, our resources could be reallocated elsewhere in the future. This approach eases the bottleneck with a smoother approval process for the engineering technicians who deal with these roadblocks on a daily basis.

As a third approach, we could train only specific representatives from each department to limit how much one would have to outsource their questions to the engineering technician responsible for approval. Selecting individuals to stay up to date on process changes within each department requires less gross training and initial time investment. This would essentially create another resource to avoid the buildup of workload for the engineering approver. This is the middle ground solution, requiring less training than the first approach and including fewer people than the second approach. It is a more reasonable expectation coming from our current situation that a few individuals would be capable of staying up to date with the documentation system.

As a last approach, we could make no changes to our documentation practices. Our current system still turns a profit and would not require any new investments. However, no risk means no possibility for reward. I believe an integration of either one or a mix of one or more of these solutions would prove to be extremely beneficial to the work environment and productivity.

Costs Associated with Recommendation

The costs associated with these recommendations would mostly include an overhead of better training for the general staff. More complicated training would be required for those specified workers in each department or new hires to check and authorize these records. All of those changes could be made in house, by reallocating talent. The cost of time for this training would vary by the talent needed to complete it: a brand new hire, an internal promotion, specified representative, or general workforce. There is an inherent cost of downtime for those employees being trained and

their trainers. As a whole this would be an investment for further improvement within our plant's documentation practices promoting efficiency and accuracy.

The potential money made comes from the time saved by everyone involved in the approval process to be productive elsewhere. Not to mention the ease of flow of the workplace module, meaning less interpersonal conflicts. The potential outcome would be an increase in accuracy and education as a whole, which would further save time from product rework and audits. The investment proves effective in time saving and accuracy efforts.

Conclusion

The current process is frustrating and inhibits possible progress within other fields at Orchid Orthopedic Solutions. The general dreading to complete paperwork with inadequate knowledge often leads to inefficiency and attempted efforts to avoid it entirely, which is against production regulations. If the investment for the aforementioned approaches were made now, we could get in front of this issue before it causes a real issue with a customer or the FDA. However tedious or costly, this change would positively impact the work environment for the future.

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Biographies

Diana Graham is a third year Industrial Engineering student at the University of Michigan Dearborn. She is very proud to attend the Dearborn campus and intends on finishing her degree there. She has worked as a Co-Op Engineer at Orchid Chelsea since May of 2018. Orchid Orthopedic Solutions has allowed her to gain valuable industry experience while still working on her degree. Her projects at Orchid include UV laser etching, image measurement system programming, and general plant optimization and ergonomic improvements. Diana hopes to work for an Industrial Engineering firm that focuses on ergonomics after graduation. In her spare time, Diana enjoys spending time with her fish and performing stand up comedy.

Kevin Bancroft is a Manufacturing Engineer at Orchid Orthopedic Solutions, receiving his Bachelor's in Mechanical Engineering Technology from Eastern Michigan University in 2017. His current role at the Chelsea facility includes leading Milling and Molding departments with efforts in ECO and pFMEA processes to support production. Kevin also leads the collaborative robot efforts that have been implemented on Fanuc RoboDrill mills and Doosan lathes utilizing specialized state programming and CAD to 3D printing design knowledge for End of Arm Tooling. His current interests include Entrepreneurship with intent to start a mini-computer case company, an interest in Philosophy and the human mind, and has a general love of knowledge and facts. Kevin currently resides in Manchester Michigan where his Condo is run rampant by several cats, especially Mr. GQ.