NYASHA MADZIVA

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PROFESSIONAL BACKGROUND

Nyasha is a passionate pharmaceutical and business professional with over 7 years of experience in program and project management, process improvement, and validation consulting. She has a proven track record of excellence by leveraging and driving collaboration with a variety of subject matter experts, as well as leading cross-functional teams to develop and deliver effective solutions to meet client needs.

Nyasha is a results-oriented and customer-minded individual who excels in a fast-paced environment working with diverse teams. She excels at applying communication skills with stakeholders of all levels, assembling cross-functional strategic teams, and analytical problem-solving to manage projects and meet objectives. Her organizational skills and attention to detail also ensures dependencies and risk across complex projects are successfully managed, ensuring the maximum value is delivered on time and on budget.

SELECTION OF RELEVANT EXPERIENCE

Project Manager

Nyasha served as a project manager on a multimillion-dollar revenue supply chain disruption initiative for a major medical device manufacturing company. The initiative focused on recovery from line shutdowns that would tackle backorder recovery and customer disruptions for their legacy medical device platforms. Nyasha led the execution of the project, from engineering design analysis, supplier management, line start-up activities, and customer supply recovery forecasting. Nyasha prepared executive sponsor reviews, established program governance, and managed more than 10 unique line shutdown recovery projects. Nyasha was responsible for coaching the cross-functional teams, seeking acceleration opportunities, and removing obstacles and impediments in order to maintain effective project execution. She maintained detailed project schedules, documented risks, and developed dashboards to track program performance.

Program Manager

Nyasha has been responsible for managing multimillion-dollar project teams tasked with gap assessments and remediation activities ahead of a U.S. Food and Drug Administration (FDA) pre-approval inspection (PAI) for a leading biopharmaceuticals manufacturer. Ms. Madziva worked closely with the project leads, subject matter experts and consultant team members to plan, develop and prioritize scope, deliverables, required resources, budget, and scheduling for manufacturing, validation, and quality assurance (PAI) projects. She assisted in the mediation of cross-department prioritization conflicts through closely monitored stakeholder engagement plans and data-driven decision-making. The completion of gap assessment and remediation activities have contributed directly to lowering the risk of an FDA observation or impediment to delaying the commercial launch of the new biopharmaceutical drug.

Industry Experience

- Cell Therapies
- Consumer Products
- Cosmetics
- Manufacturing
- Medical Devices
- Pharmaceuticals

Functional Expertise

- Program/Project Management
- Waterfall
- Agile
- Process Optimization
- Statistical Process Control
- Change Management
- Process Improvement

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SELECTION OF RELEVANT EXPERIENCE

Sr. Project Manager

Nyasha led a cross-functional team of consultant and client employees through the planning, execution, and closeout of a critical 3-batch manufacturing campaign for use in the Biologics License Application (BLA) for the FDA on a critical and competitive schedule. Ms. Madziva guided the client through a thorough review of the proposed manufacturing process documentation to ensure a robust design prior to the execution of the critical batches, as well as to identify and minimize risks early. She also assisted with the identification of critical monitoring and control sample points as part of the process validation manufacturing campaign. She worked to engage key contacts from all business units to develop, review and approve protocols that were used to drive the process validation manufacturing campaign and closeout reports. Ms. Madziva and her team successfully completed the process validation campaign for BLA use on schedule and created a benchmark for subsequent product launch projects. The on-time completion of the manufacturing batches for the BLA contributed to current dominance in the first-to-file race that has a projected $3 billion in net sales over the next 10 years.

Scrum Master/Sr. Project Manager

Nyasha led a team of 12 engineers on an accelerated operation warp-speed project for two vaccine candidates for Covid-19 to receive, test, and validate process equipment for vaccine manufacturing on a very aggressive schedule. In this role, Nyasha was responsible for both the overall project schedule and the implementation of Scrum activities to manage the day-to-day priorities and tasks. Her responsibilities included the facilitation of all Scrum ceremonies with the team, project status reporting, managing project risk/issues and escalation, communication with project sponsors, budget tracking, resource management, and coordination of dependencies between cross-functional partners and external vendors. In addition, Nyasha ensured that team members were highly focused on each deliverable throughout the effort while keeping the project objectives in sight. Ms. Madziva and her team were able to deliver results on a rolling basis matching the manufacturing train demands. This ensured the on-time manufacture of the Covid vaccine batches and ahead of regulatory approval to allow for a swift and organized distribution once approved to meet the pandemic demands.

Project Manager

Nyasha spearheaded a project to review manufacturing batches for 120 different cosmetics products ahead of an FDA inspection and to verify the robustness of the manufacturing process. Nyasha utilized an incremental project lifecycle to manage the high volume of work constrained by a tight timeline, and budget. She managed the strategic planning, organizing, and prioritizing efforts in preparation for the reviews, which included the treatment of shade and packaging differences. Ms. Madziva developed a statistical analysis template in JMP in order to streamline the review process for each product and to be able to scale up the team and standardize the quality of deliverables. The project's statistical analyses exposed several systematic manufacturing trends that were previously minimized. The manufacturing trends revealed that several products had up to 50% of the batches produced within the last 5 years below target yields, which led to millions of dollars in financial losses as each failure was being erroneously treated as an isolated event. In addition, the early identification of such critical issues led to the development of mitigation measures minimizing the risk of FDA observations ahead of the inspection.

Technology Expertise

- Microsoft Office 365
- MS Project
- JMP
- LIMS

Deliverables

- Project Schedule
- Project Roadmap
- Risk Logs
- Requirement Documentation
- Testing/Validation
- Executive Presentations
- Budget Forecasts
- Process Maps