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General Manager / Site Head 503B Compounding and Manufacturing of Sterile Injectables
Human & Animal Health Products | Small Molecule | Master's Degree, Strategic Communication and Leadership

Quva Accomplishment History
(July 2025 – January 2026)

Culture, Engagement & Communication

- Deployed an enterprise engagement survey to assess workforce sentiment and identify improvement opportunities.
- Established **employee roundtables** and launched **monthly site-level engagement sessions** with the Site GM to rebuild trust, transparency, and connection.
- Implemented a structured communication cadence, including **Manufacturing & Operations All-Hands meetings**, focused on expectations, accountability, and cultural reset principles.

Process & Reliability Improvements

- Leveraged equipment performance data to identify chronic failure points on legacy syringe fillers; implemented **preventive and predictive maintenance programs**, increasing **OEE from ~50% to ~70%** over time.
- Secured approval for **ILP headcount expansion**, increasing staffing from **~30 to ~50 employees per shift** on both first and second shift.
- Standardized ILP training pathways to prioritize **manual visual inspection qualification**, enabling higher per-employee productivity and flexibility.
- Introduced **routine aseptic observations** and monthly best-practice reviews for compounders, focusing on hand hygiene and surface sanitization. This reduced the average number of unqualified compounders from **~5–6 to ~2–3 per month**, stabilizing compounding output.
- Eliminated non-value-added syringe WIP by converting syringe operations from batch-and-hold to a fully **inline compounding-to-ILP flow**, reducing unprocessed WIP by approximately **~24K units per day**.

Accomplishment History
2015-2024

Process Improvement & Efficiency

1. Six Sigma Implementation Across Multiple Sites
   Implemented and championed Six Sigma program across multiple sites, leading diverse project teams to improve fill-to-release metric by focusing on yield, accountability, fill volume limits, right-first-time practices, QA final batch record review to improve ≤ ***30-day lot release & distribution. Successfully reduced fill-to-release metric from 54 days to 26 days, achieving a 51.85% reduction in time and generating hard savings of $1.7 million over 12 months measured by way of reduction of rejects, bulk discards and consequently improving filling yields.***
2. Spearheaded an initiative to reduce final media fill report closure time from an average of ***39 days to 30 days*** or less, successfully aligning with customer demand for critical care products and improving operational efficiency.
3. Managed event closures ***within the 30-day lifecycle*** during an increased workload due to product demand increasing ***44 number of additional batches over a 12-month period paired*** with staffing constraints both at the Manufacturing Quality Engineering [MQE] and process supervisors' levels.

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4. Spearheaded incentivized overtime plan that included critical departments by boosting filling manufacturing capacity by an additional ***44 product lots [373 to 417], which is +12%,*** generating an additional ***44 product lots over a 12-month period,*** effectively meeting customer demand and **adverting third-party penalties of *900K.***
5. Managed overtime efforts to address *backorder challenges* while maximizing production capacity within organizational constraints. Through effective coordination and commitment from all team members, we achieved a ***12% capacity increase*** despite facing such challenges.
6. Manufacturing & Validation Equipment Changes: Led a project to enhance unit throughput and ***efficiency by increasing filler speed on Line One*** **washer and filler**. Collaborated with manufacturing and validation management to raise maximum validated speeds from ***225 units per minute (UPM) to 255 UPM, achieving an 11.1% increase in capacity.*** This improvement facilitated earlier completion of filling, enabling more efficient cleaning and changeover processes.
7. Process integration of the washing, inspection, labeling, serialization and packaging processes:
   Spearheaded the integration of two fully operational inspection and packaging lines ≤ 60 days, ensuring seamless departmental relocation and meeting aggressive timelines. This project included the integration of vial washing, inspection, labeling, serialization, and packaging processes, leading to a ***20% average improvement in Operational Equipment Effectiveness (OEE) from 62% to ~82% for 300 product lots over the course of 12 months, while mitigating compliance risk.***
8. Lock In Filling Schedule
   Implemented the **Filling Lock-in Schedule** process, ensuring a three-week forward-looking filling schedule to enhance readiness and minimize last-minute changes. Week #1 focuses on the readiness and release status of equipment, materials, batch records, protocols, and labor, reducing schedule changes from ***3 out of 4 weeks (~75%) in each month to 1 out of 4 weeks (≤25%) improvement on average over a 12-month period.*** Fostered a culture where the locked-in schedule dictated manufacturing readiness, promoting efficiency, reducing confusion, and mitigating potential errors.
9. Established expectation for filling room start times of ≥90% to maximize available up time to support the filling run duration and improve filling yields.

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Accomplishment History Continued

10. Implemented Operational Excellence Efficiency (OEE) tracking software, ***ShopFloorConnect, on 100%*** of lines to analyze downtime causes, facilitating weekly reviews with manufacturing and maintenance departments to identify trends and implement corrective actions.

Business Continuity and Strategic Planning

1. **Business Continuity [Venofer Glass Issues]** Identified and implemented a plan to qualify alternate suppliers for glass components, transitioning from Gerresheimer in Chicago Heights to **Gerresheimer in India**, as well as introducing a new glass supplier **Bormioli located in Italy** over a 12-month period. This strategic plan reduced component variability and improved filling yields by ***~15%, resulting in a hard cost savings of $500,000 over the following 12 months.***
2. Business Focus / Strategic Objectives / Shared Goals and Metrics [Business Continuity]
   Developed and implemented a comprehensive site scorecard for multiple sites, focusing on critical business areas such as Customer Service, Quality, Regulatory Compliance, and Training Compliance. This included strategic objectives such as filling schedule adherence, fill-to-release time, right-first-time rate, deviation closures within ≤ ***30 days***, zero major or repeated regulatory audit observations, and ISO training compliance. Established cascading metrics and goals to ensure all sites met or exceeded scorecard targets, resulting in improved operational performance and compliance. ***For example, reduced deviation closure time by 20% and increased training compliance rates to 98%.***
3. Development of Cascading Goals Operational Excellence
   Developed internal cascading goals to support the NY Site corporate strategic objectives. Cascading goals and metrics include ***target of ≥5% OEE improvement for manufacturing & production lines, target of ≥5% reduction of bulk discards by first time right.***
4. Aseptic processing area ***cleanroom services employes,*** job description and expectations ***aligned to filling room operators*** increasing the number of filling room operators ***by 33% (from 60 to 80).*** This strategic shift expanded capability and flexibility, resulting in improved filling yield.
5. Aligned aseptic filling room operators' job descriptions and expectations ***with industry best practices,*** designating operators for setup and breakdown of the filling room, with mechanics in a secondary/supporting role. Implemented a phased approach initially targeting first shift employees, expanding to ensure training and qualification for all filling room operators and mechanics. Developed a comprehensive training and qualification plan. This transition led to a reduction in EM/PM recoveries and improved process efficiency, particularly during labor shortages. ***Resulted in on-time filling room start-up improvement from 75% to 91% over 12 months.***
6. Union Contract Negotiation Led contract negotiations resulting in a five-year agreement with Local 312 UFCW Union. Successfully established processes for voluntary and mandatory overtime, alignment with existing Cigna Health Care for non-union employees, and profit sharing. ***Negotiated an updated wage compensation schedule granting a 10% increase upon signing and annual increments of 4%, 3%, and 6% over three years, totaling a 23% salary increase over four years.*** Defined planned and unplanned absences related to PTO usage, implementing a new attendance policy. Achieved agreement approval several months ahead of schedule.

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Accomplishment History Continued

7. Covid-19 Challenges Successfully maintained and optimized the manufacturing filling schedule during the COVID-19 pandemic, ensuring no disruptions in production and meeting all customer demands. Implemented stringent safety protocols and enhanced hygiene practices, safeguarding the health of over 325 employees while maintaining full operational capacity. Led a cross-functional team to rapidly adapt to evolving health requirements and supply chain challenges, ensuring continuous production of critical aseptic products. Developed and executed a robust contingency plan that mitigated risks associated with the pandemic, resulting in zero delays or shortages in product supply. Leveraged transformational leadership to foster a resilient and adaptive work culture, enabling the team to excel in a high-pressure environment and exceed production targets. Coordinated with procurement and logistics partners to secure essential raw materials and components, maintaining uninterrupted manufacturing operations. Maintained exemplary quality standards and compliance, ***achieving 95% on-time delivery.*** Spearheaded employee wellness initiatives, providing support and resources to ensure workforce morale and productivity remained high during the pandemic. Successfully scaled up production capabilities to meet increased demand for aseptic products, contributing to the global effort to combat COVID-19.

Innovation

1. 100 million Dollar Capital Expenditure Project: Aseptic Filling in isolators directed the successful execution of a multi-million-dollar CAPEX project, expanding isolator filling lines and relocating inspection and packaging departments, ensuring zero interruptions to critical manufacturing processes. Spearheaded the transition of the project from concept to approval, securing executive management endorsement in 2020 and DS board approval overseeing key milestones from 2021 to 2024. Collaborated with the Director of Facilities Management and the Director of Engineering to manage construction and engineering aspects, resulting in the on-time completion of construction phases. ***Achieved a $14 million budget adjustment through strategic negotiations, maintaining project fiscal responsibility amidst economic challenges due to COVID-19.*** Expedited critical procurement processes, securing early purchase orders to mitigate delays and maintain pricing stability. Overcame complex regulatory and environmental challenges, including wastewater discharge and NY State Department of Conservation requirements, ensuring compliance and project advancement. Successfully integrated two fully operational inspection and packaging lines within 60 days, meeting aggressive timelines and ensuring seamless departmental relocation. Secured a ***$3.5 million tax incentive through effective collaboration with finance and legal departments, enhancing project financial viability.*** Completed final construction phases, enabling the commissioning, validation, and qualification of new manufacturing clean rooms and isolator fill lines as of 2Q24. Ensured readiness for product transfer to isolators, with critical validation stages including EMPQ, process validation, and media fill execution, positioning the site for enhanced production capabilities.

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Accomplishment History Continued

2. Aseptic Manufacturing Process Start-up / Tech Transfer
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Directed strategic planning and execution of product transfers and a new aseptic manufacturing process for pre-filled syringes, overseeing qualification of new clean rooms, development of SOPs, smoke studies, and comprehensive environmental and personnel monitoring programs. Led process qualification of equipment and validation of aseptic processes, including personal training on aseptic techniques and gowning procedures. Executed media fill simulations**,** first exhibit batches, submission, and FDA Approval Inspection (PAI). Achieved zero positive (turbid) units out of 5K media runs / 60K units during performance qualification activities, demonstrating the robustness of the validated process.

Quality & Compliance

1. Quality regulatory compliance through establishing internal compliance expectations there was ***no past due investigations or CAPAs exceeding the goal of ≥ 95%*** as measured against the NY site scorecard strategic objective.
2. Directed department heads to collaboratively establish internal compliance expectations to ensure on-time investigation closures, supporting on-time product release and meeting customer demand. Implemented a weekly compliance tracker for managers to monitor employee workloads and compliance adherence. ***Achieved an improvement in investigations closing within ≤ 30 days from 72% to 94% over a 12-month period.***
3. NY-ARI Manufacturing Site Representative Acted as NY-ARI manufacturing site representative for multi-states where product sale and subsequent distribution occurs, ensuring compliance with federal and state regulatory requirements ***through successful completion of fingerprinting, drug screening, and comprehensive FBI & state background checks.***
4. Successfully interacted with regulatory agencies including the ***FDA, MHRA, Health Canada and DEA during multiple general inspections and Pre-Approval Inspections (PAIs) for Paragraph 505(b)(2) filings.***

Manufacturing Depth & Flexibility

1. Enhanced inspection and packaging depth by revising job descriptions and implementing a training qualification plan, ensuring ***100%*** of packers, inspectors, machine operators, and leads obtain manual inspection qualification. This initiative addressed the initial 50% skill gap and established consistent inspection rates aligned with qualifications, improving technical competency and operational efficiency in the inspection department.
2. Created tiered-level positions by revising and developing job descriptions for packers, machine operators, and leads to align with production needs, technical acumen, and work experience, providing a clear career growth path within the department. Successfully implemented this initiative over a 12-month period.
3. Implemented a communication plan including weekly production meetings and shift huddles to enhance information exchange among process manufacturing teams, supervisors, managers, and cross-functional departments. These huddles drive outcomes, support process improvement, and quality efforts by discussing manufacturing updates, reportable events, projects, and processing constraints, thereby mitigating potential risks and increasing manufacturing efficiency.

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Accomplishment History Continued

4. Established a Sunday-Thursday work crew by ***redistributing labor*** to facilitate cleaning, equipment preparation, and setup of filling rooms, ensuring on-time filling room release for Monday mornings. ***This initiative improved on-time filling room start-up from 62% to 89%.***

Operational Excellence

1. Target of 100%, no rejected / scraped batches due to human errors. Equipment preparation execution at ≥ 90% to ensure filling room start times are not negatively impacted.
2. Established filling room start-up times of **NLT 7:15am** to support filling setup and startup activities. Consistent start up times were achieved through the development and implementation of **standard work @ ≥90%** ensuring expected labor allocation to timebound tasks to ensure on time filling startup.
3. Right sized product lot batches to optimize filling operations, to allow for the completion of filling within the two shift, 16 hour required run time **resulting in 11% reduction in bulk discards and an increase in filling yields of 10% for 187 product lots over a 12-month period.**

Workplace Culture, Recognition and Employee Engagement

1. Manufacturing & Quality Culture
   Fostered a robust partnership mutual respect and alignment with quality management by scheduling regular meetings, maintaining open communication channels, and aligning goals to ensure seamless operations. Facilitated joint training sessions and workshops to enhance mutual understanding and expertise. Promoted joint problem-solving and continuous improvement initiatives through cross-functional teams. Recognized and celebrated the contributions of quality management to reinforce their importance. Developed an accountability framework with shared responsibility for quality. Established regular feedback systems and diverse communication channels to keep teams informed and engaged. Organized team-building activities to build rapport and trust, promoting an inclusive culture where both teams feel valued.
2. Led initiatives to align ARI sites with One DS culture, utilizing the annual Glint survey to gather employee feedback. Implemented focus groups and strategic communication plans, including Connect Listen & Learns (CLL) and townhalls, resulting in numerous process improvements. Conducted joint townhalls with Quality, enhancing information flow and employee engagement. Developed a live One DS roadmap for transparency and management commitment tracking. ***Achieved a 5% increase in Glint survey participation, rising from 89% in 2023 to 94% in 2024, and an 8% increase in employee engagement from 74% to 82%. Enhanced scores across all 30 survey questions, indicating overall cultural improvement.***
3. Process improvement reducing batch record errors due to job performance reward recognition and accountability framework. Directed the implementation of a reward recognition and accountability framework to reduce batch record errors and improve GMP documentation accuracy. Tasked directors and managers to establish processes aimed at minimizing preventable events due to documentation errors. ***This initiative involved quarterly data reviews and resulted in a 55% reduction in documentation errors over a 12-month period.***
   Departments were rewarded on a quarterly basis, fostering a culture of continuous improvement and accountability.

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Accomplishment History Continued

4. Employee Appreciation Program [Arigato] & One DS Culture: Established a structured mechanism to consistently implement the "Arigato" employee appreciation program, ensuring regular recognition of exemplary performance, adherence to core values, and contributions to One DS Culture. Introduced monthly Manufacturing & Operations department meeting to review and reward outstanding job performance and behavior, ***resulting in a 25% increase in employee engagement.***

Operational, Capital and CAPEX Budgets

1. Project Planning & Budget
   Spearheaded the integration of finance for all capital expenditure request (CAR) processes to ensure comprehensive stakeholder collaboration and informed decision-making. Established internal protocols for early involvement of finance in planning both scheduled and unplanned capital projects, resulting in streamlined approvals and enhanced budget management. ***Achieved a 20% reduction in CAR approval time and improved financial forecasting accuracy by 15%.***

Site Training Compliance

1. Developed and implemented a strategic plan called Designated Training Days in an effort to provide a defined process to ensure ongoing training compliance. Prior to designated training days review training compliance was at ***~88% during the first three months*** of the review period. As a result, all manufacturing and operations departments ***exceeded the goal at 96% with a target metric of ≥95% over a 12-month period.*** Additionally, at no time was an employee performing a critical task that they were not trained or qualified. Due to the success of this strategic plan, Designated Training Days was implemented across multiple sites.

Leadership, Technical Acumen Development, Succession Planning

1. Developed and implemented the 21 Irrefutable Laws of Leadership Development Series for managers as well as hourly workforce over a 10-month period, designed to explore how we can enhance our leadership qualities at all levels in the organization. Although the employees who participated had a robust understanding of essential leadership principles and practical skills to apply these laws, the development of relationships was remarkable.

   The learning series environment fostered the developing of relationships, higher engagement and productivity within the workplace, leading to an overall increase in job satisfaction and team performance as seen in the site Glint survey results [ref. Workplace Culture, Bullet #2 below]. These improvements underscore the profound impact that structured leadership training can have on organizational success.

2. Implementation of a structured review of the FDA's Guidance to The Industry for Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practices [cGMPs]. This initiative significantly enhanced the regulatory understanding and compliance acumen of managers and supervisors, aligning our operational standards with the stringent FDA expectations and elevating our company commitment to quality and safety in drug manufacturing.

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Accomplishment History Continued

3. Nine-Box, Grid Succession Planning
   Implemented and managed a 9-Box Grid Succession Planning framework to identify and develop high-potential talent across multiple departments, enhancing leadership pipelines and ensuring strategic workforce planning.

Personal Development

1. **Courses and Continued Learning Events Annual Parenteral Drug Association (PDA) Conference** Attended the annual Parenteral Drug Association (PDA) conference, a leading global provider of science, technology, and regulatory information, to stay current with industry advancements. Participated in sessions designed to create awareness and understanding of critical issues facing the pharmaceutical and biopharmaceutical community. Engaged in high-quality, relevant educational opportunities to enhance knowledge in pharmaceutical/biopharmaceutical manufacturing science and regulation, supporting the mission to better serve patients.

2. **Executive Leadership Development Program (LDP)**
   Completed a 5-day immersive Leadership Development Program (LDP) by the Center of Creative Leadership in San Diego in 2023. Enhanced skills in overcoming hierarchical challenges, fostering organizational collaboration, optimizing resources, and maintaining resilience amidst uncertainty and complex challenges.