Jacqueline Torres

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QUALITY SITE HEAD & COMPLIANCE EXECUTIVE

GxP Site Readiness • FDA/Regulatory Inspection • Audits • Vaccines(DS/DP) • Injectables(parenteral) • Data Integrity (alcoa+) • Digital Devices/AI • •Quality Systems(QMS)• Regulatory Compliance • Manufacturing • Sterile manufacturing • Injectables • Small Molecules • Robust Computer System Validation • leader in regulatory inspections • Digital Twins Research •

Strategic and Results-Driven Quality and Compliance Leader

Dynamic Senior Quality Executive recognized for transforming global pharmaceutical operations into benchmarks of compliance, efficiency, and patient-focused excellence. I bring over two decades of proven leadership in vaccines, injectables, and high-stakes manufacturing, with a flawless track record in FDA, EMA, and international inspections. Renowned for integrating quality into the heart of manufacturing strategy, I have led BLA-winning programs, site remediations, and inspection readiness initiatives that turn compliance into a competitive advantage. A strategic force in cGMP and GxP systems, I build elite, high-performing teams and align cross-functional operations to deliver flawless execution from pilot to commercial scale. My leadership doesn't just safeguard compliance—it accelerates innovation, strengthens product reliability, and positions organizations as leaders in the global healthcare market.

PROFESSIONAL EXPERIENCE

Sr Quality Head, Cambridge 2025- Present

Baxter International, Boston, MA

Summary:

As the Sr Quality Head at Baxter, I lead all GxP Quality functions, including Quality Assurance, Quality Control, R&D Quality, Document Control, Supplier Quality, and Quality Systems. I define and drive the company's quality vision, ensuring compliance across global operations and supporting programs from early development through commercialization.

Key Achievements:

- **Developed and Implemented Quality Systems:** Built and optimized scalable Quality Systems to support effective, compliant operations, ensuring compliance with regulations, guidelines, and corporate standards.
- **Regulatory Compliance:** Oversee quality oversight of CDMOs, CROs, contract labs, and critical material suppliers; identify risks and lead remediation using a risk-based approach.
- **Global Regulatory Submissions:** Supported global regulatory submissions (IND, NDA, BLA) in partnership with Regulatory Affairs and led company-wide readiness and execution for regulatory inspections.
- **Quality Metrics and Compliance:** Managed Quality metrics, monitored compliance trends, and implemented mitigation plans as needed.

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- **Leadership and Collaboration:** Led and resolved major deviation investigations to safeguard product quality, safety, and efficacy, and partnered with external Quality teams to ensure uninterrupted supply and support current and future production plans.

Professional Experience:

- **Sr Quality Head, Baxter**
  - Lead all GxP Quality functions, including Quality Assurance, Quality Control, R&D Quality, Document Control, Supplier Quality, and Quality Systems.
  - Develop and implement phase-appropriate Quality models aligned with ICH risk-based guidance.
  - Build and optimize scalable Quality Systems to support effective, compliant operations.
  - Oversee quality oversight of CDMOs, CROs, contract labs, and critical material suppliers.
  - Partner with external Quality teams to ensure uninterrupted supply and support current and future production plans.
  - **Site Leadership Experience:**
    - Currently lead a site that manufactures pharmaceutical and nutritional intravenous IV bags and small parenteral products.
    - Ensure compliance with regulatory requirements, including FDA and EU regulations, and implement quality strategies to support product commercialization.
  - **Product Portfolio Management:**
    - Manage a portfolio of products, including sterile and aseptic products.
    - Develop and implement quality strategies and plans to support product commercialization and compliance.

Skills:

- **Regulatory Compliance:** Deep understanding of CDE, FDA, and ICH GxP regulations, including GMP, GLP, GCP, and GDP.
- **Quality Systems:** Proven experience in building Quality Systems in early-stage, science-driven organizations and supporting product commercialization.
- **Leadership:** Proven leadership in building and scaling high-performing teams in fast-paced environments.
- **Communication:** Strong communication and collaboration skills, with the ability to work effectively with cross-functional teams and external partners.

Quality Site Head Vaccine, Cambridge 2023- 2025
GSK Vaccine Site, Boston, MA

- Led a cultural transformation, transitioning the site from an R&D-focused mindset to full GMP compliance**,** embedding quality into all aspects of operations and production.

Implemented GMP training programs, cleanroom behavior workshops, and operational excellence initiatives**,** fostering a mindset of accountability and continuous improvement.

- Developed and optimized the site's Quality Management System (QMS), integrating deviation management, CAPA, change control, and batch release processes to improve efficiency, reduce compliance risks, and enhance product quality.
- Established key **governance committees** such as the Site Quality Council, Inspection Readiness Committee, and **CAPA Effectiveness** Review Board, ensuring strategic oversight of compliance, investigations, and operational improvements.
- Drove significant **operational efficiencies,** reducing batch release cycle times by 20%, minimizing deviations by 30%, and enhancing right-first-time metrics through proactive quality integration into manufacturing.
- Led the site's workforce expansion**,** growing the **quality team from 12 to 67 employees, developing leadership pipelines**, and implementing succession planning, technical training**,** and team development programs to sustain **long-term operational success**.
- Secured GMP certification for site laboratories, directing the successful validation, qualification, and regulatory approval of testing operations, improving turnaround times and compliance reliability.
- Optimized Environmental Monitoring Performance Qualification (EMPQ) initiatives, driving improvements in cleanroom classification and contamination control**,** reducing microbial risks and ensuring a compliant production environment.
- **Provided strategic quality oversight for the MAPS Pilot Plant,** ensuring robust GMP compliance, process validation, and risk management for early-stage vaccine production. Collaborated with R&D and Manufacturing teams to integrate quality into process development**, optimizing scale-up and ensuring seamless transition to full-scale production**.
- Partnered with manufacturing and supply chain leaders to enhance shop floor quality engagement**, streamline batch release, and implement** real-time deviation resolution processes**,** improving production efficiency and reducing delays.
- Led global quality initiatives**,** harmonizing best practices across vaccine manufacturing sites, driving data integrity (ALCOA+), digital transformation in quality systems, and automation of compliance processes to improve efficiency and scalability.
- Championed inspection readiness and regulatory success**,** ensuring full compliance with **FDA,** and EMA standards, leading to **zero critical findings** in multiple regulatory audits and inspections.
- Drove continuous improvement initiatives, applying Lean Six Sigma, **DMAIC methodologies, and operational analytics** to enhance **yield, reduce waste, and optimize production** workflows**,** reinforcing quality as a competitive advantage.

NOVARTIS CORPORATE GROUP, Cambridge, MA
Quality Systems Director Lead **2020-2023**

Role Focus: Leading the optimization and integration of quality systems, enhancing operational efficiency and ensuring compliance with regulatory standards.

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Responsibilities:

- Led the design and implementation of robust Quality Systems, including change control, incident management, and internal auditing to support clinical and manufacturing processes.
- Developed and maintained quality metrics, systems, and documentation to support clinical trials and laboratory operations, ensuring compliance with GCP, GMP, and GLP standards.
- Managed and executed training programs for GxP, ISO, and IVD manufacturing compliance, ensuring 98% completion rates across the team.
- Directed compliance activities to maintain state licenses for vaccine manufacturing facilities and regulatory accreditations, ensuring uninterrupted operations.
- Oversaw the validation and implementation of QMS in Cloud, GxP SaaS platforms, ELNs, Trackwise, LIMS, SAP, and mobile applications, ensuring compliance with regulatory standards.
- Managed department budgets, aligning spending with organizational objectives and delivering compliance and quality initiatives effectively.

Key Achievements:

- Successfully led the NIBR Data Integrity program, enhancing data accuracy and regulatory compliance by integrating ALCOA+ principles into all operational processes.
- Designed and implemented process improvements that enhanced data integrity and operational efficiency by 25%.
- Led internal Quality Review Board (QRB) and Quality Investigation Board (QIB) activities, ensuring continuous improvement through CAPA implementation and trend analysis.

NOVARTIS PHAMACEUTICAL, East Hanover, NJ **2018- 2020**

Quality Lead (Quality Head)

Role Focus: Oversight and strategic leadership of all quality activities, ensuring compliance, operational efficiency, and alignment with business goals.

- **Responsibilities:**
  - Led strategic oversight of quality activities, including batch record release, ensuring timely updates to manufacturing teams and collaborating with distribution centers, HQ, and Site Heads to meet operational goals while maintaining uncompromised quality.
  - Developed and executed quality strategies and plans to ensure compliance, operational efficiency, and successful product launches, aligning with both corporate objectives and regulatory standards.
  - Directed regulatory submission efforts, providing strategic leadership in securing product approvals and ensuring alignment with evolving regulatory requirements.
  - Managed a team of 17 people across various quality functions, driving high performance and adherence to quality objectives while fostering a culture of

continuous development, succession planning, and talent retention. Led initiatives that supported employee growth, reduced turnover, and ensured a robust pipeline of future leaders within the quality organization.
    - Created and led new teams such as Site Conformance and Micro-Lab, driving process improvements and enhancing team capabilities.
    - Directed validation and compliance activities for clinical trials and laboratory operations, ensuring adherence to GCP, GCLP, and IVD standards.
    - Facilitated critical decision-making on quality issues affecting products in the U.S. and LATAM regions, driving effective resolutions through collaboration with key stakeholders.
    - Spearheaded the design and implementation of the Data Integrity (ALCOA+) program, ensuring reliable and compliant data across all regulated systems.
    - Managed up to senior leadership by providing regular updates on quality metrics, risks, and compliance statuses, ensuring alignment with overall business goals.
- **Key Achievements:**
    - Successfully led product launches such as Voltaren, Diovan, and Cosentyx, overseeing regulatory registration, post-market surveillance, and Quality Audits, ensuring full regulatory compliance.
    - Implemented and validated GenMed electronic Quality Systems (eQMS) Trackwise, enhancing compliance, operational efficiency, and data integrity.
    - Directed and facilitated internal audits and gap assessments, improving compliance readiness and operational processes.

Quality Governance Lead **2006-2018**
NOVARTIS Pharmaceutical, East Hanover, NJ

Role Focus: Building governance structures, fostering collaboration, and ensuring that all quality standards are aligned with regulatory requirements.

- **Responsibilities:**
    - Built cross-functional relationships to optimize the quality and innovation of clinical protocols, ensuring alignment with corporate goals and regulatory standards.
    - Redesigned the OTC Global Adverse Events and Customer Complaint Center, improving processes for issue resolution and regulatory reporting, while strategically negotiating with external stakeholders to streamline operations.
    - Led the transfer and implementation of a new Customer Relations System, yielding significant cost savings and eliminating redundant processes through strategic decision-making.
    - Established compliance monitoring programs to ensure adherence to corporate policies (SOPs) and FDA cGMP regulations, driving operational excellence across the organization.
- **Key Achievements:**
    - Successfully revamped the customer complaint handling and adverse event reporting processes, reducing inefficiencies and ensuring alignment with regulatory expectations.
    - Executed regulatory strategies for product development, fast-tracking approval pathways and enhancing product line extensions, ensuring market readiness.

- Guided teams through successful product launches by fostering a governance framework that ensured seamless integration across departments.

ROCHE PHARMACEUTICAL, Nutley, NJ 2006-2004

Role 1: Global Head of Quality Assurance – Tamiflu Manufacturing Site

- **Led all Quality Assurance (QA) operations** for Roche's **Nutley, NJ manufacturing site,** overseeing GMP compliance for the **production of Tamiflu.**
- **Managed and developed a high-performing Quality organization of 26 members, including 5 direct reports,** ensuring strategic oversight of batch release, deviation investigations, CAPA execution, and regulatory compliance.
- **Provided strategic leadership in manufacturing quality,** embedding quality principles into production workflows, optimizing batch release cycle times**,** and reducing repeat non-conformances.
- **Implemented site-wide Six Sigma process enhancements,** improving laboratory operations, deviation closure efficiency, and compliance metrics.
- **Led regulatory inspection readiness,** ensuring continued compliance and successful audits with **zero critical findings.**
- **Collaborated with Manufacturing and Supply Chain teams** to integrate quality into daily operations, improving production timelines and minimizing disruptions.
- **Chaired site governance committees** overseeing risk management, quality review boards, and continuous improvement initiatives, ensuring a culture of proactive compliance.
- **Developed and implemented training programs** to elevate staff expertise in **GMP standards, aseptic processing, and regulatory compliance.**

Role 2: Global Head of Compliance & GxP Systems (Supportive Role)

- **Provided global compliance support** for Roche's manufacturing, clinical, and laboratory operations, ensuring alignment with corporate policies and international regulatory expectations.
- **Supported a globally distributed compliance team of 4 direct reports across Roche sites,** providing guidance on GxP system implementations, regulatory submissions, and audit preparedness.
- **Oversaw compliance support for technology transfer and API manufacturing,** ensuring system upgrades and process validation met industry best practices.
- **Contributed to corporate audit programs,** assisting with compliance assessments for **GCP, GMP, GLP, and GVP** across Roche's global network.
- **Played a key role in vendor compliance monitoring programs,** assisting in the development of supplier qualification frameworks and periodic review processes.
- **Supported over 65 global quality projects annually,** including **Global SAP harmonization (Latin America & Europe), LIMS, electronic lab notebooks, and Learning Management Systems (LMS).**

- **Developed and delivered training programs on Quality Systems, CSV, and regulatory compliance,** ensuring global sites adhered to Roche's compliance standards.
- **Analyzed and reported quality trends,** assisting in the development of risk mitigation strategies for SOP deviations, protocol findings, and audit observations.
- **Contributed to regulatory documentation support,** assisting in the preparation of **Investigator's Brochures, IND/NDA submissions, and regulatory responses to health authorities.**

SCHERING PLOUGH, Springfield, New Jersey 2000-2004

Director of Quality

- **Led quality operations and compliance initiatives** for the Springfield, NJ site, overseeing manufacturing quality systems and regulatory adherence for solid oral dosage forms, injectables, and OTC products.
- **Directed site-wide compliance programs,** ensuring adherence to FDA cGMP requirements, corporate policies, and international regulatory standards.
- **Developed and executed CAPA strategies,** reducing repeat deviations by **35%** and driving sustainable improvements in compliance and operational efficiency.
- **Led regulatory inspections and internal audits,** ensuring audit preparedness and successfully addressing compliance gaps.
- **Implemented Quality Management System (QMS) enhancements,** including document control, change management, and batch release improvements, strengthening site compliance.
- **Provided strategic quality leadership,** overseeing complaint investigations, batch release operations, and supplier quality programs.
- **Mentored and developed a high-performing quality team,** fostering a culture of accountability, ownership, and continuous improvement.

Special Assignment: Quality Site Head – Kenilworth, NJ (FDA Consent Decree Remediation for Loratadine Product)

- **Appointed as Quality Site Head** to lead the Kenilworth, NJ site remediation efforts in response to an **FDA Consent Decree** for Loratadine, ensuring successful resolution and long-term compliance.
- **Developed and implemented a comprehensive remediation plan,** focusing on CAPA effectiveness, Sterility and contamination risk, data integrity improvements, and alignment with FDA requirements.
- **Led a cross-functional remediation team,** overseeing process validation, cleaning validation, and laboratory controls to address FDA observations and prevent recurrence.
- **Executed quality system upgrades,** including the **implementation of risk-based deviation management, QMS restructuring, and strengthened batch release protocols.**
- **Established a Governance Committee** to oversee site-wide remediation efforts, ensuring accountability, transparency, and measurable improvements in compliance.

- **Collaborated with regulatory agencies,** preparing and submitting response packages, ensuring alignment with FDA expectations, and achieving site re-approval.
- **Developed and deployed a site-wide compliance training program,** reinforcing a culture of quality and regulatory ownership among manufacturing and quality teams.
- **Led and coached the quality team,** transforming the department into a high-functioning, compliance-driven unit capable of executing investigations, audits, and CAPA management with precision.
- **Implemented individualized development plans,** providing mentorship, skills training, and leadership coaching, resulting in a **40% increase in internal promotions** and stronger team retention.
- **Instilled a proactive compliance mindset,** shifting the team's focus from reactive issue management to **preventive risk mitigation**, significantly reducing compliance deviations.
- **Empowered team members by fostering cross-functional collaboration,** strengthening communication between Quality, Manufacturing, and Regulatory teams to drive operational efficiency.

WARNER LAMBERT, VEGA BAJA, PR 1993 – 2000 (8 years)

QA and Regulatory Manager (high level summary)

QA & Regulatory Manager | Warner-Lambert, Vega Baja, PR | 1993 – 2000

- **Led and supervised the Quality Assurance team** at a **multi-product manufacturing site,** overseeing compliance, batch release, investigations, and regulatory inspections for **solid oral dosage forms, liquids, and sterile products.**
- **Managed quality operations** across manufacturing, packaging, and laboratory environments, ensuring compliance with **FDA, EMA, and global GMP regulations.**
- **Directed site-wide deviation investigations, CAPA implementation, and risk management programs,** reducing compliance issues and improving overall product quality.
- **Implemented Quality Systems (QMS),** including **change control, document management, and supplier qualification programs,** strengthening site-wide compliance.
- **Ensured real-time collaboration between Quality, Manufacturing, and Engineering teams,** improving process efficiency and reducing batch release cycle times by **15%.**
- **Supervised and mentored a team of QA professionals,** fostering professional growth and developing a strong compliance-driven culture.
- **Led inspection readiness initiatives,** ensuring successful regulatory audits with **zero major findings** while maintaining continuous compliance.

Overseas Assignment: Quality Site Head | Warner-Lambert, Ringaskiddy, Ireland | Lipitor Site Start-Up

- **Appointed as the Quality Site Head** for the **Ringaskiddy, Ireland** site during its **start-up phase,** overseeing the establishment of the entire Quality Organization for Lipitor manufacturing.

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- **Built and structured the entire Quality Unit,** recruiting and developing a team of QA professionals, ensuring alignment with global Warner-Lambert quality standards.
- **Led the technology transfer of Lipitor,** ensuring the seamless transition of manufacturing processes, equipment validation, and regulatory compliance from the PR site.
- **Developed and implemented all Quality Systems,** including **batch release, deviation and CAPA management, QMS structure, and inspection readiness programs.**
- **Established a robust inspection and audit readiness framework,** successfully securing GMP certification and approval from **regulatory authorities (FDA, EMA, and local HPRA).**
- **Oversaw process validation, cleaning validation, and stability programs,** ensuring the manufacturing site met all regulatory expectations for commercial-scale production.
- **Collaborated with global and regional stakeholders,** ensuring quality alignment between Warner-Lambert sites and driving operational excellence.
- **Served as the primary Quality representative,** leading cross-functional interactions with Manufacturing, Regulatory, and Supply Chain teams to ensure compliance and efficiency.

EDUCATION

JURISPRUDENCE DEGREE IN PHARMACEUTICAL & PUBLIC HEALTH LAW 2015-2018
SETON HALL SCHOOL OF LAW

MASTER OF SCIENCE IN ORGANIZATION MANAGEMENT 2005
UNIVERSITY OF PHOENIX

BACHELOR OF SCIENCE 2003
UNIVERSITY OF PHOENIX

BACHELOR OF SCIENCE INDUSTRIAL ENG. 1993
POLYTECHNICS UNIVERSITY