



Top Executive & Clinical Healthcare Talent

Curated by HealthStaffingGroup – A Division of National Search Group

★ Candidate ID: 19798 – DIRECTOR OF QUALITY OPERATIONS (QA & QC)

Why This Candidate Stands Out

Seasoned Quality and Regulatory executive with over 25 years of progressive leadership and technical experience across the medical device and pharmaceutical industries. Demonstrated expertise in directing Quality Management Systems, QA/QC operations, regulatory compliance, risk management, audits, CAPA, supplier quality, validation, and continuous improvement initiatives. Extensive knowledge of FDA requirements, ISO 13485/MDSAP, cGMP, EU MDR, and global regulatory programs, including significant regulatory remediation initiatives. Proven ability to lead cross functional teams, manage substantial quality budgets and capital projects, and support manufacturing, product development, clinical operations, and supply chain functions. Skilled in Lean Six Sigma, strategic planning, business analytics, and integrating AI into Quality systems.

Key Highlights

- Over 25 years of progressive leadership and technical experience
- Medical device and pharmaceutical industry experience
- Quality Management Systems, QA/QC operations, regulatory compliance, risk management, audits, CAPA, supplier quality, and validation
- FDA requirements, ISO 13485/MDSAP, cGMP, EU MDR, and global regulatory programs
- Significant regulatory remediation experience
- Cross functional team leadership
- Quality budgets and capital project management
- Manufacturing, product development, clinical operations, and supply chain support
- Lean Six Sigma, strategic planning, and business analytics
- Experience integrating AI into Quality systems

Scope of Expertise

Quality Operations, Quality Assurance, Quality Control, Quality Management Systems, Regulatory Affairs, Medical Devices, Pharmaceuticals, Regulatory Compliance, Risk Management, Audits, CAPA, Supplier Quality, Validation, Regulatory Remediation, Lean Six Sigma, Strategic Planning, Business Analytics, Operational Excellence, Continuous Improvement.

Tools & Systems

Quality Management Systems, FDA requirements, ISO 13485/MDSAP, cGMP, EU MDR, Lean Six Sigma, business analytics systems, and AI integrated Quality systems.

Executive Summary

A senior Quality and Regulatory executive combining technical expertise, regulatory knowledge, operational leadership, and Quality systems experience across medical device and pharmaceutical environments.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs, Operational Excellence, or Director of Continuous Improvement professional.

★ Candidate ID: 19812 – Quality Engineering Manager

Why This Candidate Stands Out

Experienced Quality Engineering and Operations leader with over 20 years of experience in medical device contract manufacturing, including more than 9 years in Global Quality and extensive multi site leadership across domestic and international operations. Demonstrated expertise in quality engineering, regulatory compliance, process improvement, product transfers, process and test method validations, quality system implementations, FDA inspection preparation, CAPA, NCMRs, audits, and root cause investigations. Proven ability to lead teams through complex quality challenges, including significant manufacturing recovery initiatives.

Key Highlights

- Over 20 years of experience
- Medical device contract manufacturing experience
- More than 9 years in Global Quality
- Multi site leadership across domestic and international operations
- Quality engineering and regulatory compliance
- Process improvement and product transfers
- Process and test method validations
- Quality system implementations
- FDA inspection preparation
- CAPA, NCMRs, audits, and root cause investigations
- Manufacturing recovery initiatives
- MBA and MS in Strategic Management
- PMP certification and multiple quality and process improvement certifications

Scope of Expertise

Quality Engineering, Quality Operations, Global Quality, Medical Device Contract Manufacturing, Regulatory Compliance, Process Improvement, Product Transfers, Validation, Quality Systems, FDA Inspection Preparation, CAPA, NCMRs, Audits, Root Cause Investigations, Manufacturing Recovery, Project Leadership.

Tools & Systems

Quality system implementations, CAPA systems, NCMR processes, validation systems, FDA inspection preparation processes, audit systems, and project management practices.

Executive Summary

A senior Quality Engineering and Operations leader with extensive medical device contract manufacturing experience, combining technical quality expertise, multi site leadership, project management, and strategic problem solving.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs or Quality Engineering Manager.

★ Candidate ID: 19867 – Pharmaceutical/Medical Device Sales Manager

Why This Candidate Stands Out

Seasoned pharmaceutical and medical device sales professional with over 20 years of experience in territory growth, healthcare product launches, business development, and market development. Demonstrated expertise in working with physicians, surgeons, hospitals, healthcare systems, and key healthcare decision makers across specialty markets. Experienced in medical device sales, specialty pharmaceuticals, clinical education, territory management, and new market development. Recognized for strong sales performance and selected to train and mentor pharmaceutical sales representatives.

Key Highlights

- Over 20 years of experience
- Pharmaceutical and medical device sales
- Territory growth and market development
- Healthcare product launches
- Business development
- Experience working with physicians, surgeons, hospitals, healthcare systems, and healthcare decision makers
- Specialty pharmaceuticals and clinical education
- Territory management and new market development
- Training and mentoring pharmaceutical sales representatives
- Consultative selling and relationship management
- Customer development and territory expansion

Scope of Expertise

Pharmaceutical Sales, Medical Device Sales, Territory Management, Business Development, Market Development, Healthcare Product Launches, Clinical Education, Consultative Selling, Relationship Management, Customer Development, Territory Expansion.

Tools & Systems

Healthcare product launch processes, territory management systems, consultative selling processes, customer development processes, and clinical education programs.

Executive Summary

A seasoned healthcare sales professional with extensive pharmaceutical and medical device experience, strong territory development capabilities, and a proven record of building healthcare relationships and driving market growth.

Ideal For

Organizations seeking a Territory Sales Manager with pharmaceutical and medical device sales experience.

★ Candidate ID: 19946 – QA Validation Engineer

Why This Candidate Stands Out

Experienced QA Validation professional with approximately 6 years of experience supporting pharmaceutical, biotechnology, diagnostics, laboratory, and regulated manufacturing environments. Demonstrated expertise in Computer System Validation, Commissioning, Qualification and Validation, equipment qualification, process validation, cleaning validation, sterilization validation, and laboratory systems. Skilled in risk based testing for LIMS, Chromeleon CDS, ERP modules, DeltaV DCS, instrument interfaces, and other GxP computerized systems.

Key Highlights

- Approximately 6 years of experience
- Pharmaceutical, biotechnology, diagnostics, laboratory, and regulated manufacturing experience
- Computer System Validation
- Commissioning, Qualification and Validation
- Equipment qualification
- Process, cleaning, and sterilization validation
- Laboratory systems
- Risk based testing
- LIMS, Chromeleon CDS, ERP modules, and DeltaV DCS
- IQ/OQ/PQ, DQ, FAT/SAT, and requirements traceability
- 21 CFR Part 11 and GAMP 5
- Data integrity, deviations, CAPA, change control, and audit readiness
- Equipment installation, commissioning, troubleshooting, technology transfer, calibration, and process improvement

Scope of Expertise

QA Validation, Computer System Validation, Commissioning, Qualification, Equipment Qualification, Process Validation, Cleaning Validation, Sterilization Validation, Laboratory Systems, Risk Based Testing, GxP Systems, Data Integrity, CAPA, Change Control, Audit Readiness.

Tools & Systems

LIMS, Chromeleon CDS, ERP modules, DeltaV DCS, instrument interfaces, GxP computerized systems, IQ/OQ/PQ, DQ, FAT/SAT, 21 CFR Part 11, and GAMP 5.

Executive Summary

A hands on QA Validation professional with experience across pharmaceutical, biotechnology, diagnostics, laboratory, and regulated manufacturing environments, specializing in computerized systems, equipment, process, cleaning, and sterilization validation.

Ideal For

Organizations seeking a Senior Process Engineer with validation and regulated manufacturing experience.

★ Candidate ID: 19922 – Senior Quality Engineer

Why This Candidate Stands Out

Seasoned Senior Quality and Process Engineering professional with over 25 years of experience in regulated medical device manufacturing, process development, and engineering. Demonstrated expertise in process validation, equipment qualification, test method validation, DOE, SPC, and process capability. Extensive experience supporting NPI, design and manufacturing transfers, scale up, production launches, and continuous improvement across catheter, cardiovascular, implant, and other medical device programs.

Key Highlights

- Over 25 years of experience
- Regulated medical device manufacturing, process development, and engineering
- Process validation and equipment qualification
- Test method validation, DOE, SPC, and process capability
- NPI, design and manufacturing transfers
- Scale up and production launches
- Catheter, cardiovascular, implant, and other medical device programs
- Root cause investigations, CAPA, and NCMR resolution
- Risk assessments and DFM initiatives
- Manufacturing process optimization
- Tooling, fixtures, automation, and production systems
- Lean Six Sigma methodologies

Scope of Expertise

Quality Engineering, Process Engineering, Medical Device Manufacturing, Process Development, Process Validation, Equipment Qualification, Test Method Validation, DOE, SPC, NPI, Manufacturing Transfers, Scale Up, Production Launches, CAPA, NCMR, Risk Assessment, DFM, Automation, Lean Six Sigma.

Tools & Systems

DOE, SPC, IQ/OQ/PQ, process capability systems, DFM methodologies, tooling, fixtures, automation, production systems, CAPA processes, and Lean Six Sigma methodologies.

Executive Summary

A highly experienced Quality and Process Engineering professional with deep medical device manufacturing expertise and a strong combination of hands on technical knowledge, process development, validation, production launch, and continuous improvement experience.

Ideal For

Organizations seeking a Senior Process Engineer.

★ Candidate ID: 19865 – Director of Quality

Why This Candidate Stands Out

Seasoned Quality and Compliance executive with over 25 years of progressive leadership experience across pharmaceutical, biologics, medical device, OTC, cosmetics, dietary supplements, and food manufacturing environments. Demonstrated expertise in Quality Assurance, Quality Control, Quality Engineering, Validation, Regulatory Compliance, and Quality Management Systems within FDA regulated and global cGMP operations.

Key Highlights

- Over 25 years of progressive leadership experience
- Pharmaceutical, biologics, medical device, OTC, cosmetics, dietary supplements, and food manufacturing experience
- Quality Assurance, Quality Control, and Quality Engineering
- Validation and Regulatory Compliance
- Quality Management Systems
- FDA regulated and global cGMP operations
- FDA and third party inspection readiness
- CAPA, risk management, process and cleaning validation
- IQ/OQ/PQ, CSV/CSA, and data integrity
- Supplier quality and technology transfer
- Global Quality operations and manufacturing expansion
- Commercialization and cross functional leadership
- Quality budgets and cost savings
- Quality organization development

Scope of Expertise

Quality Assurance, Quality Control, Quality Engineering, Validation, Regulatory Compliance, Quality Management Systems, Pharmaceutical, Biologics, Medical Devices, cGMP, CAPA, Risk Management, Supplier Quality, Technology Transfer, Manufacturing Expansion, Commercialization, Continuous Improvement.

Tools & Systems

FDA requirements, cGMP operations, IQ/OQ/PQ, CSV/CSA, Quality Management Systems, CAPA systems, validation systems, supplier quality systems, technology transfer processes, and data integrity systems.

Executive Summary

A senior Quality and Compliance executive with extensive cross industry leadership experience, combining regulatory knowledge, Quality systems expertise, operational leadership, and continuous improvement capabilities.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs, VP of Quality, or Senior Director of Quality.

★ Candidate ID: 19695 – DIRECTOR OF QUALITY OPERATIONS | REGIONAL QUALITY MANAGER

Why This Candidate Stands Out

Experienced Quality executive with over 10 years of progressive leadership experience in FDA regulated manufacturing across medical device, healthcare, consumer, and food contact operations. Demonstrated expertise across Quality Engineering, Quality Systems, Compliance, Regulatory Affairs, and multi site Quality Operations. Proven ability to lead Quality Managers across multiple manufacturing facilities while standardizing QMS requirements.

Key Highlights

- Over 10 years of progressive leadership experience
- FDA regulated manufacturing experience
- Medical device, healthcare, consumer, and food contact operations
- Quality Engineering, Quality Systems, Compliance, and Regulatory Affairs
- Multi site Quality Operations
- FDA 21 CFR 820, ISO 13485, ISO 9001, SQF, and EU MDR
- FDA inspections and ISO audits
- Customer audits, CAPA, risk management, and validation

- Facility mergers
- FDA registration and medical device manufacturing licensing
- Large scale automated manufacturing work cell implementation support

Scope of Expertise

Quality Operations, Quality Engineering, Quality Systems, Compliance, Regulatory Affairs, FDA Regulated Manufacturing, Medical Devices, Healthcare, Consumer Products, Food Contact Operations, CAPA, Risk Management, Validation, FDA Registration, Manufacturing Licensing, Continuous Improvement.

Tools & Systems

FDA 21 CFR 820, ISO 13485, ISO 9001, SQF, EU MDR, QMS requirements, CAPA systems, audit systems, validation processes, FDA registration processes, and automated manufacturing work cell systems.

Executive Summary

An experienced Quality executive with multi site leadership capabilities and extensive knowledge of Quality systems, regulatory requirements, audit leadership, and FDA regulated manufacturing operations.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs, Operations Manager, or Director of Operations / Continuous Improvement.

★ Candidate ID: 19945 – Senior Quality Engineer

Why This Candidate Stands Out

Experienced Medical Device Quality Engineer with over 9 years of experience supporting regulated medical device manufacturing and quality systems. Demonstrated expertise in process validation, CAPA, risk management, regulatory compliance, and continuous improvement, with strong knowledge of ISO 13485, FDA 21 CFR Part 820, and ISO 14971.

Key Highlights

- Over 9 years of experience
- Regulated medical device manufacturing and quality systems
- Process validation
- CAPA and risk management
- ISO 13485, FDA 21 CFR Part 820, and ISO 14971
- IQ/OQ/PQ
- PFMEA/DFMEA
- Root cause analysis
- SPC, MSA, and Gage R&R
- Audits and Lean Six Sigma
- New product development and design controls
- Supplier quality and sterilization activities
- Audit readiness

Scope of Expertise

Medical Device Quality Engineering, Process Validation, CAPA, Risk Management, Regulatory Compliance, Continuous Improvement, IQ/OQ/PQ, PFMEA, DFMEA, Root Cause Analysis, SPC, MSA, Gage R&R, Audits, Lean Six Sigma, Design Controls, Supplier Quality, Sterilization.

Tools & Systems

ISO 13485, FDA 21 CFR Part 820, ISO 14971, IQ/OQ/PQ, PFMEA/DFMEA, SPC, MSA, Gage R&R, Lean Six Sigma, design controls, and audit systems.

Executive Summary

A technical Medical Device Quality Engineer with strong regulated manufacturing experience and expertise across validation, quality systems, risk management, audits, supplier quality, and process improvement.

Ideal For

Organizations seeking a Senior Process Engineer, Senior Quality Engineer, or Quality Assurance Engineer.

★ Candidate ID: 19944 – Validation Engineer

Why This Candidate Stands Out

Experienced Validation Engineer with over 7 years of experience supporting commissioning, qualification, validation, computerized system validation, and manufacturing process validation across pharmaceutical, biologics, medical device, and other regulated environments. Demonstrated expertise in IQ/OQ/PQ, validation master plans, validation protocols, traceability matrices, risk assessments, and validation reports.

Key Highlights

- Over 7 years of experience
- Pharmaceutical, biologics, medical device, and regulated environment experience
- Commissioning, qualification, and validation
- Computerized System Validation
- Manufacturing process validation
- IQ/OQ/PQ
- Validation master plans and validation protocols
- Traceability matrices and risk assessments
- Validation reports
- GMP, GAMP 5, FDA 21 CFR Part 11, FDA 21 CFR Part 820, and ISO 13485
- Data integrity
- CSV subject matter expert during audits and inspections
- Equipment qualification and validation lifecycle management
- Deviation and CAPA support

Scope of Expertise

Validation Engineering, Commissioning, Qualification, Computerized System Validation, Manufacturing Process Validation, IQ/OQ/PQ, Validation Master Planning, Validation Protocols, Traceability, Risk Assessment, GMP, GAMP 5, Data Integrity, Equipment Qualification, CAPA.

Tools & Systems

IQ/OQ/PQ, validation master plans, validation protocols, traceability matrices, GMP, GAMP 5, FDA 21 CFR Part 11, FDA 21 CFR Part 820, ISO 13485, computerized validation systems, and validation lifecycle management processes.

Executive Summary

A validation professional with strong pharmaceutical, biologics, medical device, and regulated manufacturing experience, specializing in equipment, process, computerized system, and manufacturing validation.

Ideal For

Organizations seeking a Senior Process Engineer, Quality Engineering, or CSV Engineering professional.

★ Candidate ID: 20021 – Sr. Quality Engineer

Why This Candidate Stands Out

Biomedical Engineer with over 10 years of experience spanning quality engineering, manufacturing engineering, and R&D within regulated medical device environments. Demonstrated expertise in CAPA, root cause analysis, auditing, ISO 13485, FDA 21 CFR Part 820, and ISO 14971 compliance. Experienced in leading IQ/OQ/PQ validation, equipment qualification, nonconformance investigations, supplier quality, and change control activities.

Key Highlights

- Over 10 years of experience
- Biomedical Engineering background
- Quality engineering, manufacturing engineering, and R&D
- Regulated medical device environments
- CAPA and root cause analysis
- Auditing and regulatory compliance
- ISO 13485, FDA 21 CFR Part 820, and ISO 14971
- IQ/OQ/PQ validation and equipment qualification
- Nonconformance investigations
- Supplier quality and change control
- Manufacturing process development and production scale up
- Design verification and validation
- Continuous improvement
- Clinical exposure and patient care understanding

Scope of Expertise

Biomedical Engineering, Quality Engineering, Manufacturing Engineering, R&D, Medical Devices, CAPA, Root Cause Analysis, Auditing, IQ/OQ/PQ, Equipment Qualification, Nonconformance Investigations, Supplier Quality, Change Control, Process Development, Scale Up, Design Verification, Design Validation, Continuous Improvement.

Tools & Systems

ISO 13485, FDA 21 CFR Part 820, ISO 14971, IQ/OQ/PQ, equipment qualification systems, CAPA processes, auditing systems, supplier quality systems, change control systems, and design verification and validation processes.

Executive Summary

A Biomedical Engineer with broad experience across quality engineering, manufacturing engineering, and R&D, combining technical medical device expertise with quality systems, validation, compliance, and manufacturing process experience.

Ideal For

Organizations seeking a Senior Process Engineer.

★ Candidate ID: 20020 – Associate Project Manager

Why This Candidate Stands Out

Experienced project and operations professional with over 10 years of experience spanning project coordination, project management, production planning, quality assurance, and manufacturing operations. Background includes production planning and scheduling for regulated products, inventory management, shipment coordination, manufacturing documentation, and cross functional coordination with manufacturing, quality, and shipping teams.

Key Highlights

- Over 10 years of experience
- Project coordination and project management
- Production planning and scheduling
- Quality assurance and manufacturing operations
- Regulated product experience
- Inventory management and shipment coordination
- Manufacturing documentation
- Cross functional coordination
- Managed teams of up to 10 employees
- Converted paper based documentation to digital PDF workflows
- Reported 60% increase in efficiency
- Developed inventory tracking systems
- Project and performance dashboards
- Equipment maintenance and calibration coordination
- Employee onboarding

Scope of Expertise

Project Management, Project Coordination, Production Planning, Scheduling, Quality Assurance, Manufacturing Operations, Inventory Management, Shipment Coordination, Manufacturing Documentation, Team Leadership, Process Improvement, Equipment Maintenance, Calibration, Employee Onboarding.

Tools & Systems

Digital PDF workflows, inventory tracking systems, project dashboards, performance dashboards, equipment maintenance and calibration systems, and production scheduling systems.

Executive Summary

A project and operations professional with experience supporting regulated manufacturing environments through project coordination, production planning, inventory management, quality assurance, documentation, and process improvement.

Ideal For

Organizations seeking a Project Manager, Scheduling Manager, Master Scheduler, or Production Planner.

★ Candidate ID: 20022 – Sales Manager

Why This Candidate Stands Out

Seasoned sales and business development professional with over 25 years of experience across medical, academic, corporate, and professional markets. Demonstrated expertise in managing multimillion dollar territories and complex sales pipelines, including a significant healthcare focused portfolio serving hospitals, health systems, and medical colleges. Skilled in consultative selling, customer needs assessment, product demonstrations, contract negotiation, implementation, and training.

Key Highlights

- Over 25 years of experience
- Medical, academic, corporate, and professional markets
- Multimillion dollar territory management
- Complex sales pipelines
- Healthcare focused portfolio
- Hospitals, health systems, and medical colleges
- Consultative selling
- Customer needs assessment
- Product demonstrations
- Contract negotiation
- Implementation and training
- Healthcare decision maker relationships
- Technical support and product expertise
- Clinical decision support, medical research, and healthcare solutions
- Territory growth and customer relationship management

Scope of Expertise

Sales Management, Business Development, Territory Management, Healthcare Sales, Consultative Selling, Customer Needs Assessment, Product Demonstrations, Contract Negotiation, Implementation, Training, Technical Support, Clinical Decision Support, Medical Research, Healthcare Solutions.

Tools & Systems

Sales pipelines, customer relationship management processes, product demonstration systems, implementation processes, clinical decision support solutions, and healthcare solutions.

Executive Summary

A seasoned sales and business development professional with extensive healthcare market knowledge, multimillion dollar territory management experience, consultative selling expertise, and strong customer relationship capabilities.

Ideal For

Organizations seeking a Territory Sales Manager, Sales Management, Business Development, Management, or Project Management professional.

★ Candidate ID: 19864 – Quality & Regulatory Program Leader

Why This Candidate Stands Out

Seasoned Quality and Regulatory executive with over 25 years of leadership experience within FDA regulated medical device organizations, including Class II and Class III products. Demonstrated expertise across Quality Systems, Regulatory Affairs, manufacturing quality, supplier quality, compliance remediation, and product commercialization. Extensive knowledge of FDA inspections, QMSR/QSR, ISO 13485, MDSAP, ISO 14971, design controls, MDR, CAPA, post market surveillance, and risk management.

Key Highlights

- Over 25 years of leadership experience
- FDA regulated medical device organizations
- Class II and Class III products
- Quality Systems and Regulatory Affairs
- Manufacturing quality and supplier quality
- Compliance remediation and product commercialization
- FDA inspections
- QMSR/QSR, ISO 13485, MDSAP, ISO 14971
- Design controls and MDR

- CAPA, post market surveillance, and risk management
- Global team leadership
- Manufacturing transfers and acquisitions
- Supplier governance and Quality System transformation
- Quality organization development
- MBA and engineering background

Scope of Expertise

Quality Systems, Regulatory Affairs, Medical Devices, Manufacturing Quality, Supplier Quality, Compliance Remediation, Product Commercialization, FDA Inspections, QMSR/QSR, ISO 13485, MDSAP, ISO 14971, Design Controls, MDR, CAPA, Post Market Surveillance, Risk Management, Manufacturing Transfers, Acquisitions, Supplier Governance.

Tools & Systems

QMSR/QSR, ISO 13485, MDSAP, ISO 14971, design controls, MDR, CAPA systems, post market surveillance systems, Quality System transformation processes, supplier governance systems, and FDA inspection processes.

Executive Summary

A senior Quality and Regulatory executive with extensive medical device leadership experience, combining regulatory, quality, operational, commercialization, and executive leadership capabilities.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs, Senior Director of Quality Assurance, VP of Quality Assurance, or Head of Quality.

★ Candidate ID: 19866 – Director of Quality

Why This Candidate Stands Out

Seasoned Quality and Regulatory Affairs executive with over 25 years of experience leading Quality Management Systems and regulatory strategy within FDA regulated medical device and life sciences environments. Demonstrated expertise supporting Class II and combination medical devices, including QMS development, remediation, regulatory submissions, audits, inspections, and international compliance.

Key Highlights

- Over 25 years of experience
- FDA regulated medical device and life sciences environments
- Class II and combination medical devices
- Quality Management Systems and regulatory strategy
- QMS development and remediation
- Regulatory submissions, audits, and inspections
- International compliance
- Multi site Quality organization leadership
- FDA QMSR/QSR, ISO 13485, EU MDR, and ISO 14971
- CAPA and complaint management
- Design controls and risk management
- Process validation
- FDA inspections and Notified Body audits
- QMS implementations and remediation initiatives
- FDA 510(k) and CE Mark activities

Scope of Expertise

Quality Management Systems, Regulatory Affairs, Medical Devices, Life Sciences, QMS Development, Remediation, Regulatory Submissions, Audits, Inspections, FDA QMSR/QSR, ISO 13485, EU MDR, ISO 14971, CAPA, Complaint Management, Design Controls, Risk Management, Process Validation, FDA 510(k), CE Mark.

Tools & Systems

FDA QMSR/QSR, ISO 13485, EU MDR, ISO 14971, CAPA systems, complaint management systems, design controls, risk management systems, process validation systems, FDA 510(k), CE Mark processes, QMS implementations, and Notified Body audit processes.

Executive Summary

A senior Quality and Regulatory Affairs executive with extensive medical device experience, strong QMS transformation capabilities, regulatory expertise, and proven leadership across complex quality organizations.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs, Director of Quality, VP of Quality, or Senior Director of Quality.

★ Candidate ID: 20152 – VP of Regulatory and Quality Affairs

Why This Candidate Stands Out

Experienced Quality Assurance and Regulatory Affairs leader with over 20 years of engineering experience, including more than 11 years in medical device development and manufacturing. Demonstrated expertise in leading Quality Management Systems, regulatory compliance, risk management, product qualification, testing, and quality improvement initiatives.

Key Highlights

- Over 20 years of engineering experience
- More than 11 years in medical device development and manufacturing
- Quality Management Systems leadership
- Regulatory compliance and risk management
- Product qualification and testing
- Quality improvement initiatives
- FDA 21 CFR Part 820
- ISO 13485, EU MDR, MDSAP, and ISO 9001/AS9100
- Audits, CAPA, change control, complaints, supplier quality, and quality metrics
- Regulatory submissions
- FDA 510(k) clearance and CE certification
- Class II and Class IIa medical devices
- Product development, process controls, failure investigation, and data analysis
- Cross functional problem solving

Scope of Expertise

Quality Assurance, Regulatory Affairs, Engineering, Medical Device Development, Medical Device Manufacturing, Quality Management Systems, Regulatory Compliance, Risk Management, Product Qualification, Testing, CAPA, Change Control, Complaints, Supplier Quality, Quality Metrics, Regulatory Submissions, Process Controls, Failure Investigation, Data Analysis.

Tools & Systems

FDA 21 CFR Part 820, ISO 13485, EU MDR, MDSAP, ISO 9001/AS9100, CAPA systems, change control systems, complaint management systems, supplier quality systems, quality metrics systems, FDA 510(k) submission processes, CE certification processes, and Quality Management Systems.

Executive Summary

A senior Quality Assurance and Regulatory Affairs leader combining more than 20 years of engineering experience with extensive medical device development and manufacturing expertise, strong QMS leadership, regulatory knowledge, and hands on technical capabilities.

Ideal For

Organizations seeking a Director of Quality Assurance & Regulatory Affairs, Senior Director of Quality Assurance, or VP of Quality Assurance.