

# JEFFREY R. MUNGUL

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## Objective

Creative and versatile results-oriented quality assurance and compliance professional with 11 years' successful track record of working with multiple quality systems and manufacturing processes within various pharmaceutical and biotechnology environments. Adaptable and innovative, with the ability to balance multiple priorities, manage change, and effectively deal with the most challenging situations.

## Experience

### Quality Assurance Specialist

March 2010 – Present

Plant Support Quality Assurance Department, Amgen Inc., Longmont, Co

#### Responsibilities

- Provided QA oversight of all facets of facility and utilities systems.
- Reviewed and approved maintenance work orders, job plans.
- Reviewed and approved equipment, cleaning, and process validations.
- Quality Owner for change control, nonconformance, and CAPA records.
- Quality support of new product introduction activities.
- Plant Support QA group Operational Excellence lead.
- Quality representative for various projects ranging from the commissioning and validation of new equipment to site-wide building management system upgrades.

#### Achievements

- Provided QA oversight and acted as subject matter expert, during a four-month assignment in Puerto Rico, for the successful site-to-site technology transfer of denosumab (trade name Prolia).

### Quality Assurance Specialist

March 2008 – March 2010

### Senior Quality Assurance Associate

March 2006 – March 2008

### Quality Assurance Associate III

April 2005 – March 2006

Manufacturing Quality Assurance Department, Amgen Inc., Boulder, Co

#### Responsibilities

- As Shift Lead, provided on-the-floor quality assurance support to manufacturing operations.
- Reviewed and approved batch production records, equipment clean and use logs.
- GMP document approval, including SOP, forms, production records, etc.
- Involved with lot disposition activities, including review of nonconformance, LIMS results and COA, change control status, batch status changes, and new product launch activities.
- Led cross-functional process improvement project teams that utilized LEAN Manufacturing, Six Sigma, and CQI concepts and tools.
- Led periodic manufacturing area, procedure & process audit teams.
- Assessed manufacturing production areas for regulatory compliance and inspection readiness and trained area staff on cGMP and compliance.
- Involved with various regulatory inspection teams to assess compliance risk issues and implement corrective measures.

## Skills and Experience

### Management Experience

- 4 Years Supervisory Experience
- Quality Shift Lead
- Staff Training, Mentoring, Development
- Staff evaluations

### GMP Documents

- Document Authoring, Review and Approval
- SOP
- Batch Records
- Validation IQ, OQ, PQ

### Product Disposition

- Product Launch
- Disposition Compilation

### Manufacturing Support

- Issues Resolution
- Equipment Log Review
- Compliance Audits
- Batch Record Approval

### Nonconformance/CAPA

- Record Owner
- Quality Approver
- NC Investigation
- NC/CAPA Trending
- CAPA Implementation
- CAPA Effectiveness Evaluation

### Change Control (CC)

- Quality Record Owner
- CC Review and Approval

### Regulatory Inspection

- Subject Matter Expert for Specific Quality Systems
- Presentation of Quality System to Inspectors
- Quality Support for Plant Tours
- Quality Support for Inspection Readiness Activities

## Achievements

- Successfully implemented a manufacturing operation audit program. Designed and implemented database for program to improve efficiency, interdepartmental communication, and on-time closure of observations.
- Successfully implemented of a site-wide equipment log audit program, and successfully defended the approach in several regulatory agencies and internal audit inspections.
- Managed a cross-functional, site-wide process improvement project related to equipment logs that resulted in a continual departmental cost savings of \$405,000/year.
- Managed a follow-up process improvement project that resulted in further departmental cost savings of \$51k/year.

## Quality Assurance Associate II

March 2003 – April 2005

Plant Quality Assurance Department, Amgen Inc., Thousand Oaks, Ca

### Responsibilities

- On-the-floor quality assurance support to manufacturing operations.
- Review and approval of batch production records, equipment clean and use logs.
- GMP document approval, including SOP, forms, production records, etc.
- Worked with manufacturing to correct compliance, process, procedural and documentation gaps identified by audit teams.
- Provided cGMP training for new QA and manufacturing personnel.

### Achievements

- Instrumental in PQA batch record review team reaching and maintaining 5-day batch record review cycle times.
- Instrumental in PQA reaching and maintaining disposition cycle time goals.
- 58% nonconformance rate reduction.
- Designed and implemented batch record review tracking database and associated forms, used for error trending, and the reduction of batch record review and disposition cycle times, and increased the QA group efficiency.

## Quality Assurance Associate II

2002 - 2003

Process Compliance Department, Baxter Healthcare Inc., BioScience, Los Angeles, Ca

### Responsibilities

- Provided on-the-floor quality support to manufacturing operations.
- Reviewed and approved batch production records, supporting documents and logs.
- Performed audits of manufacturing operations and helped drive corrective actions.
- Nonconformance investigation and CAPA approval and trending.
- Tracked and performed trend analysis for quality indicators and reported results to the site management review meetings.

## Quality Assurance Specialist

2000 - 2002

In-Process Support Laboratories, Baxter Healthcare Inc., BioScience, Los Angeles, Ca

### Responsibilities

- In-process testing of product intermediate, final products, buffers, media, raw materials and water.
- Prepared laboratory standards, controls, reagents and established ranges.
- Reviewed and approved analytical test data, reports and final results.
- Assisted with analytical instrument validation activities.

- Operational Excellence
- OPEX Project Leader
- Quality Support of OPEX Initiatives
- Trained and Mentored OPEX Team Members

### Internal Audits

- Development of Internal Audit Strategy/Procedure for GMP Equipment Logs
- Internal Audit Program Lead

### Facility Support

- Pest Control
- HEPA Certification
- Periodic Monitoring
- Start Up / Shutdown
- Engineering Projects
- Architectural & Utility Systems Support
- Equipment Work Orders
- Environmental Monitoring
- Cross-Functional Project Leader
- Quality Support for Site Capital Projects

## CERTIFICATION

- Project Management Certificate Program (Colorado State University)
- Six Sigma Quality Engineer (Baxter Healthcare Inc.)

## Education

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**Cell and Molecular Biology, Bachelor of Science**  
California State University Northridge, Northridge, California

2000

## Technical Skills & Proficiencies

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### Technical & Software Proficiencies

- Aseptic Processing
- Cell Culture and Fermentation Scale-Up processes (mammalian and bacterial cell lines)
- Protein Recovery and Purification processes
- Sterile Filtration and Filling

### Training & Additional Languages

- Colorado State University Project Management Certificate Program
- Baxter Healthcare Corp. Six Sigma Quality Engineer

### Other Skills

- Proficient with industry software such as LIMS, SAP, TrackWise, Maximo
- Fluent in Spanish

## References

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References available upon request.