

**Job Title:** Quality Assurance Specialist II

**Department/Division:** Quality Assurance

**Reports to:** QA Director

**Grade:** 10

# Job Summary:

Provide customers and Tapemark employees with confidence in Tapemark’s quality systems and processes by managing the preventive quality programs outlined below.

## Duties/Responsibilities:

**Responsible for acting consistently with Tapemark’s core values of Excellence, Community, and Integrity to ensure the organization’s effectiveness and success.**

**Reviews Operations documentation ensuring compliance with cGMP, ISO 13485, EU, FDA regulations, Tapemark procedures and customer needs.**

* Review executed batch records to ensure compliance to cGMP’s, ISO 13485, regulatory requirements, Tapemark’s internal procedures and customer requirements. This will include all Pharmaceutical and Medical Device products produced at Tapemark.
* Work closely with operations and quality groups to resolve discrepancies within the manufacturing batch record documentations and guide them in making the appropriate corrections per applicable requirements in a timely and efficient manner to prepare product for final release.
* Responsible for communicating with customers to ensure their needs are met and the documentation review is complete with all questions/concerns resolved prior to product release. This includes preparing appropriate Certificate of Analysis and/or Certificate of Conformance and delivering it to the customer for their review and release.

**NCM / CAPA Systems**

* Responsible for implementation and success of Tapemark’s NonConformance and CAPA system based on FDA regulations and ISO requirements.
* Supports review of investigation reports for adequate root cause analysis, comprehensiveness, accuracy and compliance to cGMPs and SOPs with efficient monitoring and closure of non-conformances and Corrective Actions.
* Responsible for tracking and trending of Non-conformances and CAPA’s through metrics (Analysis of data to identify existing and potential causes of non-conforming product or other quality issues using appropriate statistical and non-statistical methodologies to identify and define opportunities for process, product and/or system improvements.
* Provide joint leadership and support to the Material Review Board, responsible for working with the team to resolve NC’s, Customer Complaints, and arrive at Corrective Action in a timely manner.
* Cross-functional support to Quality, Engineering, Operations, and Purchasing on outstanding investigation and corrective action reports within Tapemark’s CAPA system, including MRRs, Incidents, Complaints, Audit CAs, etc.
* Initiates and writes the investigation for MRRs and Incidents when necessary. Appropriate, timely and effective follow-up with Suppliers and /or internal functions required.
* Responsible for utilizing effective CAPA and Root Cause Analysis tools during investigation of Customer complaints and non-conformances.
* Works with co-workers and employees cross-functionally within TM, providing training and support as necessary to ensure an effective NC/CAPA System. Trains co-workers on procedural or system requirements related to the NC/CAPA systems.

**Supports all Quality Assurance functions to ensure activities are completed in a timely manner.**

* Back-up other Quality Assurance Specialist(s) and Documentation Specialist(s) as needed.
* Authors/Revises SOPs related to Quality Assurance processes.
* Other duties as assigned.

**Cooperates with co-workers, supervisors, and managers to develop a team environment where individuals work in an effective and productive manner.**

* Fosters a team environment where others are treated professionally and respectfully.
* Train co-workers on reviewing a variety of batch records.
* Coach operations staff on Quality Assurance procedures and expectations of the Quality System.
* Develop QA training programs and conduct as needed.
* Communicates with co-workers, supervisors, and managers about barriers and solutions in a professional, constructive manner.
* Complies with company policies including those for tardiness and attendance.

**Participates in a variety of projects to meet Tapemark and customer quality requirements.**

* Annual Product Quality Review (PQR) report generation and assembly.
* Participates in determining timetables and scopes of projects.
* Coordinates and communicates updates to team members.
* Assists in the evaluation of issues and communicates any recommendations for dispositions.

## Education and Experience:

* 2-year technical degree required; 4-year technical degree preferred.
* 2-5 years Quality Assurance/Quality Control experience in manufacturing environment; medical device, pharmaceutical industry experience preferred.
* 2-5 years’ experience working in cGMP regulated environment.

**Preferred Skills/Abilities:**

* Ability to work independently on projects for long periods of time with little supervision from Quality Manager.
* Ability to review batch records, investigations and other cGMP documentation for completeness with no mistakes on a regular and on-going basis.
* Knowledge and ability to create and deliver effective training programs.
* Knowledge and ability to effectively coach personnel at various levels of an organization.
* Knowledge and ability of MS Office (Outlook, Word, Excel, PowerPoint) and applicable QMS software
* Knowledge of cGMP,21 CFR 210, 211, 820, ISO 13485, and other FDA regulations
* Ability to write technical reports and procedures.
* Ability to write and review corrective actions and investigation reports.
* Knowledge and ability to create/revise spreadsheets, specifications, forms, and other Quality Documents.
* Skill and ability to organize/work on multiple projects at once while meeting crucial deadlines.
* Skill and ability to communicate effectively with individuals at all levels of the organization, both verbally and in writing
* Skill and ability to communicate and develop working relationships with customers in a professional manner.
* Skill and ability to be detail oriented.
* Ability to listen and evaluate information/data and make appropriate decisions based on input and knowledge.

The above job description does not constitute a contract of employment, and Tapemark may exercise its employment-at-will rights at any time.

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Employee Signature Date