

Jet Pulverizer Co.

GMP Operations Manager

Overview

The GMP Operations Manager is responsible for all operational aspects of custom processing work that is handled under cGMP conditions, as well as any ongoing specialized production jobs as assigned. The GMP Operations Manager reports to the VP of Custom Processing.

Responsibilities

1. Responsible for the successful completion of all relevant jobs (defined as: cGMP jobs, test-work, and assigned specialized production work) as specified by the terms of the contract with the customer or as defined by the VP of Custom Processing, with deference given to the latter.
2. Responsible for fully understanding the parameters and specifications of all relevant jobs culminating in the execution of a Statement of Work with the client.
3. Authorized to change process settings and direct assigned Custom Processing Operators as necessary within best judgment to achieve the goals of the relevant jobs.
4. Development and execution of test methods as necessary in support of Quality Control and Quality Assurance, including testing manufacturing samples in the QC lab.
5. Tasked with the accurate and complete execution of all required paperwork for relevant jobs, including, but not limited to all quality, shipping, and identification documents, forms and labels (e.g. batch records, inspection & test records, etc.).
6. Will work with Custom Processing Management to supervise Custom Processing Operators with a continuous focus on safety (OSHA), quality (FDA/ISO), and environmental stewardship (US EPA/NJ DEP).
7. Maintain inventory of customer product related to relevant jobs.
8. Responsible for maintaining all cGMP facilities in a state of regulatory compliance and within validated operational parameters.
9. Assists in the maintenance of the QMS as directed by Quality Assurance including audit support, development of SOP and Job Aids, and support of the Validation Master Plan with Quality Assurance.
10. Provides quoting assistance to the Sales & Marketing Manager by providing required resource estimates and insight into unique processing challenges for relevant jobs.
11. Interacts with customer over the phone, via email, and during on- and off-site visits and tradeshows as deemed necessary by management and approved by the VP of Custom Processing.
12. Maintains database of testwork, ensuring accuracy and utility.
13. Assists VP of Custom Processing and works with the Custom Processing Foreman and Operators in day-to-day operation of the processing facility, including but not limited

to compressor operation, basic mechanical troubleshooting, hazard assessment, and opening and closing duties.

14. Authorities & Approvals: Purchasing as necessary for completion of responsibilities, supervision of assigned Custom Processing Operators
15. Performs other duties and special projects as directed.