Alembic, LLC
Job Description
FRM-0017.A

Job Title:	Manufacturing Engineer
Dept. Head/ Reporting Manager:	

Responsibilities:

This position will support daily production activities and assist on projects as part of continuous improvement (cost reduction, overall product quality, cycle time reduction, product yields, production line balance and efficiency). This position will also provide support for new product introductions involving process validation and scale up activities.

- Develop and implement new process improvements, equipment & tooling with oversite.
- Understanding of product functionality and the manufacturing processes for commercial and new product lines.
- Support scale up activities of new products including process characterization and validation, equipment procurement, and capacity/quality activities.
- Monitors and improves line yields, cycle times, and costs. Resolves production issues through troubleshooting and problem solving activities. Compile's information and communicates to Production team.
- Assesses process capabilities; innovates and implements process improvements in production on less complex processes.
- Investigates and proposes action plans based on root cause analysis.
- Performs as a support member on cross functional teams. May participate in external project; collaborate with external entities for product/material/process improvement.
- Reviews new product technology including existing or needed tooling and processes.
- Supports CAPA, NCR's, DCO's in support of production and new product development.
- Reach out to suppliers to identify new parts, materials, and equipment.
- Work with operators to resolve production line issues and improve manufacturing processes.
- Provide maintenance support for machines used to manufacture Alembic medical devices
- Support process validation documentation activities IQ, OQ, PQ, MVP.
- Write & revise work instructions; train employees as required.
- Comply with policies, guidelines, training and regulatory requirements per Quality System, Design Control, and government (e.g. FDA, CE, etc.) regulations.

Skills/Requirements:

- BS in Engineering/Technical field; 1+ years Medical Device experience required.
- Exposure to entry level experience in production environment within the medical device industry.
- Familiar with validation activities including IQ, OQ, PQ and tooling qualifications. Experieince in performing process validation activities is a plus.
- Documentation skills, familiar with regulatory requirements per Quality System, Design Control, and government (e.g. FDA, CE, etc.) regulations.
- Must have strong verbal and written communication skills.

Signature of Reporting Manager:	
Signature of Employee upon Hire:	

DOCUMENT CHANGE HISTORY				
Rev	**DCO No.**	**Release Date**	**Description of Change**	**Originator**
A	DCO-14-0035	11 APR 2014	Initial release.	L. Yen