Alembic, LLC
Job Description
FRM-0017.A

Job Title:	Senior Manufacturing Process Development Engineer
Dept. Head/ Reporting Manager:	Greg Welsh

Responsibilities:

- Generates and reviews validation protocols and reports applicable to new product development and production.
- Applies technical knowledge and statistical tools to develop, characterize, and optimize processes.
- Assesses process capabilities, prioritizes process improvement opportunities, and innovates and implements process improvements on new products and production.
- Trains and/or provides work direction to product builders when required as part of engineering builds and validation activities.
- Optimizes manufacturing efficiency by analyzing and planning work flow through lean principals.
- Provides Design for Manufacturability (DFM) input to product development team and production.
- Provides technical leadership in process validation activities and master validation plans, IQ, OQ, PQ, and equipment software validations.
- Assesses process capabilities and innovates and implements process improvements on multiple and moderately complex processes as part of production and new product introductions.
- Serves as a key contributor and participant in technical reviews.
- Typically serves as a core team member or SME (subject matter expert) on new product development processes. Contributes to team effort by accomplishing related results as needed.
- Ensures proper documentation is completed to meet quality systems requirements. (e.g., BOM's, DMR's, Routers, Process Instructions, FMEA's, etc.); Generates documentation changes/justification through DCO process.
- Supports new product development activities and product manufacturing transfer into production.
- Plans, organizes, and supports all aspects of technical reviews. Oversees engineering builds using special work requests.
- Able to develop tooling fixtures and equipment through suppliers to aid in process manufacturability.
- 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; 7-10 years Medical Device experience minimum required.
- Must have hands-on experience in process validation activities including IQ, OQ, PQ and tooling qualifications.
- Must have catheter manufacturing experience preferably from development through and including commercialization.
- History of success in being able to conceptualize, design, assemble and debug tooling; optimize existing and new manufacturing processes.
- Strong documentation skills, familiar with Regulatory requirements.
- Proven results in reducing product cost.
- 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