Overlook Industries, Inc.
193 Northampton Street, Easthampton MA 01027
888-4NEEDLE • www.ovlk.com

Company Overview:	Manufacturer of Filling Needles and Fluid Path Assemblies, Incorporated in 1993.
Type of Business:	Privately Owned
Total Size of Facility:	~ 10,500 sq. feet. Contains (3) ISO 7 Clean Rooms (~365 sq. feet) & (1) Machine Shop (~1800 sq. feet)
Business Hours:	Monday-Friday, 8am-4:30pm
Certifications:	ISO 9001:2015 Certified since 06Dec2017. Please see attached
Personnel:	Total Number of Employees: ~21 Number of Quality Employees: 3
Key Site Personnel Information:	***CEO:*** John Morin Email: jamorin@ovlk.com Phone: 413-527-4344 x 2800
	Quality Manager: Shawn Cohen-Sherry email: sfsherry@ovlk.com, Phone: 413-527-4344 x 2802
	Operations Director: Saharra Pensivy email: sapensivy@ovlk.com, Phone: 413-527-4344 x2806
	Business Development Department email: sales@ovlk.com, Phone: 413-527-4344 ext. 2810

Quality Systems Overview:	
System:	**Description:**
Quality Manual / Policy	Overlook has a Quality Manual and a Quality Policy. These are reviewed annually at Management Review.
Organization Chart	There is an Organization Chart that lists all key employees. Please see attached.
Visitor Policy	Visitors are welcomed at Overlook Industries for reasonable business purposes. All visits will be scheduled during normal business hours. There is a key-coded security system in place to prevent entry of unauthorized personnel.
Employee Training	There are written job descriptions for all employees. Employees attend an annual GDP Training that includes an exam. Other training includes read and acknowledge SOPs, attend lectures/seminars, and receive on-the-job training. Employees must pass a skills exam prior to working on client orders. All training is documented and retained in individual employee training records.
Document Control	Overlook has a Document Control Program. Only approved and current SOPs are available for use. Quality maintains this program.
Environmental Monitoring	Environmental Monitoring is performed on a routine basis. The results are reviewed to identify any trends or areas for improvement.
Equipment Control and	All equipment is included in the Equipment Control Program. The equipment is calibrated annually based on the calibration schedule. Preventive

Calibration	Maintenance is performed per a defined schedule. Records are kept for all equipment.
Internal Audits	Management is responsible for planning and scheduling Internal Audits. Each main activity comprising the Quality Management System is audited at least once per year.
Customer Audits	Overlook Industries does host Customer Audits. This provides opportunities for improvement for our systems. Please notify Management to schedule an audit.
Manufacturing In-Process Inspections	Inspections are performed to ensure product quality. All product is 100% inspected prior to being shipped to the client. Non-conforming product or material is quarantined for investigation. All documentation is maintained in the job packet. Critical areas are monitored and maintained. There is an Incoming procedure for materials. All materials are quarantined until they have been inspected, documented and labeled.
Final Product Inspections	
Incoming Raw Material Inspections	
Customer Service	Overlook welcomes feedback from our customers to determine client satisfaction and to help us improve. This information is discussed at Management Review.
Customer Complaints	Customer complaints are tracked, investigated and documented. Customer complaints are reviewed during Management Review.
Management Review	Management Review is performed annually. It Includes evaluation of the Quality Policy, customer satisfaction, nonconformities, CAPAs, audit results, review of suppliers and opportunities for improvement.
Change Control	Changes to facility, equipment, utilities, documents and blueprints are managed through the appropriate change control process. Impact to customer product and all related processes are assessed. All changes are approved by Quality. Customer notifications are performed as necessary and documented.
Standard Operating Procedures	SOPs are written for all areas of operation. Revision histories are maintained. SOP distribution is tracked by Quality. All SOPs are readily available to employees.
Suppler Qualification and Disqualification	Supplier risk-assessments are performed to determine criticality. Supplier audits are performed either in a paper-based format or during an on-site evaluation based on client risk.
Corrective and Preventative Actions	CAPAs are investigated and documented; follow-up effectiveness is performed.
Job Records	Hard copies of job records are retained for ≥5 years and backed up electronically both on-site and offsite indefinitely. All raw material certs, inspection logs, and routing sheets are maintained with job records.
Clean Rooms	Certified to ISO 7 (ISO 8 for gowning entry rooms) quarterly. SOPs are in place for cleaning, gowning, and operation within clean rooms.
Pest Control	Overlook maintains a program for internal and external pest control. An outside vendor is used for the external areas. Overlook maintains and documents the inspections.

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Quality System Procedures	
SOP-001	Purchasing
SOP-002	New Job Processing
SOP-003	Customer Service
SOP-004	Customer Complaint
SOP-005	Manufacturing Package
SOP-007	Cleanroom Routing Sheet
SOP-008	Boxing and Shipping
SOP-010	Equipment Control and Calibration
SOP-011	Pest and Rodent Control
SOP-012	Critical Area Monitoring and Maintenance
SOP-013	General Maintenance
SOP-014	Incoming Material Handling and Storage
SOP-015	Document Control
SOP-016	Nonconformance
SOP-017	Corrective and Preventive Actions
SOP-018	Supplier Approval and Disqualification
SOP-019	Job Release and Finalization
SOP-020	Part Number Change Notice
SOP-021	Change Control for Equipment, Systems, and Utilities
SOP-023	Good Documentation Practices
SOP-024	Return Goods Authorization
SOP-026	Cleanroom Entry, Gowning, and Staging of Materials
SOP-027	Cleanroom Maintenance
SOP-028	Cleanroom Assembly and Inspection
SOP-029	Integrity Testing
SOP-030	Component Cleaning and Transport
SOP-031	Passivation and Cleaning
SOP-032	Records
SOP-033	Internal Audits
SOP-035	Forklift Procedure
SOP-036	Management Review
SOP-037	Employee Training Program
SOP-040	PFM Molding Operations
SOP-041	PFM Molding Press Operations
SOP-042	Quotation
SOP-043	Part-Numbering System
SOP-044	Hazardous Waste
SOP-045	OneShot^{tm} Manual Assembly
SOP-046	Work In Progress
SOP-047	Non-Sterile Product Bagging
SOP-050	Environmental Monitoring
SOP-054	Visitor Policy