

## Design Hardening and Scale-up Production Under ISO13485:2016

After a design has been verified through testing of hundreds of devices, the design can be 'hardened' and scaled seamlessly to thousands of devices. During the process of design hardening, critical in-process and final QC checks are tailored to the specific product requirement. Even with the production of thousands of devices per lot, 100% QC inspection of the final product is performed before packaging.

The design and process are co-developed to ensure yields of 95% on final inspection for manual assembly of devices.

Documentation and in-process QC ensure all builds are within defined process parameters. Serialized packaging and labeling provides traceability to lot and shipment date.

## Early Development

We start from the first design concept, implementing our well-documented design rules and fabrication processes into the design, ensuring functional performance in the first batch delivered. Every batch of parts, starting from the first build, includes:

- Design & revision control documentation
- Material lot numbers
- Lot numbers on any customer supplied components
- Equipment parameters
- In process QC

Final assembled parts are delivered to you with packaging that captures: date, quantity, lot number and part number.

Final assembled parts are shipped with a test report that captures three levels of QC evaluation on 100% of the parts:

- 1) Visual inspection up to 7x to scrap parts with particulates, debris or other defects
- 2) Measurement on an optical comparator up to 20x for critical alignment tolerances and to verify dimensions
- 3) Non-destructive functional testing with pressure or vacuum
- 4) Destructive testing with fluids with video recording, accessible via a unique customer link.

## What's Unique About Our Processes?

ALine integrates a rigorous post-cutting cleaning process to reduce debris and residuals on laser cut or machined parts before they are laminated together. Components processed in sheets are protected during singulation and cleaned before being assembled to other components. Clean, dry compressed air is used to dry the parts which are then stored in a class 7 cleanroom and staged for further assembly.

Upon request, substrate materials can be plasma treated, silanized, or treated with a customer-specific protocol to eliminate, for example, RNAases.

### What Can You Expect From ALine

- Knowledge of the materials and processes best suited for your cartridge
- Attention to detail and a high level of customer service
- Experience with difficult production schedules
- Quotes delivered in less than a week
- Delivery within three weeks

### Have a design, and ready for scale-up?

We stock most of the commonly used materials and will happily work with you to develop a cost-effective, rapid process for scaling your production.

**Contact our Production Department at [Justinp@alineinc.com](mailto:Justinp@alineinc.com)**

### 'One-stop-shop' for scale-up needs

ALine can simplify your transition from a cartridge design, built and tested in the hundreds, to pilot production of a pre-commercial device, suitable for clinical trials. We support your volume production needs, as you develop your supply chain, and transition to a high volume manufacturer. We also serve as a second-source manufacturer and a trusted partner for the development of the next generation product.

Eliminate long lead times to prepare for volume production

- In-house production of laminates
- In-house assembly using a programmable pick and place robot
- 100% QC inspection for incoming components
- 100% QC inspection for outgoing assemblies.

We transition our customers smoothly from early design development to a final proof of principle design that can be quickly scaled for production into tens of thousands of units per month.

We work with you to:

- Integrate reagent storage
- Identify and source the correct packaging and QC procedures
- Establish simple, and cost-effective QA inspection protocols with 100% inspection.

Our facilities and equipment:

- Industrial CO<sub>2</sub> lasers, with capability for roll to roll cutting
- 30 ton thermal press
- 3 laminators with heated rollers
- Programmable UV glue dispenser and a UV cure conveyor
- SCARA robotic pick and place.

### Batch manufacturing processes with measurement of Cpk

We have spent 13 years perfecting our batch production processes. We achieve alignment tolerances of +/- .003" (.075 mm), but recommend +/- .005" (.125 mm) to be compatible with most high volume processes. We design all our devices to be readily transitioned to roll to roll production with feature sizes and stack tolerances suitable for either laser or die cutting.

Our finished parts are cut from a sheet, producing even and clean edges that simplify assembly into a molded or machined part. Processes used during development are also used for scale-up, so there is no further development required to produce tens of thousands of parts.