



## MEDICAL DEVICE PRODUCTION WITH QUALIFIED MIKRON AUTOMATED ASSEMBLY SOLUTION

Assembly systems for manufacturing medical devices that are used for administering medication or diagnostics, demand engineering expertise and must exhibit an absolute level of safety for the user, as well as reliably for the administrator of the medications. The assembly must pertain to defined safety and contractual requirements. This criteria, developed by the pharmaceutical and medical device industry, are based upon the requirements of the US Food and Drug Administration (FDA).

### INHALER

Manufacturers of MDI and DPI Inhalers are introducing more complex functions such as dose counting systems and electronics. Reliability of dose counting and inhalation mechanisms demand high quality assembly processes and test operations including vision inspection, ultrasonic / laser welding, torque control, set-up of the mechanism, preparation and insertion of the packaged medicant, flow test, laser / ink-jet marking, labeling, functional test and traceability.

### SYRINGE / CATHETER

The handling of needles on a high-speed system demands experience. New laws that obligate the use of safety syringes and catheters to avoid needle stick injuries have increased the complexity of the devices. Standard assembly operations are now designed with special features to accommodate high-speed manufacturing. These operations include: leak test, occlusion test, small spring handling, hot marking, ultraviolet gluing, needle quality control with vision, and needle attachment control.

### PUMP / NEBULIZER

Used in a wide range of applications, pumps and nebulizers require precise assembly to ensure the device will handle many cycles of use. Cutting, forming and inserting small tubes at high production rates are some of the challenges of assembly. The assembly system must be efficient to provide a competitive cost per device for these typically low cost products.

### MEDICAL DIAGNOSTICS KITS / FILTERS

Diagnostic kits for pregnancy tests normally consist of plastic outer housings that contain a sophisticated internal test strip which are often fed from trays. The precision of the assembly equipment ensures the quality and safe handling of the test strip assembly. Other diagnostic kits and filters require precise mechanical punching or laser cutting of sensitive filter material. Typical processes include ultrasonic welding, marking and labeling.

### PEN INJECTOR

The assembly system must insure 100% functionality of each pen for the proper dose of the insulin required for each injection. Quality is controlled after every assembly and process operation. To fully assemble a pen, the system features the following operations: dosing mechanism assembly, set-up of the mechanism with NC motor and torque control, all sensitive processes to be controlled with vision systems, insulin cartridge type checked by vision, final assembly, laser marking, control and traceability.



# MIKRON OFFERS A LEVEL OF EXPERTISE UNMATCHED IN THE PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRIES. WE MANAGE PRODUCTION PROCESSES AND **GAMP 5 CERTIFICATION STANDARDS** FOR BOTH HIGH AND LOW VOLUMES

## MIKRON AUTOMATION

With close to 40 years experience in manufacturing high-speed assembly solutions and more than 3000 installations, the Swiss based company has been continuously innovating to supply the best automated assembly solutions and services for pharma and medical devices such as inhalers, syringes, pen-injectors, auto-injectors, e-devices, diagnostic kits and pumps to major players. Mikron Automation, with more than 500 employees, has facilities in Switzerland, Germany, USA, Singapore and China.

### COMPANY

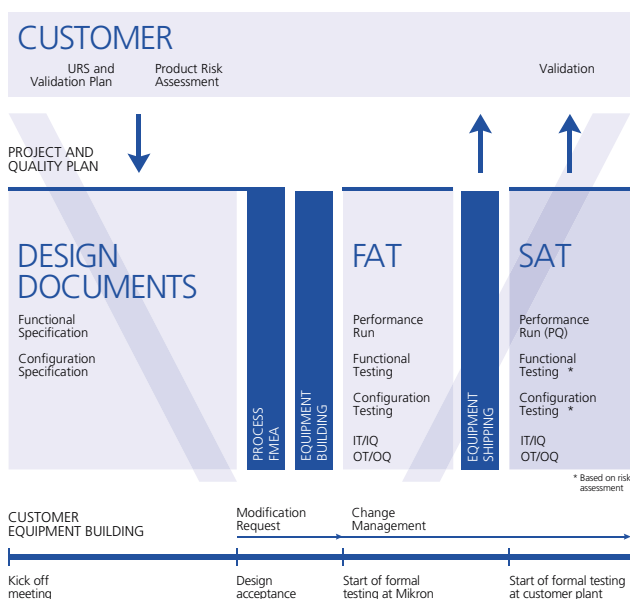
A proven project management tool establishes the guidelines for deadlines, budget and performance. Projects are handled through a project team organization from the kick-off to start of production. Mikron Automation sites are ISO 9001 certified.

### SUPPORT

Mikron Automation supports its customers in the validation process by assisting in the qualification of the assembly systems. Production support is available to help our customers in the ramp-up phase of the project and to minimize the effects of the operator learning curve. After sales service is available 24/7.

### PRODUCTS

A full range of standard, proven platforms allows Mikron to provide our customers the best solution. The modular, hybrid concept permits a progressive investment from the PoP, through the Pilot line up to the full automatic solution. All standard systems are ISO 7 (class 10,000) clean room compatible. Specific emphasis has been put on ergonomic and cleaning tooling to meet the GMP norms. Moreover, the basic machines – hardware and software – are validated according to GAMP 5 and are 21 CFR part 11 compliant.



Mikron G05™  
Assembly Automation



Mikron EcoLine™  
Assembly Automation



Mikron Tray Handler