Introduction

In the medical device industry, every device that treats an illness comes with a pledge. With each device, manufacturers promise their commitment to every individual patient that they are not just selling a durable product, but are providing a weapon and a shield against the unknown. Moreover, they pledge hope.

In a recent project, a premiere US medical device manufacturer contacted AMS to discuss complex challenges that they were experiencing in the assembly of their novel wearable drug injection products. In particular, the manufacturer was in search of a custom quality inspection system that would improve their product quality and throughput, while reducing operator input. As the client explained their expectations, we quickly recognized that this client whole-heartedly embraced their patient pledge more than most. Inspired by the client's aspirations, our dedicated Medical Device Automation division responded in kind, and together we set off to develop the best quality inspection solution possible.

Company Overview

Automated Machine Systems (AMS) is an Industrial Automation Integrator located in Cincinnati, Ohio. We specialize in advanced automation solutions for Medical, Plastic Processing, Consumer Goods, and Transportation industry manufacturers. With 99.5% on-time delivery, 97% customer satisfaction, 24/7 service, and over 20 years of earning our customer's trust, AMS is your partner for industrial automation. To chat, reach us online at https://amsmachinesinc.com/, by phone at (513) 771-3525, or by email at info@amsmachinesinc.com.

Application

Given how much medical technology has advanced in the last century, readers might assume that the rate of chronic illness would have proportionally decreased. Unfortunately, the opposite is true. The United States' Center for Disease Control (CDC) reports that as of 2018, over half of the US population suffers from a chronic illness, and growing. To keep pace with this alarming trend, pharmaceutical manufacturers have responded by inventing entirely new technologies that can serve a wide array of illnesses and treatment profiles. One such technology is known as wearable injectors, which treat therapeutic areas such as autoimmune, cardiovascular, metabolic, oncological, and neurological disorders by automatically injecting drugs over the course of a treatment program.

Traditional treatments for such disorders require multiple, frequent drug injections performed via intravenous (IV) injections at a doctor's office. This treatment method takes time, coordination, and tolerance for multiple needlesticks (which many patients dislike). Wearable injectors offer a much less invasive alternative by affixing a small medical device to a person's skin that automatically injects drugs as needed. With wearable injectors, patient treatment becomes much more convenient, less intrusive, less risky for microbial contamination and dosing errors, and more effective overall. In addition, wearable injectors offer care providers more control over treatment programs, allowing for granular refinement of dosing rates, volumes, and patterns at any time during treatment.

Challenge

Our client's wearable injector device consisted of a fluid chamber that supplied flowable drugs to an extendable hypodermic needle. When activated, this needle would extend to deliver drugs subcutaneously (under the skin) at a prescribed rate, dosage, and frequency. Because this needle was the injector's sole intrusive feature, each patient's experience would be largely predicated on the needle's condition and quality. Poor needle conditions could lead to discomfort, pain, insertion errors, incorrect dosing, and injection site contamination. Our client made it crystal clear that none of these outcomes were acceptable, and that 100% of defective needles simply must be caught on the manufacturing line, without fail.

Here at AMS, we use a proprietary 17-Step Automation Process to manage every project. From initial inquiry to post-startup visits, our process provides clients with digestible, goal-oriented steps that keep all project activities aligned to

a master plan. Using this proven sequence, clients pass through discrete approval gates that give them maximum control over their risks, costs, and technical requirements. As an example, on this project we spent a healthy amount of time on our Step 5 – Program Deliverables, working with the client to viscerally translate their requirements into tangible project objectives, including:

- **Needle Presence** - in their current operations, the client would at times experience missing needles in their devices due to upstream assembly errors. This gave us our first testing parameter, to digitally confirm that a needle was present in every tested device.

- **Needle Straightness** - needle insertion was least uncomfortable for patients when the needle was as close to perpendicular to the skin as possible. The client established a very tight straightness range that our system needed to confirm, and any needles installed beyond this angle were to be rejected.

- **Needle Bevel Angle** - where the above needle straightness was established by profiling a needle and measuring against a derived centerline, the needle's surface also needed to be measured against that centerline to derive a bevel angle. Any bevels that were too flat would cause discomfort and were to be rejected.

- **Needle Surface Finish** - we know from having blood drawn that rougher finishes lead to more discomfort and irritation than smoother finishes. As such, we were required to measure surface roughness and reject any needles with excess roughness, burrs, or blemishes.

- **Needle Consistency** - with all the above requirements in mind, the client expressed interest in understanding how repeatable these compounded reject limits would be in practice. In other words, how consistent would our inspection solution be in identifying true rejects. To answer this question, we turned to our development process Step 7 – Prototyping, in which we fabricated a prototype pilot system, completed an exhaustive Cpk statistical process control study, and demonstrated a 99.99% reliability level that we would happily guarantee.

Solution

After breaking our client's challenges down into actionable project requirements using our 17-Step Automation Process, our engineers formulated a plan of attack in short order. As we proceeded into our Step 9 - Detailed Engineering, we visited the client's existing manufacturing facility to gather site-specific design criteria, interview operators, and confirm constructability elements. With every base covered, we compiled a final design comprised of the following features:

- **AMS Medical Division Specialization -** since this solution would serve a regulated medical device application, our Medical Automation team took the lead on assigning global project requirements including hygienic design standards, FDA-compliant materials and fabrication methods, third-party validatable performance, and fabrication in our 8,000 square foot hygienic manufacturing facility.

- **Automated Inspection System Platform** - our solution would take the form of an automated inspection system that would mechanize all actions needed to hold, test, and document each wearable injector's needle conditions. We would custom design this system based on our semi-standard inspection equipment platform that includes PLC controls, a color HMI touchscreen, automatic poka yoke safety devices, and real-time condition capture instrumentation.

- **Hygienic Handling Fixtures** - with our design, operators would load each wearable injector into a hygienic fixture and start the automated inspection process. Once started, the fixture base would automatically grip, orient, align, and rotate the injector's needle through inspection. A radial mandible would extend the needle tip during inspection and retract the needle once complete. After inspection, the fixture would release the injector, which the operator would then remove and replace with the next injector to be inspected.

- **Machine Vision System** - to evaluate all the specific needle conditions described above (such as needle presence, straightness, etc), we selected a high-speed, high-resolution 3D Laser Vision System as the instrument of choice. Using this vision system, we were able to capture an extremely accurate 360° image of each needle at resolutions down to 0.9 x 5.0 µm, repeatable within 0.2 µm. For practical purposes, we set the camera to 0.5mm fidelity and +/- 1mm error deadband. Even at these levels of detail, each scan completed in less than 5 seconds.

- **Operational Reliability** - as with all of our medical device projects, AMS worked with our client to establish and conduct an industry-standard IQ/OQ/PQ qualification battery specific to this application. This process spanned our Steps 12 – Factory Acceptance Testing and 15 – Final Startup and Commissioning. Through this process, we fully tested and verified all critical specifications, performance metrics, calibrations, and tolerances, including long-run repeatability and testing of induced failure reactions. Every qualification step passed as expected, and we thoroughly documented all results in forms that would stand up to a regulatory audit.

Results

After our client accepted our proposed solution, we delivered, installed, and commissioned the inspection system just in time to serve a large wearable injector order. Because of this growing demand, our client requested additional help in automating some of their other assembly and packaging processes, which we gratefully jumped into next.

As our client explained, wearable injectors provide a treatment path for countless patients that do not otherwise have convenient, safe, and reliable options. For this reason, we commend our client for their commitment to pushing medical device technologies forward, and for continuously demonstrating their pledge to support patients on the path to better health.

Data Points

- **5.0 µm** camera resolution (detecting defects smaller than a single red blood cell)
- **99.99%** system effectiveness validated upon final performance qualification
- **163 million** points per second 3D camera scan rate
- **85%** improvement in needle testing time