PRODUCT SHOWCASE: ZwickRoell Autoinjector Testing Platform

The autoinjector market is one of the fastest growing across almost all pharma applications. Global market volume of approximately US$2.5 billion (£1.9 billion) is expected by 2020, with autoinjectors representing the largest segment.

Strict US FDA regulation of these Class II devices means that testing to ISO11608-5 is a critical step for manufacturers to ensure product quality and safety. Whether testing is managed in-house or by a contract testing laboratory, for one or for many different product designs, these organisations are turning to testing platforms that are both versatile and comprehensive. Testing must support manufacturing protocols and industry regulations, while maintaining absolute accuracy and reducing time-to-market.

"Manufacturers need solutions that help them test complete device functionality on a single platform in an all-in-one test," explains Erik Berndt, Medical Industry Manager at ZwickRoell. "Market demand and growing expectations when it comes to time-to-market mean our customers are operating in high-throughput environments where there is no margin for error. After all, patients everywhere are depending on reliable test results."

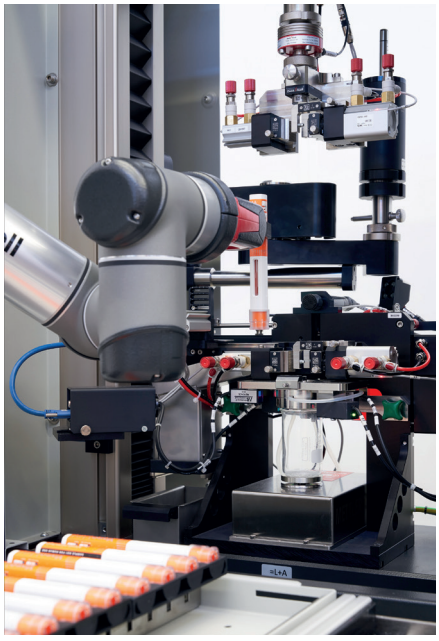

Figure 1: The roboTest R system.

That is why pharma manufacturers strive to achieve a high level of automation in autoinjector technology. The patient simply removes the safety cap, positions the injector, and injects the drug by pressing a button – the injection process is completely automated. However, this also means that all of the injector's relevant functions must be checked before the production batch is released on the market. "During our discussions with pharma, we identified a need for one testing system that can perform all standard tests," says Berndt. Those tests are:

1. Removal force of the safety cap
2. Activation force and displacement
3. Injection time
4. Determination of the administered drug volume, including the last drops
5. Effective needle length
6. Safety function of the needle guard
7. Other optional testing steps.

The answer for these six testing steps is a two-column materials testing machine with safety device, with non-contact sensors that measures the injection time and the effective needle length by means of light barriers. An integrated scale measures the quantity of the administered drug. This ZwickRoell solution is able to perform all of these test steps on just one specimen, reducing the number of specimens required, and increasing throughput.

A typical market solution is a semi-automated testing machine that requires an operator to load the specimen, close the safety door, and start the test. From that point forward, all steps in the test sequence are carried out automatically by the machine within just a few minutes per injector. ZwickRoell also offers a robot-driven fully automated testing system. "The roboTest specimen handling system (see Figure 1) removes the autoinjector from the magazine and inserts it into the testing machine. This solution removes the risk of operator error," explains Berndt.

ZwickRoell's fully automated solution is an efficient system that measures up to 10 different parameters in one continuous process. roboTest is controlled by ZwickRoell's automation software, AutoEdition 3, which directs the robot to remove the injectors one-by-one from the magazine, feed them into the machine, and start the test. Results are accurate because operator influence is minimised and the process is significantly more efficient because of increased specimen throughput. The testXpert III testing software, together with the Expanded Traceability option to FDA 21 CFR Part 11, make it possible to create documentation for the testing process that is complete and tamperproof.

Growth in market demand for autoinjectors is placing greater emphasis on throughput. Yet accurate test results are critical when it comes to patient health. This challenge has motivated manufacturers to seek solutions that streamline and automate the testing process without sacrificing accuracy, repeatability, reproducibility and traceability. Implementation of mistake-proofing mechanisms ensures consistency in testing programs, further elevating accuracy in measurement and supporting excellence in manufacturing in alignment with GMP standards and FDA CFR Part 11 regulations.

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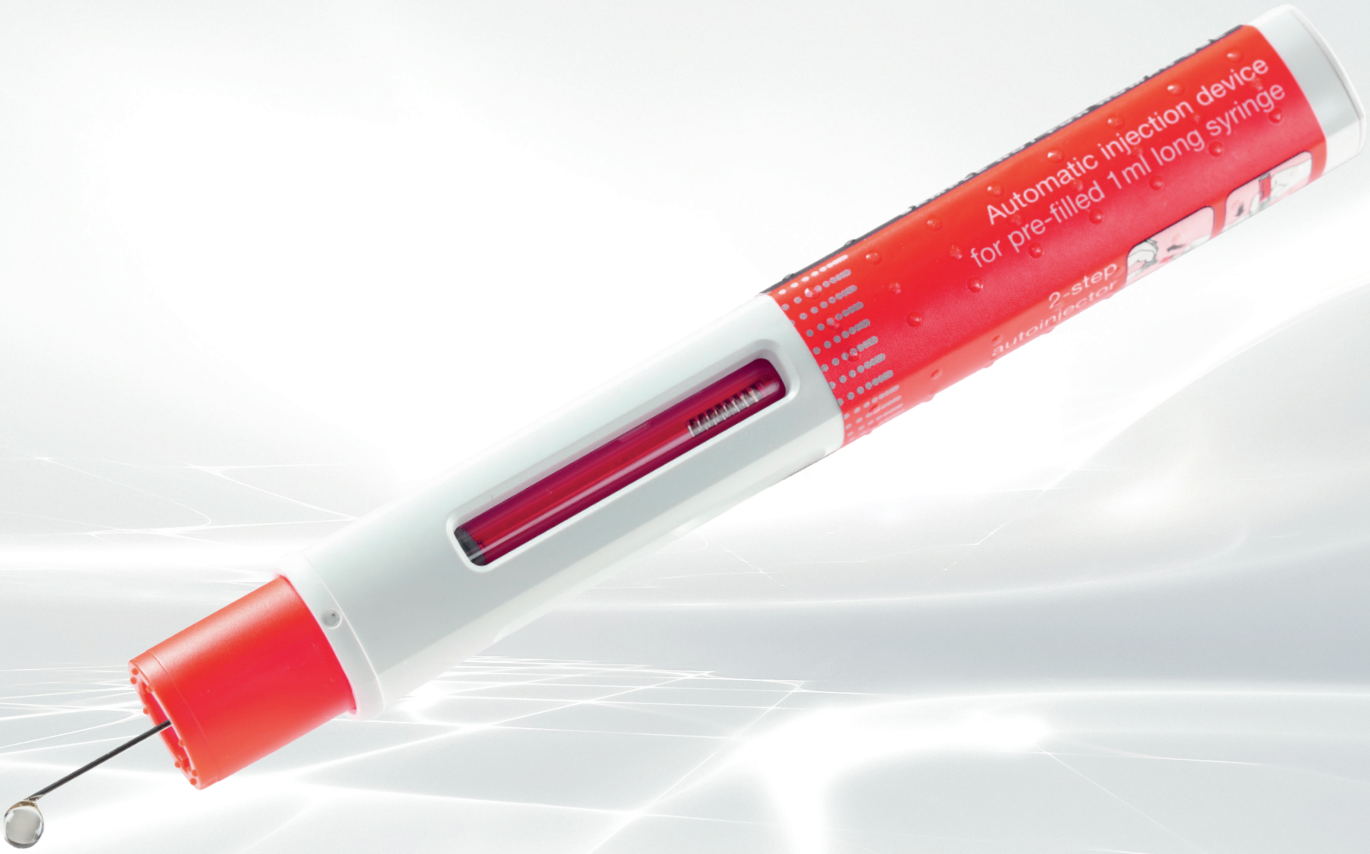
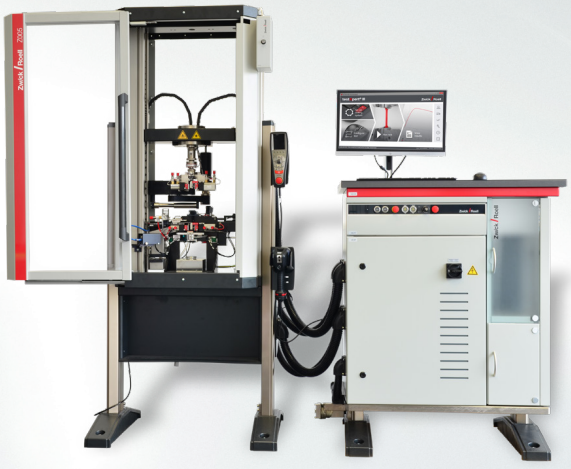


Testing systems for the pharmaceutical industry

Hardly any other industry faces regulations as stringent as those of the pharmaceutical industry, where reliability and traceability come first. Our tried-and-tested industry-specific solutions for syringes, insulin pens, and autoinjectors help you achieve reliable test results up to the last drop.



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