

Deaton Engineering Measures Up for Good Manufacturing Practices



The Need: Accurate Measurement of Thin Films

Transdermal patches have become increasingly popular for the administration of various drugs. While convenient and effective, patches present several challenges to formulation. Timed release of the drug is a function of the patch's surface area and thickness so accurate measurement of these physical dimensions is critical. Recognizing this need, Deaton Engineering agreed to develop a laser measurement gauge capable of making highly accurate measurements of thin films. The gauge would be purchased by a contract formulator for in-process testing of manufactured films impregnated with a drug substance.

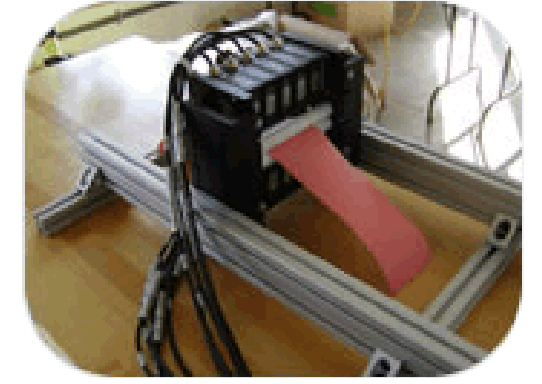
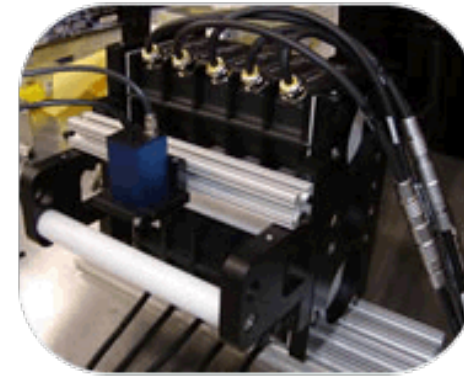
The Challenge: Design a Film-Thickness Measurement Technique

The gauge would need to perform continuous thickness measurements of thin film polymer extrusions in a GMP manufacturing environment. The tolerances for film thickness in this application were extremely narrow so innovative techniques would be required. Product not meeting these criteria would be physically marked as out-of-specification. The size of the film and high rate of production would require multiple measurements to be taken across the film and processed in real time. Since it would be used for drug product formulations, the machine would have to be designed for validation and the control system would have to meet 21 CFR Part 11 requirements.

The Solution: A Validated, In-Line Gauge for Analysis of Film-Thickness

Deaton Engineering began by developing specifications to define the function, operation, installation, and acceptance testing of the measurement gauge. A design employing 5 laser displacement sensor pairs controlled by a PC was developed and proven against an application test plan. From these specifications, a turn-key film thickness measurement system was constructed at Deaton Engineering. The measurement gauge was successfully integrated into the customer's process and calibrated by the engineering team.

Deaton Engineering's validation team was involved in creating the functional specification of the gauge to ensure that critical functions could be validated in accordance with GMP requirements once installed. A set of protocols were created to challenge the system and ensure it complied with the functional specification. Each validation experiment was successfully executed and the results presented in a report suitable for FDA audit review.



Engineering Highlights:

- Technique for making very accurate film thickness measurements successfully developed and proven
- The design for validation facilitated a smooth and efficient validation process - including Part 11 compliance validation of the control system
- Delivery of a turn-key in-line process measurement system ready for GMP application