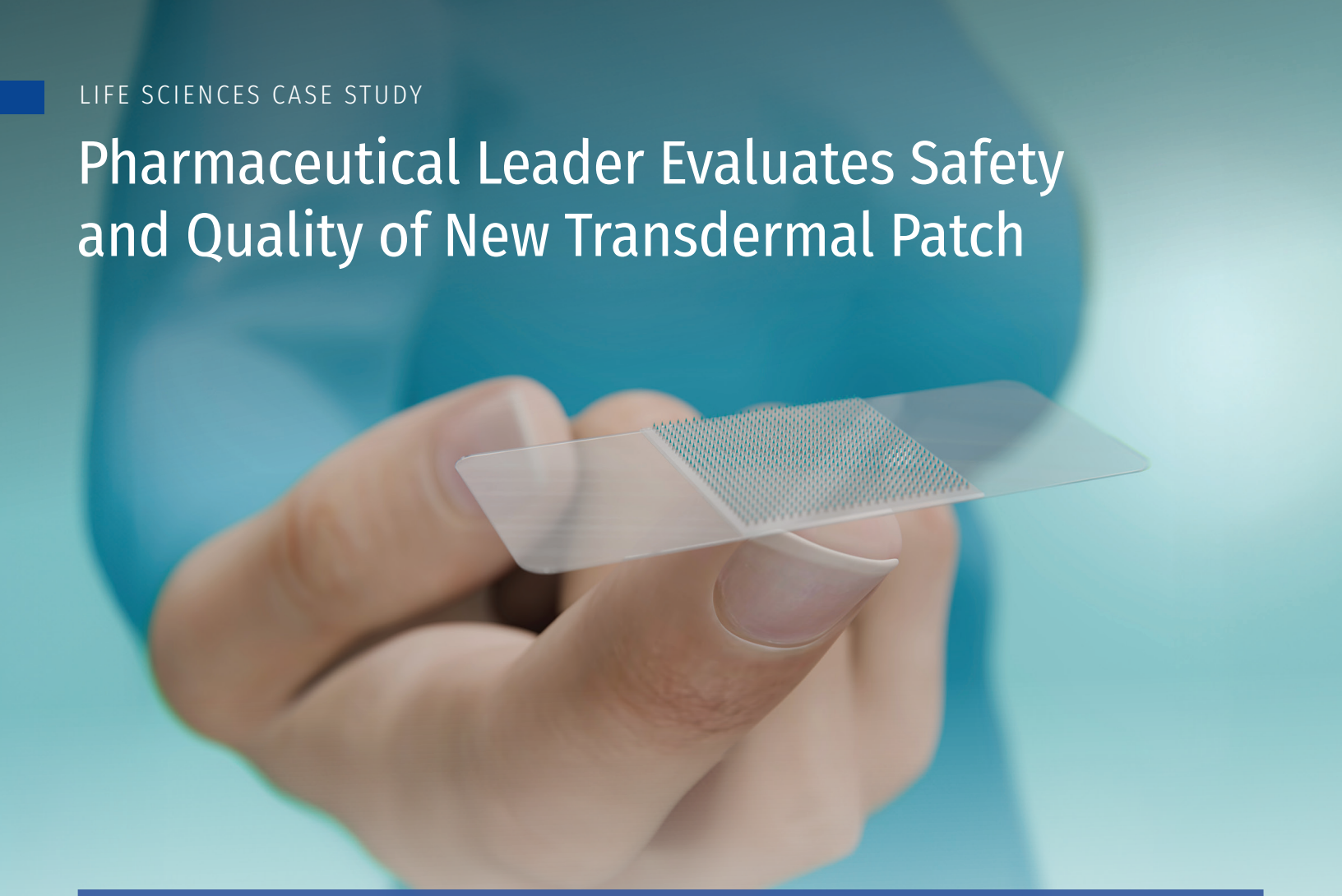
LIFE SCIENCES CASE STUDY

Pharmaceutical Leader Evaluates Safety and Quality of New Transdermal Patch



CHALLENGE

A pharmaceutical leader needed to ensure the safety of a transdermal patch after the formulation of a component was modified.

SOLUTION

SafeBridge partnered with the pharma company to perform extractables and leachables (E&L) testing and toxicological assessment of the results to assess the product's safety and quality.

RESULT

SafeBridge enabled the company to efficiently meet deadlines, established safety of the new formulation, and facilitated a smooth review by the FDA.

A global pharmaceutical leader is committed to providing medicines and therapies that improve outcomes for people with a wide range of health conditions. One of its products, a transdermal patch, is critically important not only to the health of the patients who use it but also to the company's bottom line, so when the company learned that one of its suppliers had changed the formulation of one of the components, leaders knew they needed to take action. The company engaged SafeBridge, part of Trinity Consultants, to assess potential risks to product safety and quality and ensure regulatory compliance.

CHALLENGE

The U.S. Food and Drug Administration (FDA) typically requires comprehensive evaluations of extractables and leachables (E&L) as part of the approval process for new or existing pharmaceutical products, including transdermal patches. In addition to being an important part of the regulatory evaluation process for new products, E&L testing is also required when there is a change in the packaging of an existing product, such as a change in any packaging that directly or indirectly comes into contact with the drug.

This evaluation includes conducting studies to identify and quantify the leachables and assess the potential toxicity of substances that may migrate from the patch components into the drug formulation or the patient's skin. The testing and evaluation process, however, is highly complex and can feel a bit like the Wild West—there's limited guidance and a lack of standardized methods, leading to variability in testing protocols and analytical techniques. The pharmaceutical leader turned to SafeBridge to design, perform, and analyze the results of E&L testing.

SOLUTION

The SafeBridge team began by finding a laboratory to perform the testing, then designed and reviewed the analytical protocol that would be used. SafeBridge then performed an extractables study to mimic the characteristics of the product under investigation as well as a simulated leachables study using artificial sweat as the extractable solvent.

Then, the team analyzed the results of the E&L testing. During this process, SafeBridge calculated the "Worst Case Patient Exposure" using the maximum daily dose (MDD) and performed a toxicological assessment on compounds above the Analytical Evaluation Threshold (AET) using a Threshold-of-Toxicological-Concern (TTC). SafeBridge also performed a health-based risk assessment by calculating Permitted Daily Exposure (PDE) values for each compound and applying adjustment factors to the Point of Departure (PoD), which is a critical step in using toxicological data to establish a safe exposure level for leachable compounds. When data was not available for the specific chemical, the team conducted a literature search to adjust the Point of Departure (PoD), including looking at analogous compounds, and leveraged in silico modeling to evaluate genotoxicity potential. After calculating the PDEs, SafeBridge compared them to the worst-case patient exposure to determine the acceptable Margin of Safety for patient exposure.

RESULT

Throughout the process, the SafeBridge team leveraged its extensive experience and expertise in chemistry, toxicology, and project management to ensure that the testing and analysis avoided common pitfalls and delivered the scientific rigor needed to support its findings—and delivered those findings in a report designed to facilitate a smooth review by the FDA and avoid numerous follow-up questions that could delay approval.

As a result, the pharmaceutical leader was able to efficiently meet the first significant milestone in releasing a transdermal patch using the new formulation, speeding regulatory approval and helping ensure that patients will have timely access to the medication they need.

ABOUT TRINITY CONSULTANTS

Trinity Consultants, a leading global environmental consulting firm, provides services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Founded in 1974, Trinity has the technical expertise, industry depth, and capabilities to help clients achieve their goals across the natural and built environments.

HEADQUARTERS 12700 Park Central Dr, Ste 600, Dallas, TX 75251
P 800.229.6655 / P 972.661.8100

trinityconsultants.com