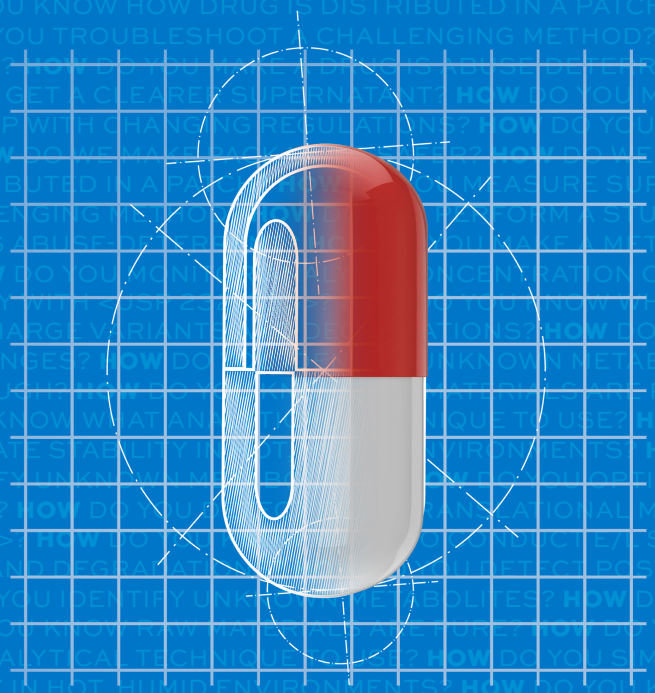

HOW DO YOU GET GENERIC DRUGS TO MARKET SMARTER, FASTER AND WITH LESS RISK?

GENERIC DRUGS: HOW WE CAN HELP

EAG scientists have worked with virtually every class and type of compound, across most indications and all common formulations. We have contributed data to and drafted sections of ANDA submissions and provided method remediation, commercial stability, QC release testing for dozens of generic drugs. And we've helped hundreds of companies like yours overcome R&D roadblocks, respond to regulators and uncover sources of problematic manufacturing issues.

How do you get generic drugs to market smarter, faster and with less risk? Turn to EAG. **WE KNOW HOW.**

REVERSE ENGINEERING (DEFORMULATION)

RLD (Reference Listed Drug) reverse engineering services for Q1 (qualitative) and Q2 (quantitative) equivalency of most formulation types including topicals, tablets, capsules and controlled release products, transdermal patch delivery systems, and ophthalmic solutions and creams, with expertise in the grade determination and quantitation of excipients, including hydrocarbon-based ingredients, polymers, modified cellulose, surfactants, emulsifiers, polyols and many others

COMPOSITION & SURFACE ANALYSIS

Analysis of layer structure and chemical composition, evaluation of particle size and composition, chemical imaging of drug and drug product, as well as the quantitation and distribution of active ingredients, excipients and coatings at the sub-micron level

DERMAL ABSORPTION TESTING

Evaluation of skin absorption in topical drug delivery systems and OTC pharmaceutical products, including testing outlined in OECD 427 (*in vivo* studies in rodent models) and OECD 428 (*in vitro* studies using human and animal skin), which are often performed in parallel to predict dermal absorption in humans—sometimes called "the triple pack" or "parallelogram" approach

CHEMISTRY, MANUFACTURING & CONTROLS (cGMP)

Analytical method development expertise and comprehensive analytical support for API and drug product, performed under phase-appropriate cGMP, including developmental and commercial stability, QC release testing and reference standard program management

CONTAMINANT ID/TROUBLESHOOTING

Multi-disciplinary expertise in the isolation, elucidation, identification and characterization of trace levels of knowns and unknowns for regulated and non-regulated studies, including elemental contaminants in packaging, ingredients and final products, as well as full extractables and leachables programs, with ability to quantify elemental contaminants at ppm levels

RADIOLABELING & CUSTOM SYNTHESIS (cGMP AND R&D)

Stable-label, radiolabel, and custom synthesis of small and large molecule compounds and reference standards under cGMP, with dedicated analytical support for generation of certificates of analysis

ENVIRONMENTAL ASSESSMENTS

The full package of required product chemistry, ecotoxicology and environmental fate testing, including synthesis of ^{3}H or ^{14}C-labeled materials for metabolism studies

CONSULTING & LITIGATION SUPPORT

Technical consulting, problem solving and litigation support, including expert testimony for patent violation investigations, product liability and other legal issues unique to medical devices

EAG LABORATORIES | WE KNOW HOW™

EAG Laboratories is a global scientific services company serving clients across a vast array of technology-related industries. Through multi-disciplinary expertise in the materials, engineering and life sciences, EAG helps companies innovate and improve products, ensure quality and safety, strengthen supply chains, protect intellectual property and comply with evolving global regulations.

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