Efficacy Testing Market Assessment, By Service Type [Antimicrobial/ Preservative Efficacy Testing, Disinfectant Efficacy Testing], By Application [Pharmaceutical Manufacturing, Cosmetics and Personal Care Products, Consumer Products, Medical Devices], By End-user [Pharmaceutical Companies, Laboratories, Research Institutes, Others], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global efficacy testing market is projected to witness a CAGR of 7.34% during the forecast period 2024-2031, growing from USD 366.63 million in 2023 to USD 646.29 million in 2031. The expansion of the efficacy testing market is propelled by the advent of revolutionary, novel drugs and therapies. Regulations governing pharmaceutical and cosmetic products emphasize product safety, with a central focus on ensuring the efficacy of the active pharmaceutical ingredient (API). The marketplaces significance on regulatory compliance and validation of pharmaceutical products, incorporating diverse approaches such as preservative efficacy testing (PET). These methods have evolved over the years through collaboration among regulatory agencies, standards organizations, industry groups, and individual companies. The primary objective of these regulatory entities is to adhere to high documentation standards and scientific regulations. Significant investments are being made in emerging economies, driven by the untapped potential and substantial growth prospects in markets that are yet to be fully explored.
Strategies, such as partnerships, collaborations, agreements, and mergers and acquisitions, are taking place between different pharmaceutical companies, research institutes, and government support. In March 2022, PFNonwovens and Smart Plastic Technologies entered an exclusive joint development agreement to incorporate Smart Plastic's patent pending SPTek ECLIPSE technology into PFNonwovens' hygiene and medical nonwoven products. This agreement marked a step toward utilizing bio-assimilated materials in nonwovens for medical and hygiene applications, following thorough research and efficacy testing of the products.
In August 2022, Biocytogen Pharmaceuticals (Beijing) Co., Ltd. engaged in a global licensing arrangement with Merck to utilize

Biocytogen's RenMice platform. As per the agreement, Merck gained complete access to Biocytogen's RenMice platform for the exploration and advancement of fully human antibody therapeutics across an extensive array of drug targets.

Rising Demand for Novel Drugs and Therapies

The global efficacy testing market is poised for growth, driven by the increasing demand for innovative drugs and therapies worldwide. This demand emerges from the increasing prevalence of chronic and infectious diseases like cancer, diabetes, tuberculosis, and heart diseases. The expanding geriatric population, often afflicted with chronic conditions, contributes to the increased demand for novel drugs and therapies. Government initiatives will improve healthcare infrastructure and fuel the growth of the pharmaceutical industry and efficacy testing market. Moreover, the rising incidence of genetic disorders and cancer is driving the demand for personalized drugs as well. Additionally, the varying susceptibility of individuals to infections and the inter-individual unpredictability in designing prognosis and treatments contribute to the growing need for personalized medicines. The substantial patient pool results in significant variations in individual behavior and bodily response, highlighting the demand for personalized medicines to enhance efficacy and, consequently, driving the demand for drug efficacy testing.

For instance, on July 26, 2023, the EU Commission published Regulation (EU) 2023/1545 amending Cosmetic Regulation (EC) 1223/2009 concerning allergens. This update includes new substances and revised restrictions on Cosmetic Product Labelling, expanding the number of allergens to be indicated in the INCI list of a finished cosmetic product if present at levels greater than 0.001% for leave-on products or 0.01% for rinse-off products.

Growing Adoption of Quality by Design (QbD) Approach

The healthcare sector is currently witnessing a notable trend as pharmaceutical and biotechnological companies increasingly embrace the quality by design (QbD) approach. This adoption stems from the critical emphasis on ensuring the stability and efficacy of drugs, both for patients and the companies. Many organizations are integrating the QbD approach to systematically identify, explain, and manage all sources of variability affecting a process, thereby safeguarding the quality of drugs. This ensures that the finished medicine consistently adheres to predefined performance characteristics right from the outset. Since the inception of QbD concepts, the industry has promptly embraced them to guarantee the quality of pharmaceutical and biotechnological products in compliance with regulatory requirements, employing approved research and development (R&D) and manufacturing procedures. Numerous quality requirements have been made mandatory for pharmaceutical or biotechnological products. The QbD approach has proven to be advantageous for pharmaceutical and biopharmaceutical companies, emphasizing that enhancing drug quality requires more than just increasing tests, thereby a proper R&D approach is indispensable.

A study in July 2023 highlighted that incorporating the Quality by Design (QbD) principle in the development of bilayer tablets will enhance product design and improve the quality, safety, and efficacy of drug products. According to the study, bilayer tablets have shown promising results for the development of fixed-dose combination (FDC) formulations.

Dominance of Pharmaceutical Manufacturing Applicants

The segment focusing on pharmaceutical manufacturing by application is poised for substantial growth in the forecast period. Clinical testing of drugs not only validates their performance and safety, but also enhances the credibility and authority of their packaging and marketing. The rising usage of drugs and vaccines contributes to an increased demand for efficacy testing, consequently propelling the growth of this segment. A considerable amount of testing and trials is required to give support to a newly developed drug throughout its manufacturing process. From discovery to development, and till the launch of a drug, a manufacturing company makes sure to pass its drug through many different phases and trials. Consequently, numerous companies are placing emphasis on efficacy testing for drugs in every phase. Efficacy testing, integral to drug research and development, verifies claims made on packaging or in marketing and ensures the intended use of the product. Preservative efficacy tests, crucial for confirming the safety of topical drugs for direct skin application, are also conducted. The mandatory regulation of these tests creates numerous opportunities for drug related efficacy testing.

Various countries are implementing rules and regulations to ensure compliance with claims made about drugs and vaccines. For example, Pfizer-BioNTech COVID-19 vaccine in May 2022, exhibited robust immune response, notable efficacy, and favorable safety in children aged 6 months to under 5 years after the administration of the third dose. The descriptive analysis revealed a vaccine efficacy of 80.3% during the period when the Omicron variant was predominant.

North America is Dominating the Global Efficacy Testing Market

Throughout the forecast period, North America is expected to lead the efficacy testing market, driven by factors such as increased

research and development (R&D) activities and the widespread adoption of the quality by design (QbD) approach among regional market players. The pharmaceutical sector in North America is increasingly emphasizing outsourcing to contract research organizations (CROs) for drug development. Additionally, investments by government in contract development and manufacturing organizations (CDMO), drug substance, and drug product manufacturing capacities contribute to this dominance. The region boasts a well-established pharmaceutical industry, substantial R&D spending, a strong presence of major service providers, and a growing inclination among pharmaceutical and cosmetic companies to outsource analytical testing. According to OECD, in October 2022, pharmaceutical spending as a percentage of gross domestic product (GDP) was 2.08%, 1.72%, and 1.34% in the United States, Canada, and Mexico, respectively. This highlights the significant involvement of major players, manufacturers, and government organizations in product development, fostering demand for efficacy testing services and contributing to the overall growth of the examined market.

Future Market Scenario (2024 – 2031F)

Growth in demand of novel drugs and therapies to tackle numerous diseases presents the biggest opportunity for the efficacy testing market. Adoption of advanced and effective approaches have been devised to ensure the efficacy of APIs, which presents yet another opportunity in the market. R&D and heavy investments made by governments and healthcare companies is promoting developments in the efficacy testing market, and new labs and brands in this area of development are introducing advanced technologies, which, in turn, is propelling the market. For instance, SkinScience Analytics aims to transform the testing domain through its dedication to stringent scientific methodologies and commitment towards consumer welfare. Launched in August 2023 and based in Tucson, AZ, the lab specializes in various essential tests for product safety, encompassing the human repeat insult patch test (HRIPT), cumulative irritation testing, and safety-in-use evaluations.

Key Players Landscape and Outlook

Numerous companies, such as Eurofins Viracor, River Laboratories International, Inc., Becton, Dickinson and Company, Societe Generale de Surveillance, Merck KGaA, bioMerieux SA, Pacific Biolabs Inc, WuXi AppTec, North American Science Associates LLC, Accugen Laboratories, Inc., etc., are directing their attention towards organic growth initiatives, including product launches, approvals, and endeavors like patents and events. Organic growth strategies observed in the market include acquisitions, partnerships, and collaborations. These initiatives have facilitated the expansion of business operations and the customer base for efficacy testing market players. Market players in the efficacy testing market are poised to encounter promising growth prospects in the global market. The primary focus of these leading players is directed towards the rapidly expanding market segment, aiming to thrive and excel in a competitive market environment. Additionally, these market players emphasize collaboration and license agreements as strategic initiatives that are anticipated to propel market growth.

In June 2022, SGS inaugurated a dedicated biosafety level-2 microbiological laboratory within its testing facility in Phoenix, Arizona. Occupying approximately 4,000 square feet within the 12,000-square-foot building, this new laboratory will specialize in conducting efficacy testing for hand sanitizer and antibacterial hand soap.

In June 2022, Eurofins Cosmetics & Personal Care acquired CRA Korea Inc., a clinical testing laboratory situated in South Korea. This laboratory predominantly specializes in delivering safety and efficacy studies, consumer tests and personal care industry.

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