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Pharmaceutical Cleaning Validation Market Size, Share & Trends Analysis Report By Product Type (Small Molecule Drug, Proteins, Peptides), By Validation Test, By Region, And Segment Forecasts, 2021 - 2028

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Abstracts

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Pharmaceutical Cleaning Validation Market Growth & Trends

The global pharmaceutical cleaning validation market size is expected to reach USD 22.8 billion by 2028 and is expected to expand at a CAGR of 5.5% over the forecast period, according to a new report by Grand View Research, Inc. Global pharma companies are focusing their efforts on their R&D facilities and pushing for innovation to boost drug discovery and development.

This new wave of transformation in pharma manufacturing is being supported by several scientific breakthroughs. The U.S. FDA is supporting these advancements by opting for a more pragmatic approach to regulation which assists the sector in accelerating the throughput of therapeutics and lifesaving medicines. The rising demand for medicinal drugs is contributing to the surge in demand for cleaning validation to ensure drug safety, monitor residues, impurities, and other potential contaminants, which could cause cross-contamination from the previous manufactured batch. Since cleaning validation makes an integral process in pharmaceutical manufacturing processes, the need for spreading awareness and educating market players of the same is growing.

The International Society for Pharmaceutical Engineering (ISPE) to spread awareness

on drug discovery, approvals, and inspection management organized its inaugural ISPE APAC Pharmaceutical Manufacturing Conference in September 2019 and its second edition in September 2020, wherein, one of the key topics covered were cleaning validation and cross-contamination control.

The regulatory standards about the adoption of cleaning validation in drug manufacturing are established and revised majorly by the U.S. Food and Drug Administration (U.S. FDA) and the European Medicines Agency (EMA). The EMA is a frontrunner when it comes to developing risk-based cleaning validation standards to prevent cross-contamination in shared manufacturing facilities.

Pharmaceutical Inspection Co-operation Scheme (PIC/S) followed EMA's lead and laid down its own set of new guidelines in association with cleaning validation to prevent cross-contamination and establish Health-Based Exposure Limits (HBEL) in share manufacturing facilities in June 2018. Next, an AIDE-MEMOIRE was published to outline the checklist that regulators would be meticulously inspecting. The abovementioned factors have resulted in boosting the demand for cleaning validation for drug manufacturing companies and have positively impacted the growth of the market. Since the pharmaceutical industry is more crucial compared to other industries and non-compliance could lead to negative consequences on human health, the regulatory standards are more stringent for the companies.

Moreover, key players are focused on developing more advanced analytical testing products to improve procedures. Companies are either solely or partnering with other key players to accelerate product development. For instance, in December 2020, Suez launched their latest Sievers TOC online analyzer, the M500 for the life science and pharmaceutical industries. This advanced analyzer enhances efficiency by cutting down analysis time by 50% and includes digital upgrades like Wi-Fi capabilities, enhanced security features to protect data integrity, and improved data transfer. Similarly, in August 2020 HORIBA Ltd and Shimadzu Corporation entered a strategic collaboration to develop and distribute LC-Raman analytical and measuring instruments using the combined resources and capabilities of the two companies. Such initiatives are expected to boost the growth and development of the market during the forecast period.

Pharmaceutical Cleaning Validation Market Report Highlights

- The small molecule drugs segment dominated the market and accounted for a revenue share of 46.9% in 2020

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The product-specific analytical tests segment dominated the market in 2020 owing to the rising preference for HPLC and UV spectroscopy by the market players. HPLC tests are used to detect small molecule drugs and detergents for swab and rinse samples

North America dominated the market in 2020 owing to the high adoption of cleaning validation by pharmaceutical companies due to stringent FDA and Health Canada regulations

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