

Averica Discovery Services Inc. “Green” Separation Technique Reduces Solvent Use by 90%

Background

Averica Discovery Services Inc. is a specialty contract research organization (CRO) in Marlborough, Massachusetts. The biotech and life sciences industries rely on the services of CROs like Averica to support their work to develop potential new drugs. Compound supply and proper analytic services are critical to a fast-moving, chemistry-driven research and development program. Averica’s services enable mechanistic studies, early stability assessment, analytical development and purification for small molecule drug study applications with the U.S. Food and Drug Administration (FDA).

Chromatography is a common and essential technique to measure quality and purity by separating mixtures into pure components and analyzing them. For this reason, chromatography is essential to the safe development of pharmaceutical drugs, agricultural and food products, cosmetics and



Averica scientists running SFC equipment in Marlborough

cleaning products, as well as a host of processes in which control of chemistry is crucial. Because chromatography is the technique of choice for analyzing both pure and impure substances, its use is mandated by the FDA at all stages of commercial drug development.

Supercritical Fluid Chromatography

Averica stands out from other CROs due to their expertise in, and pioneering commercial use of, supercritical fluid chromatography (SFC). When compared with conventional liquid chromatography, SFC replaces the use of more toxic chemicals with pressurized Carbon Dioxide (CO₂). This limits the use of hazardous solvents consumed during chromatography, such as hexanes, heptane, methylene chloride (DCM), tetrahydrofuran (THF), ethyl acetate, methyl tertiary butyl ether (MTBE), and acetonitrile. SFC does this by taking advantage of the fact that at certain pressures, CO₂ will behave like a fluid solvent, serving as both carrier (by dissolving and moving a substance) and eluant (a solvent used to remove something from a substance). The result is a process that is faster and more efficient that can be used for analysis and production of pure samples.

SFC systems can reduce the generation of solvents by 80-90% compared to conventional liquid chromatography. The technology can replace conventional liquid chromatography at any scale, from

one liter per day to thousands of liters per hour. By using captured rather than newly-produced CO₂, Averica actively reduces their contribution to greenhouse gases, while increasing the economic value of carbon capture and recovery.

The high cost of implementation and expertise required while running an SFC system limits its adoption in the biopharma industry. Companies interested in the technology have turned to Averica to avoid the expense and complexity associated with the equipment, while accessing the benefits of a significantly more efficient process. Averica uses about 1% to 5% of the hazardous solvents, and about 50% less hazardous alcohols compared to conventional chromatography. The resulting decrease in hazardous waste generation reduces exposures in the workplace, waste generation, air emissions, as well as the increasing costs of transportation, storage and production of hazardous solvents.

Streamlining New Product Development

Averica's skillful ability to use SFC to produce highly pure material at the exact scale needed reduces the number of times a new product development program will be interrupted due to problems arising from the use of impure materials. According to Averica President and Founder Jeffrey Kiplinger, deciding whether to nominate a compound for a full development effort "requires a deep understanding of risks and efficacy, potential toxicity, as well as scalability and stability." Averica's services help companies assess the "developability" of compounds, reducing the expenses of complex assays, and reducing waste from unsuccessful development.



Conclusion

Averica's efforts to bring a new, more efficient technology and approach to biopharma companies have revealed a "green" solution to a problem common to the entire industry that compounds reductions in environmental waste and impact, drug development cost, and the delivery of novel therapies to the market. Solvent costs for storage, licensing fees, taxes, facility modification and hazardous waste disposal are increasing and broadening. While limiting solvent use directly benefits Averica in the form of saved dollars, Averica's success demonstrates a much deeper value to life sciences and other industries.

This case study was prepared by the Office of Technical Assistance and Technology (OTA), a branch of the Massachusetts Executive Office of Energy and Environmental Affairs. The OTA helps businesses and other organizations improve their environmental performance by helping them comply with relevant regulations, reduce toxics use, and conserve energy, water, and other resources.

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