

ASM Research Chemicals Commercially Launches Development Packs for API Manufacturing

Hannover, Germany, 24 May 2023 – [ASM Research Chemicals](https://asm-research.de), a contract research and development services provider specialized in organic chemistry, is launching its new development pack (referred to as DevPack) service intended for active pharmaceutical ingredients (APIs) manufacturing. The service was developed and optimized across ten core partners to establish a standardized and robust dataset of development process steps. Now fully optimized and streamlined, the DevPack service is commercially available to help overcome resource bottlenecks and streamline API research, development, troubleshooting and scale-up activities.

“The concept of DevPacks has evolved since 2019 and we can now prepare them within six to twelve months, depending on the complexity of the synthesis. Datasets cover route scouting and optimization with a focus on commercial viability and the cleanest chemistry possible, identification of critical process parameters (CPP’s) through design of experiment (DoE) methodology, and initial identification of critical safety parameters for all steps,” said Dr. James Lawler, Head of ASM Research Chemicals. “The DevPack is beneficial for contract manufacturing organizations (CMOs) or pharmaceutical companies seeking to speed-up the early-stage development of manufacturing routes for synthetic or extracted APIs.”

The DevPack also covers analytical method development for IPC and release methods, setting of proposed specifications, fate / purge studies and genotoxic assessments for process impurities to facilitate regulatory submissions. In parallel, preparation of non-GMP samples up to 100 grams is available to help ease the transition into subsequent GMP scale-up operations.

“Reliable CMC data allows the customer to focus on the scale-up and GMP validation operations at commercial manufacturing facilities without having to tie up resources for non-GMP organic chemistry and analytical work in the lab” continued Dr. James Lawler. “Our skilled team of PhD Chemists understand the depth, sensitivity, and confidentiality of these projects. Now that we have completed an extensive evaluation, we will further streamline and standardize this service for the market.”

Additional non-GMP scale-up services have been expanded with a kilo-lab setup for stress testing the scalability of the designed chemistry. And when needed, impurities can be manufactured to accelerate analytical method validation and complete purge studies.

A full list of services offered by ASM Research Chemicals can be found at asm-research.de, or reach out directly at info@asm-research.de.

About ASM Research Chemicals

ASM Research Chemicals delivers contract research and development services to pharmaceutical and chemical companies worldwide. The range of services includes process development for organic compounds, phytochemicals extraction, non-GMP custom synthesis from milligram to kilo scale, analytical development and testing services as well as sourcing services.

For more information visit: asm-research.de