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Our experts answering your questions

Route scouting for a cost-effective process development

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You asked, we answered. Thermo Fisher Scientific's subject matter experts answer your most frequently asked questions on route scouting for a cost-effective process development.

Q1: How many actors or extras are typically required for a project, and which departments are involved?

A1: The resources needed for a project vary depending on the scope and specifics determined by the client. Typically, a small project might require about 1.7 full-time equivalents (FTEs), usually broken down as follows: 1 FTE for a lab technician, 0.5 FTEs for a process development manager, and 0.2 FTEs for analytical work, totaling approximately 272 hours for four weeks.

Q2: What makes your route scouting offering unique?

A2: Thermo Fisher's route scouting is distinguished by its extensive network and collaborative approach. The team includes ten chemists at the Regensburg site, supplemented by experts across other sites. This multidisciplinary team, including chemical engineers and safety analysts, ensures a comprehensive approach to process development, addressing both chemical and technical challenges.

Q3: When should crystallization process development start?

A3: It's advantageous to initiate crystallization process development as early as possible, ideally before entering toxicology studies or Phase I trials. This early start helps in adapting the process to large-scale production needs.

Q4: Why is route scouting important, and why is it located in Regensburg?

A4: Route scouting is crucial for ensuring the scalability and efficiency of drug production processes. The Regensburg site is strategically placed with access to a pilot plant for immediate scale-up trials, making it an ideal location for conducting and transferring route scouting results.

Q5: How do you facilitate cross-site brainstorming sessions to ensure all ideas are considered?

A5: Brainstorming sessions involve experts from various sites and incorporate a mix of experienced and new chemists to cover a wide range of perspectives. These sessions are generally held virtually, allowing for broad participation and diverse input.

Q6: How many projects have you worked on to date, and what does the future hold?

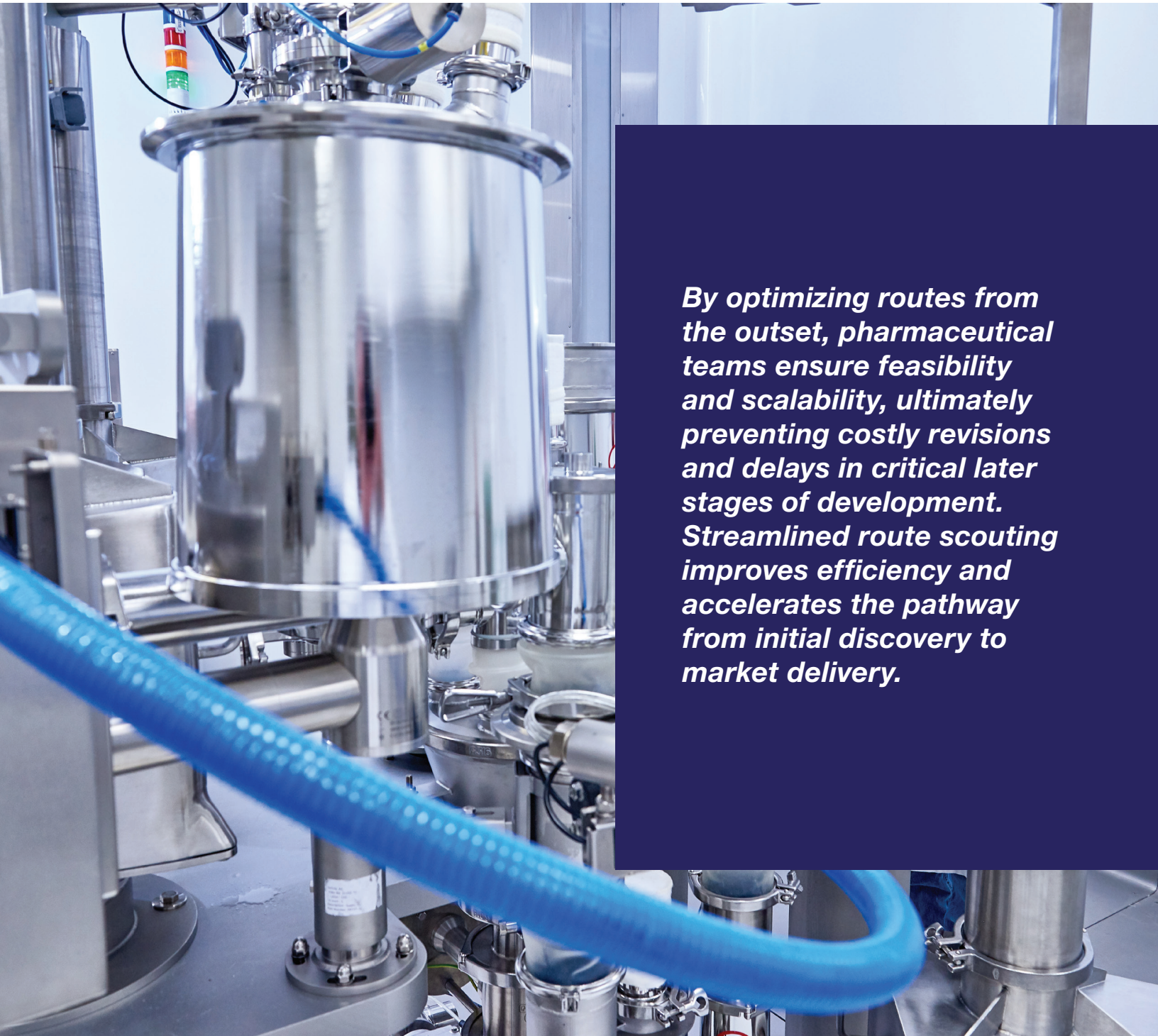
A6: To date, six projects have been successfully completed, with two ongoing and two more expected to commence soon. The team anticipates more projects as the route scouting group continues to expand.

Q7: What is the difference between polymorph and salt screening?

A7: Polymorph screening involves studying the API alone under various conditions to discover all potential solid forms. In contrast, salt screening requires the API to have an ionizable functional group, combining it with counterions to form various salts.

Q8: How is a polymorph screen conducted?

A8: Polymorph screening should be conducted as early as possible, ideally before or during early clinical phases. This proactive approach helps in identifying the most stable and suitable form of the API for further development.



By optimizing routes from the outset, pharmaceutical teams ensure feasibility and scalability, ultimately preventing costly revisions and delays in critical later stages of development. Streamlined route scouting improves efficiency and accelerates the pathway from initial discovery to market delivery.

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