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Filter and Sensor Sets for Single-Use Filtration in Pharmaceutical Industry

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Innovative solutions from Sartorius enable the manufacturers to implement single-use filtration operation with ease, bypassing many in house requirements of validation, sterilization and assembly operations.

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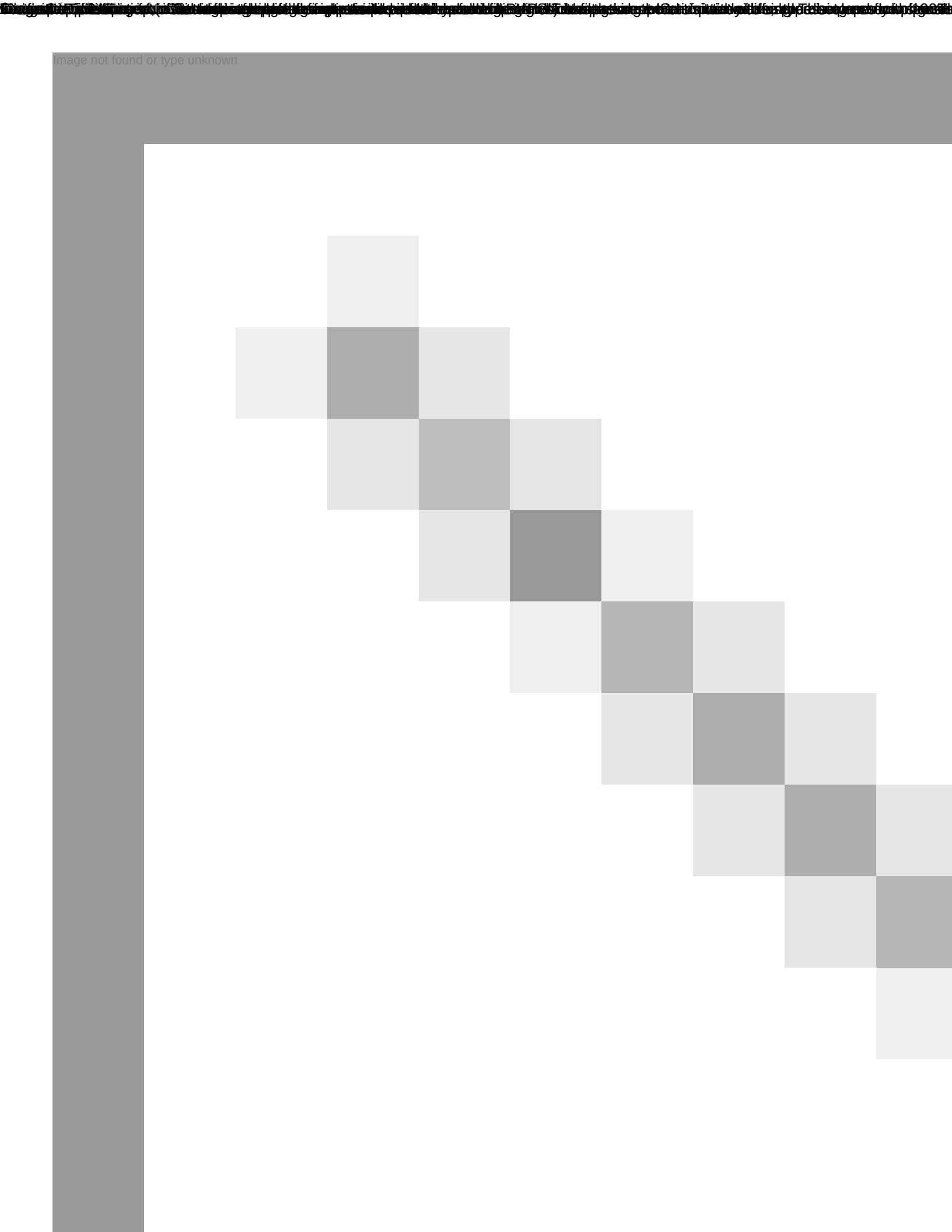
Amit comes from a Biotechnology background and has over 13 years of experience working in the field of Separation Technologies. He handles a team of Separation Technology Experts, gives product & application trainings to internal & external customers and has publications in leading Indian Industry journals. His expertise includes filter selection, scale up trials, integrity testing, process optimization & troubleshooting filter failures.

Traditional filtration operations in pharmaceutical industry involved Stainless steel-based lines, housings and associated sensors and other hardware. A typical operation would involve water flush, steam in place and post use clean in place procedures along with pre and post batch integrity testing. This further involves validation of steaming and cleaning

procedures for filters and their re-use in the process.

In the last decade, manufacturers have moved towards single use of critical sterile filters and associated tubing set up in view of ever-increasing regulatory compliance on cleaning validation to prevent endotoxin or bioburden carryover. It also decreased the change over time for the campaign since no exhaustive cleaning and sterilization is required.

A single-use filtration set would require sterilization & assembly of filter, tubing and end connections along with the pressure resistant cable ties. All of these components these must be maintained in stock from separate vendors and then assembled correctly for sterilization and operation. Sterilization validation of a complex assembly may be difficult.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