ARE YOU READY?

PHARMACEUTICAL COMPANY, *MULTIPLE FACILITY SITES*

MULTIPLE FILL LINE DELIVERY EXPERIENCE

CASE STUDY: EXECUTION EXCELLENCE

Multiple Fill Line Delivery Experience

CAI has established itself as a leader in the startup, commissioning, and qualification (C&Q) of complex filling lines across multiple pharmaceutical and biologics facilities, showcasing expertise in automated aseptic filling operations under barrier isolation. Our extensive portfolio demonstrates our ability to deliver engineering support, streamline operations, and effectively manage quality and regulatory compliance across various site configurations and project complexities.

FIELD-TESTED PROCESSES

In one significant project for a multi-national pharmaceutical company, CAI was instrumental in executing a global strategy for insulin cartridge filling across two newly constructed greenfield facilities. We conducted comprehensive design reviews, authored detailed classification and commissioning master plans, and led Factory Acceptance Testing (FAT) for various critical systems including autoclaves, WFI still systems, air handling units, and cartridge filling lines. Our responsibilities included creating reusable commissioning and qualification test cases, computer system validation, and managing engineering change control. The successful execution, adhering closely to global standards yet tailored to local procedures, minimized schedule impacts significantly.

In one example, CAI successfully provided comprehensive engineering and operational support for two Automated Aseptic Filling Lines, including liquid filling and lyophilized products. Acting as the “first responder,” our teams efficiently coordinated troubleshooting among operations, automation, maintenance, SMEs, and equipment vendors, maximizing line performance. We delivered critical Manufacturing Quality Assurance (MQA) support, facilitated rapid issue diagnosis using data historian analytics, provided technical support for multiple product validations, and offered dedicated quality, regulatory, and continuous improvement guidance. Ultimately, our SMEs collaborated closely with vendors and operational teams, achieving consistent line performance and maximized operational efficiency post-process validation.

STRATEGIC READINESS

Since 2015, CAI has continuously supported a range of Drug Product/Biologics filling processes across multiple facilities. Our ongoing engagements include Liquid Vial Filling Lines, Clean Utilities, packaging lines, Continuous Manufacturing, CSL New Filler installations with Lyophilizers, and Project SAFE OPM and CQV. Our consistent presence and support have enabled rapid and seamless operational readiness across diverse filling and packaging line configurations.

On another project involving insulin cartridge filling line expansions, CAI developed and implemented a global C&Q strategy for facilities in Indianapolis and subsequently four additional global sites. Our role included comprehensive support from Design Reviews and FAT execution for critical equipment, to developing reusable C&Q test cases that facilitated global standardization. Our proactive management of engineering changes and validation efforts minimized project disruptions, resulting in significant schedule efficiency.

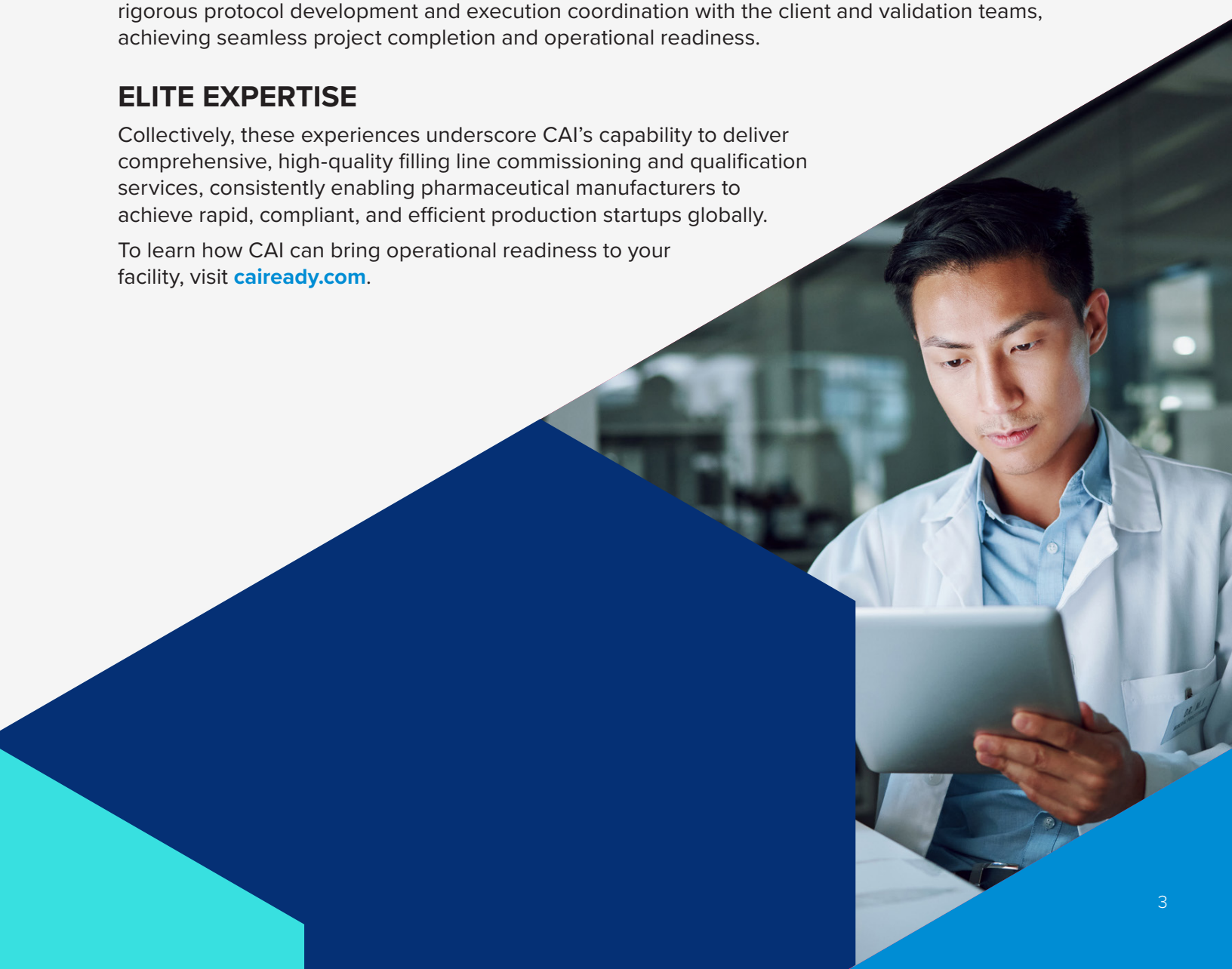
CAI also demonstrated flexibility and strategic foresight through our leadership in a sterile injectable tech transfer project from an aging facility to a new greenfield parenteral plant. Utilizing a scale-down and characterization strategy supported by retrospective Quality by Design (QbD), our approach accelerated regulatory submissions, enabled efficient inventory resupply, and prevented potential drug shortages. The scale-up strategy and thorough risk assessments allowed for seamless regulatory approval with zero deviations during process validation, saving nearly six months on the overall project timeline.

Additionally, in an aseptic filling line installation for contract manufacturing, CAI effectively conducted constructability reviews, construction management, and equipment integration, including vial and syringe lines with isolators and lyophilization equipment. Our Lead Validation personnel ensured rigorous protocol development and execution coordination with the client and validation teams, achieving seamless project completion and operational readiness.

ELITE EXPERTISE

Collectively, these experiences underscore CAI's capability to deliver comprehensive, high-quality filling line commissioning and qualification services, consistently enabling pharmaceutical manufacturers to achieve rapid, compliant, and efficient production startups globally.

To learn how CAI can bring operational readiness to your facility, visit **caiready.com**.



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