Case Study

Rapid Response to a U.S. FDA Emergency Request

The Challenge Our client had received an emergency use authorization for their product from the U.S. FDA. Speed to production to meet this urgent increase in demand was critical. Patheon was chosen for the project based upon our readily available capacity and resources, as well as our expertise in sterile production.

The Solution The first step was to immediately transfer, qualify and validate the product to the Patheon Ferentino plant for the emergency use supply. In parallel a second site, the Patheon Monza facility, was qualified to ensure a robust commercial supply moving forward. The keys for success were the open communication between the client's and Patheon's dedicated teams, as well as the seamless integration of the Patheon sites. This fluid collaborative environment simplified the alignment of operational and regulatory details. These two complex tech transfers were accomplished with the ease of one, even given the urgent timeline.

The Outcome Both tech transfers, qualifications and validations were completed within six months of the first meeting. The emergency use supply and commercial supplies were released and delivered on time and on budget. In fact, due to Patheon's available capacity and resources, the client was able to save on validation costs and capital expenditure while answering the U.S. FDA request without delay. And what began as a single project, quickly grew into an ongoing working relationship.

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