

# TAKING THE PAIN OUT OF MANAGING FDA CLEARANCE

PHARMA  
CASE STUDY

## // THE SITUATION

Due to repeated delays being encountered when dealing with the Food and Drug Administration (FDA) and US customs clearance, a leading European manufacturer of medical equipment needed a partner that could manage the entire FDA process for them - for shipments travelling from Germany to the USA.

The company, which supplies ophthalmic surgery equipment, had also suffered temperature excursions during transportation, on products that needed to be maintained at between 15-25 °C.

## // HOW RHENUS HELPED:

Rhenus teams in the Netherlands and the US work in close collaboration to manage monthly consignments. Products are transported from Germany to the Rhenus Amsterdam warehousing facility. Security checks are then performed before shipments are forwarded to ground handlers at Amsterdam airport and on to New Hampshire in the US, via airlines that offer a Pharma PIL Temperature Controlled service.

The final leg of the journey to the consignee is also managed by Rhenus, under strictly controlled temperature conditions.

Crucially for the client, Rhenus handles the entire FDA and customs clearance process. Rhenus has extensive experience of managing these procedures and keeps clients up to date on progress every step of the way. Being able to trust Rhenus to manage this element of the journey has not only accelerated the shipment process for the client but it has also freed up valuable administration time.

## // WHY RHENUS?

Proof of delivery reports, provided by Rhenus, demonstrate how temperature excursions and FDA / customs delays have been eliminated. The client has complete visibility over and confidence in the service being provided.

But Rhenus also goes the extra mile for its clients. When the original destination airport in the US was closed due to severe weather conditions, for example, Rhenus quickly re-routed to an alternative airport and oversaw the last mile delivery to ensure that the shipment was temperature controlled throughout. Rhenus also conducts a Route Risk Assessment for all clients. This close examination of every stage of the journey identifies where improvements can be made.

That's why leading pharmaceutical and medical device organisations put their faith in Rhenus.