



THE GENEVA UNIVERSITY HOSPITAL (HUG) CORNEA BANK



THE CASE STUDY :

For your easy reading, we have divided this report into three parts.



1. THE CLIENT'S CHALLENGE



2. NV LOGISTICS ANSWER



3. THE END RESULT



1. THE CLIENT'S CHALLENGE

Historically there was no cornea bank in the Geneva catchment area. Patients who needed a cornea transplant had to rely on cornea stocks located in other Swiss cantons, or even abroad. Cornea banks exist at Lucerne, Zurich, Berne, Lausanne, and Olten.

Beginning 2013, Hôpitaux Universitaires de Genève (HUG) decided to establish a cornea bank for patients in the Geneva region.

The process of stocking human tissue for transplantation is highly regulated both at Swiss and international levels. Swissmedic*, the Swiss regulatory agency, sets strict rules at every step of the process.

Collaboration with a Swissmedic certified shipping company was an absolute must for HUG.

*Swissmedic is the Swiss therapeutic agency monitoring authority.



2. NV LOGISTICS ANSWER

Through extensive interaction with many clients over the years, we at NV Logistics observe an increasing and world-wide move towards ever more stringent safety regulations in the life sciences field.

Eager to stand out from the crowd and remain a top notch supplier, we wanted to get our competencies, our process and our infrastructure validated.

Hence, we allocated time, effort and resources to acquire the much sought after Swissmedic certification for transporting, distributing and stocking medicinal products.

NV Logistics gained Swissmedic certification in February 2013 and to our knowledge we're currently the only certified shipping company in the French part of Switzerland.

We were extremely pleased to be chosen by Hôpitaux Universitaires de Genève as their privileged partner for cornea transportation. The partnership agreement between HUG and NV logistics was signed in April 2013.

In order to be selected by HUG as their preferred partner, we were required to fulfil 6 selection criteria which we list here below:

<p>YES</p>	<p>1. SWISSMEDIC CERTIFICATION.</p>
<p>YES</p>	<p>2. ADHERE TO THE GOOD DISTRIBUTION PRACTICES (GDP) SCHEME.</p> <p>GDP is quality scheme for warehouse and distribution centres. We closely collaborate with Mr.Claude Ammann who brings to the table 25 years of experience in the pharmaceutical industry and biotechnology fields (Zyma, Ciba-Geigy, Novartis, Valibio, Apoxis, Topotarget)</p>
<p>YES</p>	<p>3. GUARANTEED CRT (CONTROLLED ROOM TEMPERATURE)</p> <p>NV Logistics guarantees a CRT of +15°C to +25°C for HUG cornea transport. This implies maintaining the CRT from the moment the cornea leaves the hospital’s clean room to the moment the cornea is safely deposited into the hands of the recipient. Reporting: Temperature data is being captured throughout the whole transport journey and assembled in a report which is delivered to the client at completion of the transport mission. See also point 5. Real Time Shipping Visibility.</p>
<p>YES</p>	<p>4. UP-TO-DATE KNOW-HOW AND CONSULTING SERVICES.</p> <p>We share our extensive knowledge and expertise in key areas such as Classification, Packaging and Transport.</p> <p>a. Classification Based on interviews with the cornea bank’s scientific team and our deep understanding of the classification regulations as determined by UNEC / ADR, we were able to identify our client’s cornea shipments as meeting the Exceptions regulations under section 3.6.2.2.3 of the IATA Dangerous Goods Regulation (DGR) manual. Consequently, we recommended the classification as “non-infectious biological substance”.</p> <p>Shipping corneas as non-infectious biological substance is an opportunity for HUG to make considerable cost and time savings. Two previous articles in our series “Shipping biological substances” talk extensively about the merits of judicious classification. We’ve written short tutorials and provide cheat sheets you can download. Check them out by clicking on the titles here below.</p>

Are you reckless or overcautious (1/3)
and It's all about smart classification (2/3).

YES

b. Packaging

We were delighted to be part of the Cornea Bank's scientific team. Based on in-depth discussions and insights gained, we were able to draw up customised to create a project-specific cornea packaging solution for HUG.

Corneas are immersed in a biological solution which ensures their conservation. Maintaining the solution at pre-defined and constant temperature levels is essential for preserving the tissues at their optimum state. We achieve this with a Triple Layer System for packaging, and a fleet of vehicles who're equipped to maintain the packaged substance's temperatures at requested levels.

The photo here below shows the various components:

- ✓ The primary receptacle: Sealed plastic flask (packed in a leak proof plastic bag).
- ✓ The secondary receptacle: a sealed pot.
- ✓ The tertiary receptacle: an aluminium-clad thermo protection box.



YES

c. Transport
 We own the transport chain from A-Z. Entirely in-house - and using our own modern fleet of cold-chain approved vehicles - we're able to guarantee a controlled and seamless transport solution during which temperature is maintained at the prescribed range of +15°C à 25°C.

5. REAL TIME SHIPPING VISIBILITY

NV Logistics is equipped to provide GPS & GSM real time tracking. We use RouteWatch® to improve shipment visibility. Through our TEMS Web Portal (Transportation Environmental Monitoring System), our client has access to live monitoring - for example by viewing a map indication the exact position of the transporting vehicle. The TEMS portal also handles alerts through its alerts management system, and more. Our RouteWatch web page explains the menu of services which fulfil the specific needs of pharmaceutical and biotech industries.

YES

6. COST

Our handpicked and loyal staff brings up-to-date know-how and emotional commitment to the task. Being able to rely on competent and committed people makes it possible for us to continuously fine-tune and improve our internal processes. Being agile and lean is a competitive advantage for us, making our solutions, performance and pricing extremely competitive.

COLD CHAIN TRANSPORT.

The success of cold chain transport relies on eliminating all possible leak points throughout the whole shipping journey. When we coordinate shipping missions on behalf of our clients, these 3 elements are essential, and dear to us:

- 1. Safe isothermic packaging.**
- 2. Exact shipping documentation.**
- 3. Product temperature integrity proof.**

1. Safe isothermic packaging.

Each isothermal packaging system comes with its own (sometimes complex) instruction set. The availability of competent packaging staff is, therefore, essential.

For Debiopharm we ensured that:

- The packaging system - ordered by NV Logistics on behalf of the client was sent to the departure point in Austria in good time.
- A Controlled Room Temperature (CRT) storage space and a freezer was provided. Both are integral parts of the isothermal packaging solution.

2. Exact shipping documentation.

For optimal cold chain shipping, time is of the essence. We ensured that documents such as bills of lading and pro-forma invoices strictly conformed with the regulations of the importing country.

We have an attitude to shipping documents that could be qualified as a little pedantic ;-)
but our zeal is usually rewarded! We consistently achieve highly performant import events.

For Debiopharm, we submitted initial drafts to our importing agent in the USA who suggested a few minor changes, thus ensuring smooth customs clearance.



3. THE END RESULT

Geneva's Cornea Bank is one of only few in Europe who respond to the latest and strictest regulations at all levels of the supply chain.

As a Swissmedic certified shipping company we're pleased to be the privileged shipping partner of this worthwhile project.

Transport is, indeed, a crucial safety element and hence a responsibility we take very seriously.

As and when HUG extends its collaboration to include other cornea banks, inside and outside of Switzerland, everything is already in place. As Swissmedic certified shippers, we are always up-to-date with the latest regulatory information, we make sure all necessary authorisations are in place, and we deliver on time.

In a field as new and delicate as shipping biological substances, an ongoing and mutually trusting working relationship between the client and the supplier is absolutely essential. Our partnership with HUG continues to be highly successful because the corneal bank's busy team knows that they can rely on us, come what may. This makes it possible for the HUG team to dedicate more of their precious time to what they're really good at: being doctors and scientists.

Disclaimer:

Whilst we strive to make our articles and tutorials as accurate as possible, NV Logistics SA cannot be held responsible for any changes in rules & regulations initiated by various worldwide organisations, including governments and others.