



Toll Manufacturing Partnerships

International



About Us

Kedrion Biopharma

At Kedrion Biopharma, our mission is to enhance lives through our work in the **field of rare and ultra-rare diseases**.

With a global community of 5,200 people, **we are committed to collecting plasma and producing plasma-derived therapies that treat and prevent rare and debilitating conditions** such as Coagulation and Neurological Disorders, Immunodeficiencies, and Rh sensitization.

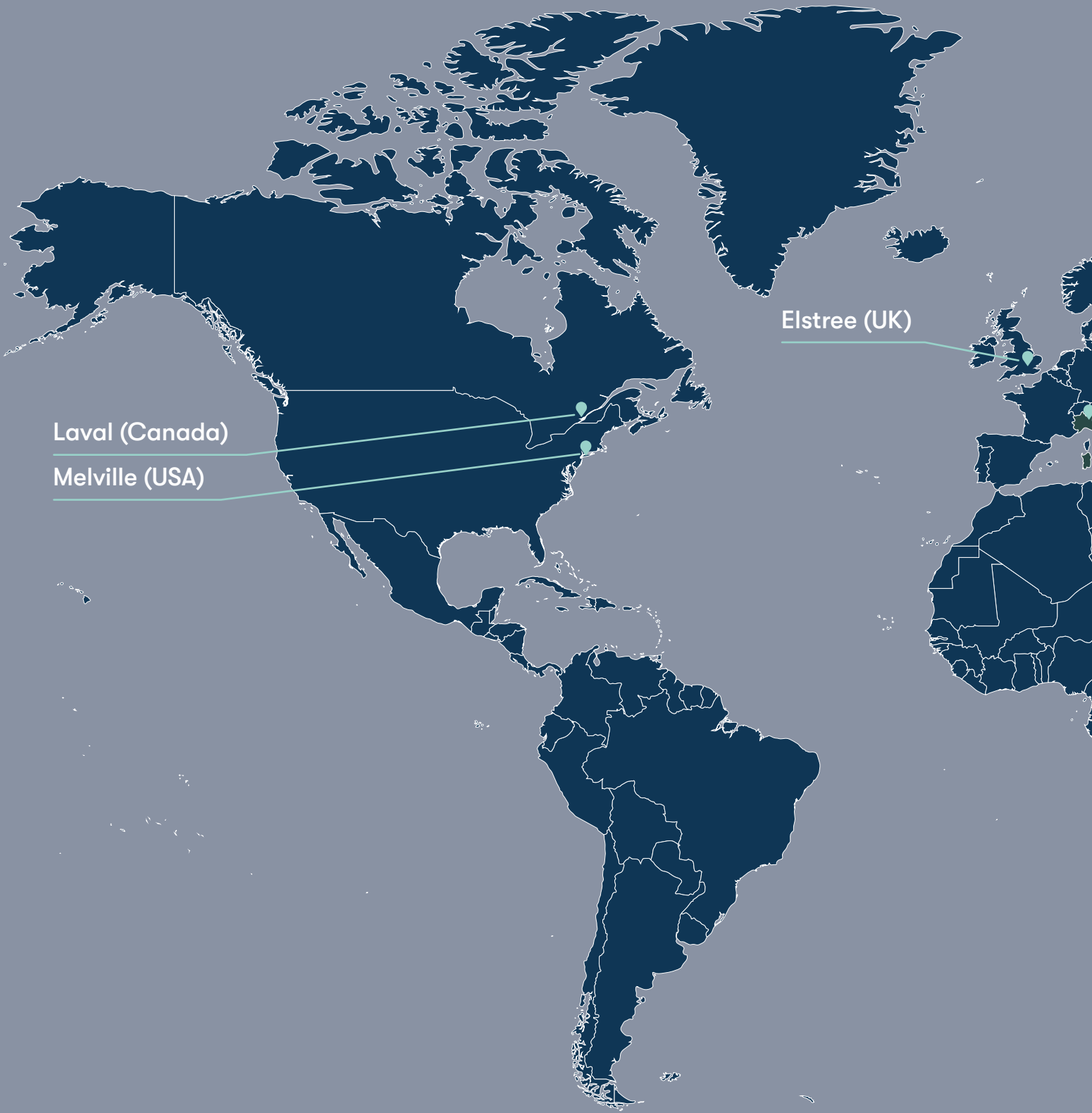
Our network includes 7 production facilities across 5 countries. This infrastructure enables us to distribute **38 life-enhancing and life-saving products in over 100 countries**, positioning us as **the fifth largest player in the plasma-derived sector worldwide**.

With our dedication to developing solutions that address unmet medical needs in rare and ultra-rare diseases, **we envision a world where the union of science and care knows no bounds**.

In partnership with the medical and scientific community, institutions, patient advocacy groups, and research organizations, **we drive sustainable innovation and improve patient care**.

What sets us apart from other biopharma companies is our commitment to every detail, every person, every interaction. Whether engaging with donors, supporting patients, empowering our employees, every connection we make impacts someone, somewhere. **We call these “rare connections”**.

Kedrion's Production Plants



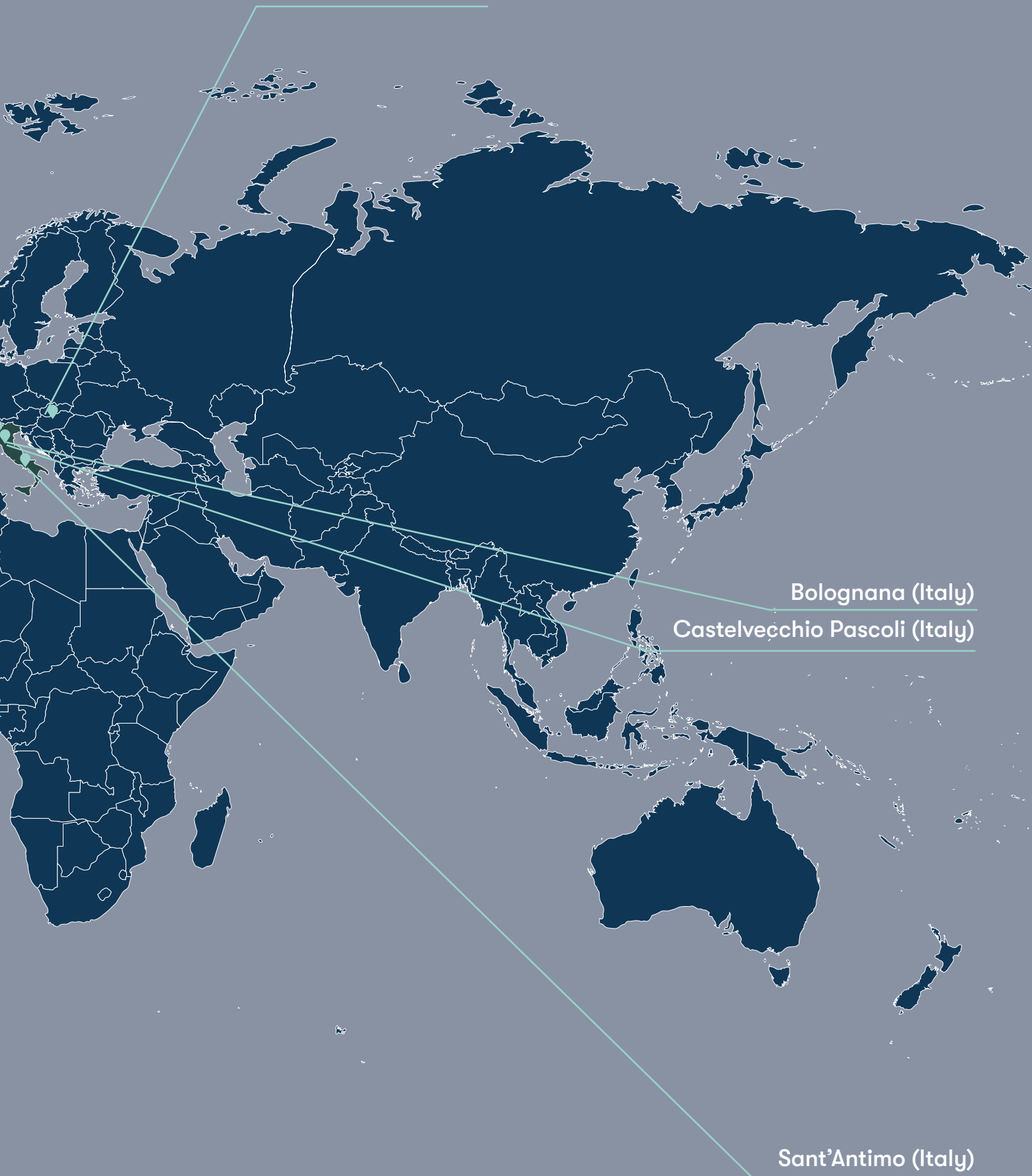


Gödöllő (Hungary)

Bolognana (Italy)

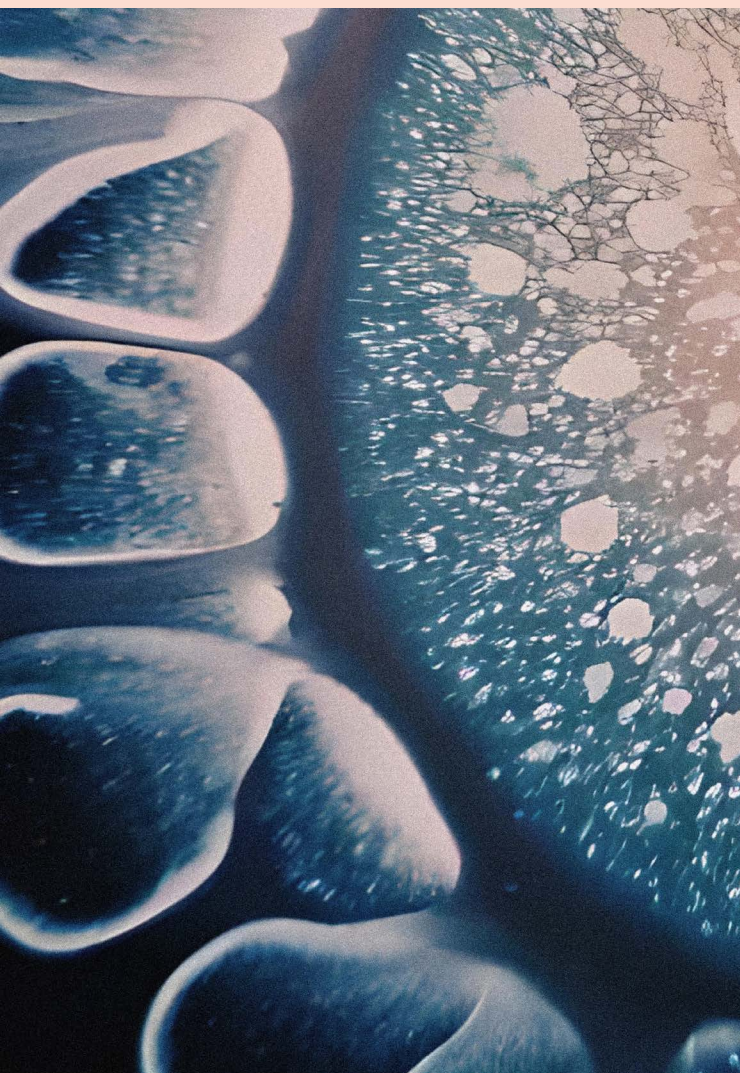
Castelvechio Pascoli (Italy)

Sant'Antimo (Italy)



Plasma

A unique and irreplaceable resource



In an international environment increasingly affected by geopolitical instability, supply chain disruptions, and regulatory uncertainty, Kedrion's ability to centrally manage the entire manufacturing cycle represents a strategic advantage and a key element of operational security.

Plasma is a **unique and irreplaceable biological resource** that cannot be reproduced in a laboratory. Its availability depends entirely on the generosity of donors.

Each donation, an expression of solidarity and responsibility, helps transform a generous act into a life-changing therapeutic opportunity for patients affected by serious and often rare diseases.

The quantity of therapeutically useful proteins contained in plasma is extremely limited. Consequently, hundreds of donations may be required to treat a single patient. In some cases, **up to 900 donations per year** are necessary **to ensure treatment continuity for just one patient**. We provide a unique guarantee: from plasma receipt to the production of finished medicinal products, **every phase is carried out in certified and controlled facilities**, without reliance on third countries.

Toll Manufacturing Partnerships

Kedrion Biopharma

At Kedrion, we believe **that achieving self-sufficiency** in plasma collection and plasma-derived medicines is in the best interest of communities worldwide.

For this reason, **we support healthcare systems** across different countries and regions, helping them progress toward this objective.

Over the years, we have developed extensive expertise and capabilities, which we make available to countries and healthcare institutions seeking to strengthen their autonomy.

We have successfully collaborated with numerous partners to offer a **comprehensive model** capable of supporting the transition from dependence on external suppliers to self-sufficiency in plasma collection and fractionation.

Within our **Toll Manufacturing Partnerships** model, we do not position ourselves merely as a contract manufacturer. Rather, we act as an active industrial partner.

We contribute **scientific expertise, manufacturing capabilities, investments, and know-how** to support the development of a robust, sustainable, and long-term national model.



Customer service

Kedrion Biopharma

Our support includes:

DEDICATED
BACK-OFFICE
TEAM



A **dedicated back-office team**, supported by advanced information systems and an organizational structure designed to ensure timely execution of planned activities, address the needs of each partner, and guarantee full plasma traceability from donation through delivery of the final medicinal product.



GLOBAL AND INTEGRATED LOGISTICS NETWORK

An **extensive and integrated logistics network**, managing the entire supply chain from plasma collection to the delivery of finished products, using hybrid and environmentally sustainable transportation solutions.

Quality in Kedrion

Kedrion Biopharma



We operate in full compliance with internationally recognized quality standards, including:

- **Good Laboratory Practice (GLP),**
- **Good Clinical Practice (GCP),**
- **Good Manufacturing Practice (GMP),**
- **Good Distribution Practice (GDP).**



KEDRION'S FACILITIES ARE INTERNATIONALLY CERTIFIED

Kedrion's facilities comply with stringent standards of quality assurance by adhering to quality guidelines from the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). **These same standards are applied in the selection of our suppliers**, who are also required to adhere to the highest quality standards.

PLASMA RECEIPT AND PROCESSING CONTROLS

Upon arrival at our facilities, plasma units collected undergo **Quality Assurance Department** inspections to ensure the quality of the raw material intended for plasma-derived medicinal products.





PROCESSING

Plasma sourced from abroad is **processed separately** and in full compliance with contractual agreements.

We carefully record plasma volumes, plasma types, and the plasma-derived medicinal products required.

Manufacturing efficiency is **continuously monitored**, and results are reported in a transparent and detailed manner.

FINISHED PRODUCT INVENTORY AND SUPPLY

We **continuously monitor the availability of finished products** and share this information with our partners.

This level of oversight enables us to **ensure the timely** supply of the plasma-derived medicinal **products required by our partners**.

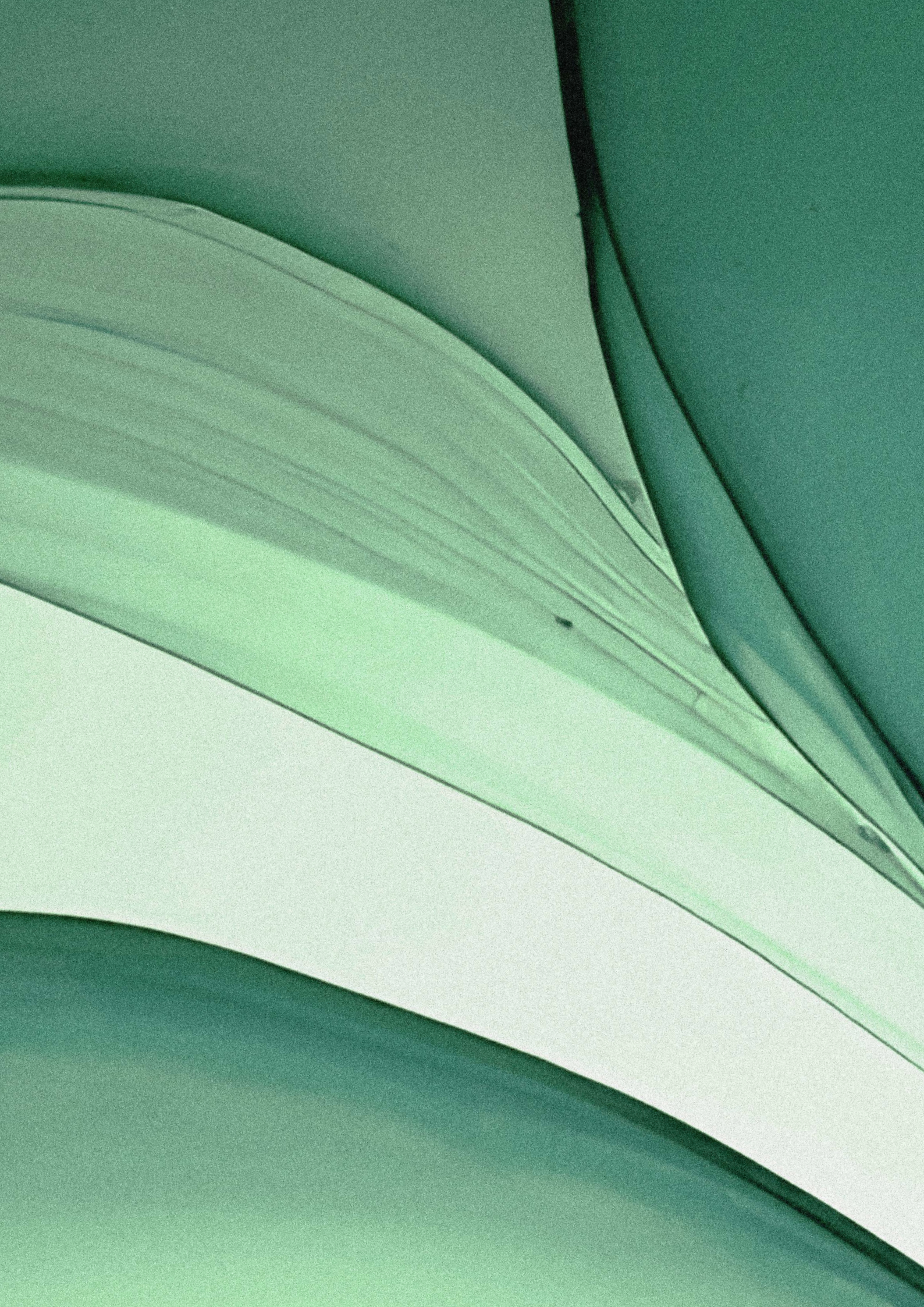




DISTRIBUTION

Distribution schedules are established **according to the specific requirements** of each partner.

Our **Customer Service team maintains ongoing communication** and provides timely updates whenever changes to agreed plans occur. The distribution service is customized to meet individual partner needs while ensuring **complete traceability across the entire supply chain**.





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