TLS
TOSCANA LIFE SCIENCES

LOOKING TO GAIN TIME

Finding a cure for even one patient

A rare disease is a disease that affects fewer than 5 patients out of every 10,000.
My name is Lorenzo Terranova and I am the Quality Assurance Manager and Qualified Person at the Kedrion Orphan Drug facility in Siena. Kedrion Biopharma is the fifth company in the world in the plasma-derived drugs business.
It is an Italian company with headquarters in the province of Lucca, but it has several production plants and plasmapheresis centers throughout Europe and in the United States.
We have a small facility for the production of plasma-derived orphan drugs.
Orphan drugs are those drugs that treat extremely rare diseases in which pharmaceutical companies tend not to invest, as the return would be very low.
Kedrion has instead decided to invest in this sector because it has always been involved in the field of rare diseases.
Our facility was created within the Toscana Life Sciences Foundation as part of a regional project for the development of orphan drugs.
The authorization of a drug facility is a long and complex path, and it is necessary to meet all of the GMP requirements, which are the European guidelines that regulate the production of drugs.
A complete restructuring of the facility was necessary to adapt it to the requirements of the authorities, as well as a lot of work at not only an engineering level, but also a procedural and documental one.
At the end of this process we were inspected by the Italian Medicines Agency in March 2015.
The result of the inspection was positive, and in October 2015 the Italian Medicines Agency issued the authorization for the Kedrion Orphan Drug facility to produce plasma-derived drugs for clinical trials in humans.
Through a similar path, we were also able to obtain the Italian Medicines Agency certification for several new quality control laboratories that we have also created at Toscana Life Sciences.
These two certifications obtained in such a brief time have been a success truly above our initial expectations.
We can now say that it was well worth the effort.
Our work didn't start from scratch. The fact of being created within TLS obviously helped us in many ways.
In our case we are participating in the development of a drug to treat a single patient currently known in Italy.
There are many people that don't have access to effective therapies and I want to continue to work for them.

Lorenzo Terranova
QA Manager & Qualified Person, Kedrion Orphan Drug Facility