STEM CELL THERAPIES ARE GOING TO CHANGE THE WORLD

"I am proud to be part of the revolution"

During childhood, Chiemezie Nwakire dreamt of being a computer or electronics engineer. Instead, he ended up being the quality assurance manager and Qualified Person at a stem cell biotech in the Netherlands, replacing his old dream with a new one: "We are giving hope to patients who do not have any other alternatives. And we need systems and processes to prevent things from going wrong."

"I always wanted to be a computer or an electronics engineer while growing up in Nigeria. But at one point, I found myself studying microbiology, safety and environmental management, and medical biotechnology in the UK instead."

After studying bachelors in microbiology for four years, Chiemezie changed to a master in safety and environmental management and master in medical biotechnology. After graduating, he explored different industries, including medical devices, bio-pharmaceuticals and Advanced Therapy Medicinal Products (ATMPs).

Then, he immersed himself in the world of stem cell therapies. Chiemezie: "Cell and gene therapies are changing the world because they offer groundbreaking new treatment opportunities to diseases where there is no other option to the patients. I am very proud to be part of this revolution."

Quality assurance for Neuro-Cells® manufacturing and control

Chiemezie is the quality assurance manager and Qualified Person at Neuroplast, a Dutch biotech that develops and manufactures autologous stem cell therapies that combat degenerative diseases, such as spinal cord injury and frontotemporal dementia. Existing treatments for these conditions are only symptomatic.

"We are giving hope to patients who do not have any other alternative. We give them an outlook on improving their quality of life."

Chiemezie elaborates on his work: "One of my main responsibilities is to ensure the Neuro-Cells® product is

Chiemezie Nwakire

NEURO-CELLS® IS A LIVING THERAPY SUPPORTED BY GROWING CLINICAL EVIDENCE

Neuroplast is a clinical stage stem celbiotech combatting the common cellular processes in neurodegenerative diseases. Neurodegenerative diseases include traumatic spinal cord injury, traumatic brain injury and frontotemporal dementia.

manufactured and tested according to our written and approved procedures."

Chiemezie and his team check that all protocols are followed and signed before the formal batch certification is done by the Qualified Person (QP). Then, Neuro-Cells® is shipped to the clinical site. The responsible doctor, in turn, will administer the treatment to the patients with traumatic spinal cord injury in the ongoing Phase II-III clinical trial.

"One of my main responsibilities is to ensure the Neuro-Cells® product is manufactured and tested according to our written and approved procedures."

Track, check, detect

Chiemezie understands his position comes with great responsibilities. An obligation he does not take lightly: "People could die if something goes wrong. That's why we have processes, systems and protocols in place to prevent such from happening."

This is exactly where Chiemezie's work comes in. He makes sure that all applicable procedures are followed correctly through the entire process of production, testing and logistics. "It's all about tracking, checking, and detecting risks early before anything happens. When something goes wrong, it is too late."

Next to overseeing the quality assurance during a production cycle, Chiemezie was also closely involved in the regulatory submission to obtain a Good Manufacturing Practice license extension for the Quality Control laboratory in the Maastricht site. Compliance to GMP license ensures that medicinal products are consistently produced, tested, stored, and shipped according to the appropriate quality standards.

"I wrote the change control to document and assess the potential impact of building a new lab with other Neuroplast's stakeholders. Together with my team and the rest of the company, we wrote all impacted Standard Operating Procedures and forms"

Once the GMP license was obtained, the work continues. Chiemezie: "We make sure that all procedures are compiled accurately. It can be challenging, but my team and I take those challenges on the chin."

Management really listens and offers career opportunities

Next to the ground-breaking nature of Neuroplast' stem cell therapy - Neuro-Cells® does not involve genetic manipulation, it is manufactured from the patients' own stem cells and adapts itself to the needs of the patients' microenvironments – Chiemezie particularly values the team spirit: "Executive management actually listens to what employees have to say, regardless of position or age. Perhaps not all your ideas will be adopted, but at least management will explain why or give alternatives."

Chiemezie has been able to advance his career quite quickly. "When I joined Neuroplast in 2020, I gave myself five years to complete the training and to become an EU Qualified Person. But due to the rapid growth of Neuroplast, I was given the opportunity to start the training much sooner than I'd planned. I became successfully licensed within three years by the Dutch health authorities Farmatec."

By EU law, a Qualified Person is the only one allowed to officially certify that batches of medicinal products are manufactured according to the rules and regulation of GMP before the release for patients' administration. "QP training involves a lot of training and investment, and sometimes I had to take time off work to attend courses". "If you have the attitude and ability to learn, Neuroplast supports you in realizing your ambitions."

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WANT TO KNOW MORE?

Neuroplast is always looking for new talent, clinical partners, and investors to accelerate realizing our mission: Using stem cell technology to regenerate futures.

Contact us via info@neuroplast.com or follow us on LinkedIn