
QUALITY TIMES



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CHRISTMAS PARTY UPDATE

Making Quality a Way of Life



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SPGL's vision is "making quality a way of life". But what does it mean? Well...

"Quality" refers to how good something is compared to other similar things. It is relative and not absolute! In other words, its degree of excellence.

"Life" means the ability to grow, change, etc., so in essence it means to excel as we grow, change and evolve.

In the context of what we do at SPGL, we need to treat quality as a behaviour and a culture, rather than a task. Therefore, in our everyday work it means to excel in our service delivery and to continuously improve by:

- Doing things right 1st time
- Striving for zero mistakes and zero defects – No re-work
- Thinking, planning, organising and executing with focus and persistence – Never give up attitude!
- Focussing on the details – The devil is always in the detail!
- Working safely, going home fit and well each day

For any vision to be realised, it must be supported by a clear 'mission' and a set of 'values', and values are crucial as they are the glue that holds everything together. At SPGL, our mission is to 'Manage Quality & Improve Performance' for all our customers and we hold values of Excellence, Client Focus, People Centric, Teamwork and Trust.

However, making quality a way of life goes beyond the workplace. It's about how we truly think and behave, which ultimately shapes our character and our lives. It is up to everyone to decide on the things that matter to them and create the habits that will allow them to excel in their lives. Some people are passionate about having...

- Quality Health – Regular exercise, meditation, mental wellbeing, etc.
- Quality Food – Eat foods that have good ingredients, well made and tasty.
- Quality Clothing – Wear clothes that are well designed, made from good material and are durable.

For me, it means ALL of the above and Quality Time, especially as time is the ultimate currency and is finite. Therefore, during this festive period, I intend to spend quality time with friends, family and loved ones as well as eat great food, get into shape and buy quality clothes! Time is precious and it ticks by very quickly so choose to use it wisely.

2021 is almost over and despite the pandemic, it's been another enjoyable and successful year, so thank you all for your continued support, hard work, flexibility, commitment and above all resilience.

Take care, keep safe and I look forward to seeing you all next year. Wishing you a Merry Christmas and happy, healthy and prosperous New Year.

Make quality a way of life in 2022!

Jay Lad, Managing Director

MENTAL WELLBEING



Snoozen, Dormir, Schlaaf or Sleep: it's one thing that we all need and its linked to our mental and emotional wellbeing. It is the foundation of good health.

Giovanni Mazzella **Client Development Director**

Sleep is the centre of a revolving cycle that is critical to our mental wellbeing and yet sleep quality is often taken for granted. The effects of sleep deprivation can lead to depression, anxiety, bad decisions, lack of motivation, decreased physical health, and general lethargy and each one of these effects can themselves lead to a lack of sleep, creating a negative continuous cycle.

We will spend approximately 25 years of our lives sleeping, and incredibly an additional four years trying to get to sleep, so it's clear that we need to develop a plan to maximise positive sleeping patterns.

So how do we do this? What prevents us from having a good nights rest and how can we improve our relationship with our sleep?

Poor sleep affects 32% of the population and there are four main factors that affect the quality of your sleep: (HEAL Paradox)

Health

Physical and mental health problems can stop us from achieving good sleep.

Environment

The place of sleep should be somewhere that we associate with rest and peace. Where possible, we should try to remove distractions, and be mindful of the presence of electronics, phones, tablets and TVs e.g. The backlit 'blue light' on our displays, suppress melatonin production and therefore enhances sleep disruption.

Other important environmental factors are light, noise and temperature.



Attitude

Many people can over-think before sleeping in the form of worry and anxiety, especially when they are contemplating the day that's been or the day that they are facing.

PRT or Progressive Relaxation Techniques can help you to unwind before going to sleep, therefore enhancing the potential of positive sleep and generating an effective routine.

Techniques can include white noise, meditation, 4-7-8 breathing exercise, reading etc.

PRT encourages a positive attitude, which can then help to break the negative cycle, and can help you to develop a healthier sleep pattern.

Lifestyle

There are a number of things that you can do every day to improve the quality of sleep. Food items such as rice, oats and dairy products can produce chemicals that increase our desire to sleep. Alcohol often impairs the quality of your sleep and makes you more likely to wake up during the night.

Exercising on a regular basis is thought to help us sleep, however, it is important to exercise at the right time, to avoid increased adrenaline production, therefore making it more difficult to sleep.

In summary;

- **Identify the HEAL factors that work for you.**
- **Establish a nightly routine that is specific to your needs.**
- **Stick to a set of habits that help you prepare you for rest each night.**

It is the key to successful and effective behaviour and a quality way of life.

ANNOUNCEMENTS

Our staff have celebrated some landmark achievements over the past year. Congratulations to you all! Thank you to the following people for letting us share their news.



Hugues De Ghellinck celebrates his 15-year anniversary at SPGL

I joined Skanska Pharmaceutical Group Limited in 2006 and in 2008 I became part of the newly created SPGL company after the successful de-merger. It was a really exciting time to participate in this new adventure to support

and serve the pharmaceutical industry.

During all those years, SPGL provided me satisfaction in my job, listening to my wishes and offering a perfect balance between autonomy and support.

SPGL has shown a continuous growth since the start, and I am pleased to feel that the company could preserve the same family spirit it had since the creation of the company.



Sam Deckers celebrates 10 years at SPGL

I am proud to have been part of SPGL since 2011. Looking back over the past ten years, I learned a lot and evolved from a young Automation Engineer to an Automation CSV Consultant, with the support of SPGL. I have

also gained experienced working at several key pharmaceutical companies. I am curious to know what the future will bring, but I'm convinced that many valuable years will follow. Thanks SPGL!

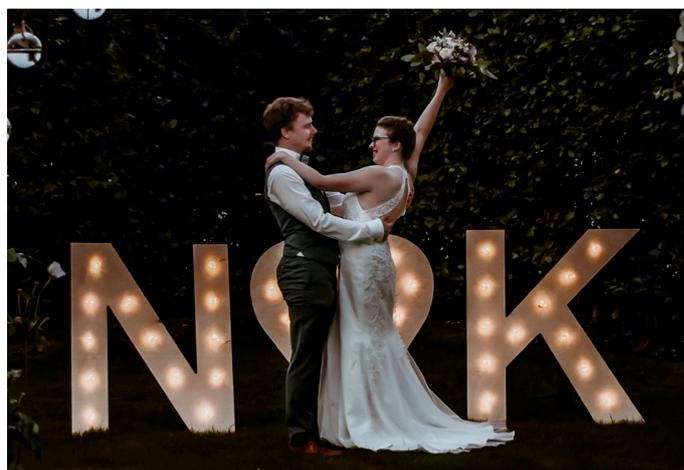


Jahed Khawaja celebrates 20 years at SPGL, what a fantastic achievement

Being part of a company for over 20 years means a great deal to the individual and the company. As well as developing the experience and skills in one's line of work, one also develops friendship and strong

professional bonds within the organisation. It has been an enjoyable journey with educated, talented and professional colleagues in an evolving company which always has room for juniors, medians and seniors.

Great to be here and look forward to carrying on along with everybody at SPGL.



Kelly Rymenams got married this year, she would like to share a quote that she featured in her wedding décor

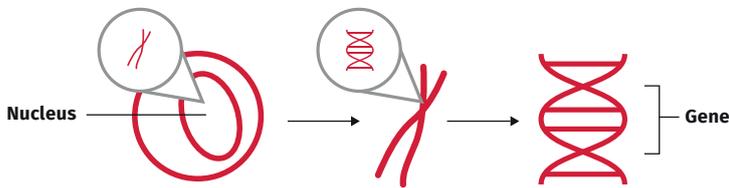
We are all a little weird and, life's a little weird, and when we find someone whose weirdness is compatible with ours, we join up with them and in mutual weirdness and call it love. *Dr Seuss*

An introduction to cell and gene therapy

What are cells and genes?

Cells are the basic building blocks of all living things, and genes can be found deep within cells. Genes are small sections of DNA that carry genetic information and instructions for making proteins, which help build and maintain the body.

Genes are a part of DNA:



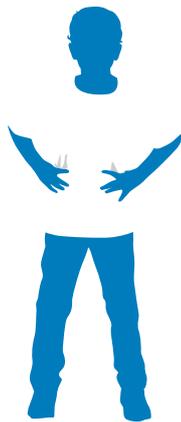
Cell

The nucleus controls the processes of the cell

Chromosome

Chromosomes are thread-like structures made up of DNA tightly coiled many times around proteins called histones

DNA



EVERY PERSON HAS AROUND

20,000

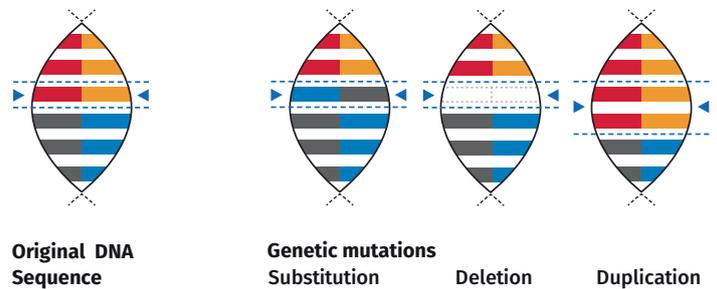
GENES AND TWO COPIES OF EACH OF THEIR GENES — ONE FROM EACH PARENT

Small variations in genes result in differences in people's appearance and, potentially, health

What are genetic diseases?

Genetic diseases happen when a critical piece or whole section of DNA is substituted, deleted or duplicated. These changes are called genetic mutations.

Genetic mutations can cause genetic diseases:



Original DNA Sequence

Genetic mutations Substitution

Deletion

Duplication

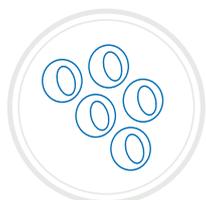


Some serious genetic diseases caused by genetic mutations can be passed to future generations

How do cell and gene therapies help treat genetic diseases?

Cell therapy and gene therapy are overlapping fields of biomedical research and treatment. Both therapies aim to treat, prevent, or potentially cure diseases, and both approaches have the potential to alleviate the underlying cause of genetic diseases and acquired diseases. But, cell and gene therapies work differently.

The difference between cell therapy and gene therapy:



Cell therapy aims to treat diseases by restoring or altering certain sets of cells or by using cells to carry a therapy through the body. With cell therapy, cells are cultivated or modified outside the body before being injected into the patient. The cells may originate from the patient (autologous cells) or a donor (allogeneic cells).



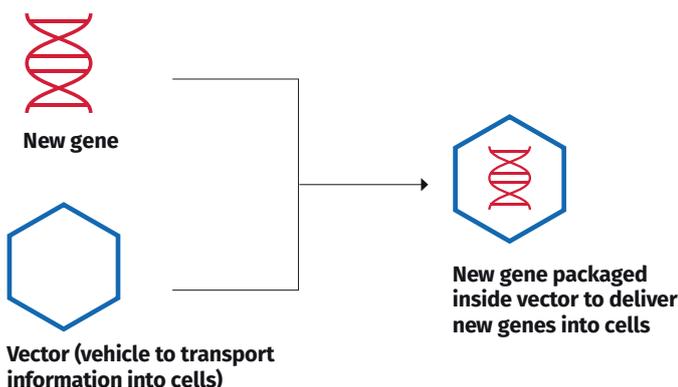
Gene therapy aims to treat diseases by replacing, inactivating or introducing genes into cells—either inside the body (in vivo) or outside of the body (ex vivo).

Some therapies are considered both cell and gene therapies. These therapies work by altering genes in specific types of cells and inserting them into the body.

How do we use cell and gene therapies?

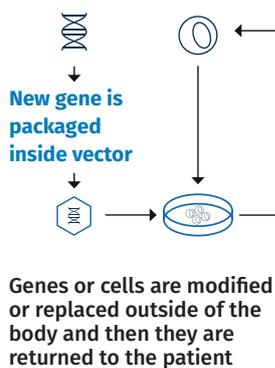
Scientists have been researching gene therapy for over 50 years. Today, they transfer new genes into cells using transporters known as vectors, which are often made from modified, inactivated viruses that do not cause disease.

Packaging the new genes:



Once packaged, there are two ways to deliver the new gene—ex vivo or in vivo

EX VIVO outside the body



IN VIVO inside the body



Why is cell and gene therapy important?

It is estimated that millions of people globally suffer from more than 10,000 rare diseases caused by mutations of single genes. For these patients, cell and gene therapies offer hope and potential cures for previously untreatable diseases and difficult-to-treat diseases across a wide array of medical fields.



10,000

RARE DISEASES AROUND THE WORLD ARE CAUSED BY MUTATION OF A SINGLE GENE

Cell and gene therapies offer hope for a wide array of untreatable diseases and difficult-to-treat diseases in:



SPOTLIGHT

Ilias Janssens

Validation Analyst at Pfizer Puurs

Hi there! I'm Ilias, 26 years old and started with SPGL in August 2020.

Tell us a bit about your background and what you did before you joined SPGL?

I came straight from school before joining SPGL. As far as I can remember, I studied sciences for almost whole my entire life. I graduated as a conservation biologist at the University of Antwerp. From then on I was looking for a challenge and before I knew it, I ended up applying for SPGL.

How do you find working for SPGL from a technical and personal perspective?

To be honest, as a biologist, it is quite unusual to end up in the pharmaceutical sector. However, I discovered a unique and interesting world. I am very grateful to SPGL for giving me opportunities without even doubting me. Now it is my goal to provide quality services to Pfizer Puurs in the name of SPGL. This is how every relationship should be, you give and take.

Getting to know Ilias!

What is your favourite food?

Sushi, by far. 😊

What do you enjoy doing in your spare time?

Quite a wide spectrum of things to be honest: from playing basketball and making music (guitar and piano) to playing video games with my crew.

If you were stuck on a desert island and you could have two people with you who would they be?

Definitely my boyfriend Yannick. Although our chances of survival would be pretty slim, so to compensate, I would bring my handy mother as well.

If you could live anywhere in the world, where would you choose?

I would move to Australia with Yannick and our two adorable kitties, Flinn and Basil.



RECRUITMENT

Lee Morley



Earlier this year, Lee Morley was appointed as our new Talent Manager. Welcome aboard!

"I joined in October this year and during my first week, I hit the ground running by attending the social gathering in Antwerp. It was great to meet people F2F after such a long time and to see a good blend of professionals – young/experienced, men and women.

Since joining the group, I have been busy reaching out to our people and trying to establish contact by email, calls as well as LinkedIn. I look forward to developing relationships with you all.

As I am focussed solely on recruitment, having the right system to manage personnel data in an efficient and secure manner is crucial. Therefore, in the first few weeks I reviewed our existing Recruitment/CRM system and decided to upgrade it to the latest version. Since the upgrade, I have started to develop and build Talent Pools within the system, which is growing by the day!

The market is busy, and we are in a major recruitment drive, therefore the search never stops! So, if you have any friends or colleagues that may be interested in joining our group, please send them my way."

Lee.Morley@spgl.eu

Medical Devices & Diagnostics



By Kathleen Van Asten Project Leader

In this edition, Kathleen Van Asten shines a light on the world of Medical Devices & Diagnostics and talks about her current client, Biocartis, and their Automated Diagnostic Kit.

Biocartis

Biocartis is an innovative molecular diagnostics (MDx) company. It provides next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians and industry.

In 2013, Biocartis introduced Idylla™, the trademark name for its innovative and high-quality platform.

The Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in almost any setting.

Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide.

Today, Biocartis has five oncology tests and three infectious disease tests on the market.

Idylla™ – Ease of use

MDx generally involves a series of specialized, laboratory-intensive and time-consuming steps. To optimize costs and processing times, traditional MDx tests are mainly performed on multiple instruments, in batches and operated by highly trained personnel.

Idylla™ overcomes the traditional barriers of MDx, making these types of tests widely accessible to all types of clinical laboratories.

Idylla™ is the only system that requires less than two minutes of operator time to run a sample. It is a fully integrated sample-to-result solution that eliminates the need for manual sample preparation, addition of buffers or master-mix, premixing of reagents or centrifugation.

After the patient sample is inserted, the cartridge is hermetically sealed to prevent the spread of any DNA amplification products, which might cause contamination of the laboratory environment or equipment.

Idylla™ – All processing steps in one cartridge

The process includes following steps from sample to result:

- Homogenization of solid/viscous samples by use of chemical reagents, enzymes, heat and high-intensity focused ultrasound (HiFU).
- Lysis of the cells, containing nucleic acids to be analyzed, by using chemical reagents, enzymes, heat and HiFU.
- Filtration of the lysed sample.
- Extraction, purification and concentration of nucleic acids.
- Real-time amplification in up to five individually controlled PCR chambers, each containing 25 µl of eluate.
- Primer/probe mixes and enzyme mixes pre-spotted in every PCR chamber, including primer/probe mix to detect/amplify a sample processing control (e.g. endogenous control).

- Detection of six different fluorophores per PCR chamber, allowing simultaneous identification of up to 30 different molecular targets in standard mode in each cartridge.
- Full interpretation of results.
- Automatic creation of Idylla™ test result report.

Worldwide commercial footprint

Biocartis covers over 75 countries through four sales channels:

1. Direct sales force covering Western European countries, US and Canada.
2. Distributor contracts in place covering ~ 60 countries. Distribution agreement with Nichirei Biosciences for Japanese market.
3. Joint venture in China with Wondfo.
4. Pharma collaborations (e.g. Merck KGaA (Darmstadt, Germany), Amgen, AstraZeneca, BMS and Kite/Gilead) and content partnerships (e.g. Immunexpress, GeneproDx, Endpoint Health, SkylineDx).

SARS-CoV-2

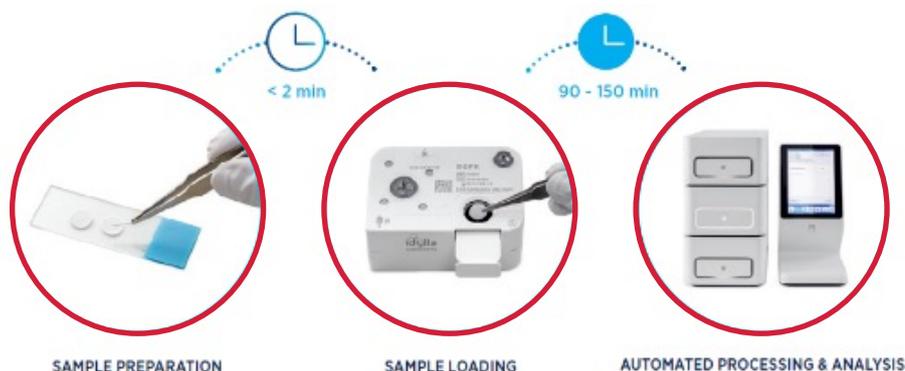
Last year, the world turned upside down when SARS-CoV-2 unexpectedly entered our lives.

Consequently, Biocartis joined forces with 18 healthcare companies in a COVID-19 Testing Industry Consortium, with the aim to improve, innovate and accelerate all aspects of testing, including research, regulatory oversight, clinical implications, reliability and access.

As a result, in August 2020, Biocartis launched the Idylla™ SARS-CoV-2 Test. The Idylla™ SARS-CoV-2 Test is intended for the qualitative detection of RNA from the SARS-CoV-2 virus in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Recently, a new test was launched with an expanded panel: The Idylla™ SARS-CoV-2/Flu/RSV Panel Test cannot only detect SARS-CoV-2 (N & ORF1b genes), but also Flu A (2x M gene), Flu B (M & NS genes) and RSV (F & N genes).

By the development of these products, Biocartis, as an innovative MDx company, also contributes and plays its part in the COVID-19 pandemic.

For more information on this topic contact: kathleen.vanasten@spgl.eu



Over the past few months, it has been great to get back out meeting people in the industry and of course being face-to-face with our staff. Here is a snippet of what we have been up to!

SPGL – SUMMER EVENT

A business update held in our Antwerp Office where we enjoyed Mexican food and catching up with our colleagues!



ISPE UK ANNUAL DINNER 2021

An award ceremony held at Lancashire Cricket Ground in Old Trafford, Manchester. An exhibition in the day with an even better dinner in the evening.



MANAGEMENT MEETING 2021

The London office held a virtual meeting with some members of the Antwerp office to carry out workshops on 'Sustainable Growth'.



The poster features a light grey background with festive illustrations. On the left, a penguin in a red scarf is shown against a green background with white stars and a red Santa hat. On the right, a green and white Christmas tree is depicted against a pink background with white stars and a red Santa hat. The text is centered and written in a red, cursive font. The title 'Christmas Jumper Competition' is the largest. Below it, the rules and prizes are listed in a smaller, red, sans-serif font. The prizes are listed as: 1st Place – €100 gift voucher, 2nd Place – €50 gift voucher, and 3rd Place – €25 gift voucher. There are also small yellow starburst graphics scattered throughout the page.

spgl

Christmas Jumper Competition

Christmas hampers are currently on their way.

All you have to do, to be in it to win it, is pose next to your hamper in your best Christmas jumper!

The funnier and more inventive the better.

Prizes awarded to the best & funniest entries:

- 1st Place – €100 gift voucher**
- 2nd Place – €50 gift voucher**
- 3rd Place – €25 gift voucher**

The SPGL New Year's party will hopefully take place on January 21st 2022, COVID regulations permitting. If we are prevented from celebrating together again, we will of course come up with a creative solution, so watch 'People HR' and your email for further announcements.

