

QUALITY TIMES



PLAYING THE LONG GAME

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CHRISTMAS PARTY UPDATE

Playing the Long Game



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In many ways, running a business can be regarded as playing a game; there are two types of games that can be played, an 'Infinite' game or a 'Finite' game.

A finite game is one in which there are known players, fixed rules, and an agreed objective. A chess or football game, for example, has identifiable players, strict rules and a pre-set ending point where one player/team wins and the game stops.

In contrast, an infinite game has both known and unknown players, changeable rules and no clear ending point where one person/team is declared the winner. The objective is to perpetuate the game and stay in it as long as possible. A race for launching a product, politics or education can all be regarded as infinite games. Essentially, we are all players in infinite games every day of our lives!

Running a business can be regarded as an infinite game at play, as it shares some of the same characteristics, i.e.

- There are many players, even some you don't recognise.
- There are no fixed rules – other than acting legally, there are infinite ways to conduct business.
- There's no agreed-upon objective. One person's definition of success may not be the same as another's.
- There's no end, when a player leaves the game, it continues.

A business run with an infinite game mindset will make decisions based on long-term strategies to develop enduring strength, whilst a business with a finite game mindset will aim for short-term wins that might, ultimately, weaken the organisation.

So how does one develop an infinite game mindset? By embracing the following attitudes:

- **Play versus win:** Don't set out to defeat others, but instead, aim to maintain a healthy position within a competitive field.
- **'Us' versus 'Me':** Consider the impact you will have on your people, your community, the economy and the outside world.
- **Be proactive, not reactive:** Anticipate outcomes and prepare for disruptions instead of merely reacting to them.
- **Think of long-term goals:** Work towards a longer-term view of success rather than worrying primarily about the near-term bottom line.
- **Focus on long-term threats:** Don't centre your strategies around specific, definable threats posed by rivals. Instead, explore opportunities or develop innovations that might strengthen your organisation sustainably.
- **Aim for resilience over stability:** Strive not just to weather storms but to be made stronger by them.

Business leaders who play an infinite game, that is constantly evolving and never-ending, are generally more successful in the long-term than those who aim for short-term wins. Moreover, a crucial aspect of running a business is to unleash the passion of the people within the organisation. It takes courage to completely change our mindset in the way we perceive the world. I truly believe that if we can all learn to embrace infinite mindsets, not only will we enhance innovation, see trust and cooperation thrive, but we may actually come to love what we do!

Wishing you a Merry Christmas and a happy, healthy and prosperous New Year.

Jay Lad, Managing Director



SPGL Staff Survey

By **Lindsay Marsh**

Administration & HR Associate Director

As you all know, earlier this year we sent out a survey to all our staff, the purpose of which was to harness the power and experience of our people and to make SPGL a better place to work. The thoughtful insights provided have been truly valuable in better understanding both our people and our company.

Feedback

Thanks to everybody who took part, we had a participation rate of over 70%, and overall engagement score of 67.2%, which is an excellent result for a first survey. Over the coming months, we hope to gradually improve this score.

We have reviewed all of the feedback and are making positive changes which will hopefully ensure that SPGL is an even better place to work; an environment where everyone feels connected and are able to work more productively.

Our People

Our people are always top priority, so implementing this platform has enabled us to have a secure two-way anonymous platform for sharing ideas, innovations, suggestions and general feedback.

There were three key themes that came out of the survey:

1. Clarification of our 'Company Purpose' & 'What we Do'
2. Communication
3. Providing a technical Q&A forum

Actions

Here is a summary of the actions we have already taken as a result of your feedback:

- The first video in our campaign has been released highlighting 'What We Do'. Visit:



- We have added an additional management member, who has been hired to support individual follow up.
- SPOC (Single Point of Contact) Programme has been implemented.
- Technical Q&A Forum has been launched.
- Suggestion box feature has been enabled within the survey platform.

Moving forward, we plan to carry out another survey in Q1/Q2 next year and we look forward to sharing ideas and insights with you all!

Thanks for taking the time to give us your Feedback

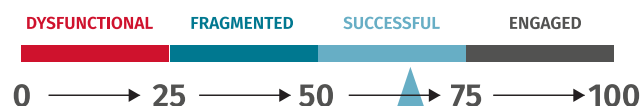
Participation Rate

70%



Our Engagement Score

The 'Engagement Score' is a measure of our organisation's level of engagement and how present, focused and energised our people feel at work.

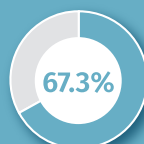


Our Engagement

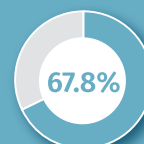
67.2%



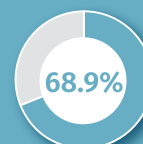
Our Engagement Dimensional Scores



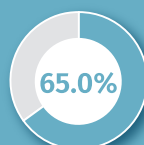
PURPOSE
Employees' connection to the organisation's purpose.



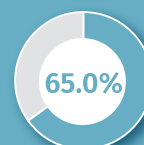
COMPANY
How senior leaders, the culture, and strategy are perceived.



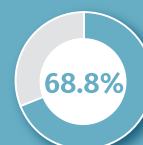
LEADERS
Employees' perceptions of their direct supervisors.



EMPLOYEES
People's perceptions of their colleagues and peers.



CUSTOMERS
How employees perceive your customers' experience.



INDIVIDUALS
How people feel about their individual experience at work.

What exactly are ATMPs and how are they classified & regulated?

By **Jay Lad**

Advanced therapy medicinal products (ATMPs) including breakthrough cell and gene therapies, offer unprecedented promise for the long-term management and even cure of disease – especially in areas of high unmet medical need. These advanced therapies are driving an exciting and revolutionary new paradigm in science and healthcare.

But what exactly are ATMPs? In this article, we take a closer look at this exciting therapy.

What are ATMPs?

ATMPs are medicines intended for human use that offer revolutionary opportunities for the treatment of both disease and injury. They are classified as:

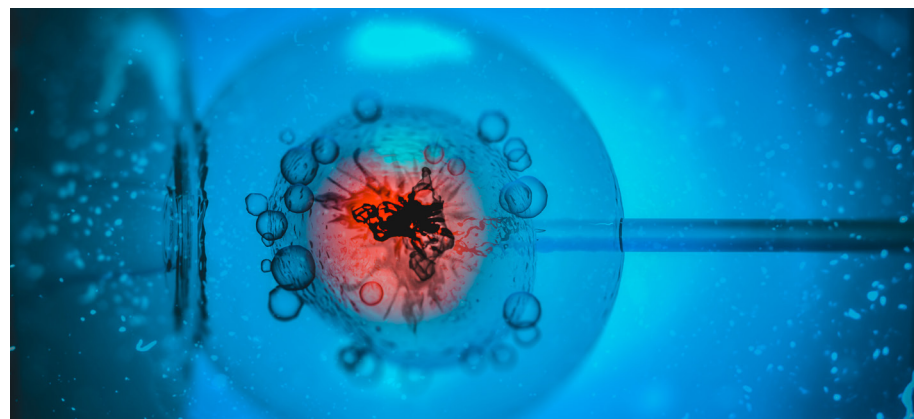
- **Gene therapy medicines:** Medicines containing genes that lead to therapeutic, prophylactic, or diagnostic effect, they work by inserting 'recombinant' genes (a stretch of DNA created in the laboratory) into the body to treat diseases.
- **Somatic-cell therapy medicines:** Medicines used to cure, diagnose, or prevent diseases, somatic-cell therapy medicines contain cells manipulated to change their biological characteristics, which may not be used for the same essential functions as before.
- **Tissue engineered medicines:** Medicines that contain modified cells or tissues used for the repair, regeneration, or replacement of human tissue.

As of August 2022, no more than 16 ATMPs are approved by the European Medicines Agency (EMA). So far, 11 ATMPs have valid marketing authorisation, with more expected to meet approval in the coming years.

Like any medicine, ATMP regulation is strictly controlled. In Europe, the EMA's biological products framework regulates ATMPs (Directive 2001/83/EC), and defines the legal basis for development. In the UK, however, ATMPs are regulated by The Medicines and Healthcare products Regulatory Agency (MHRA), which authorises ATMP clinical trials as well as ATMP manufacturing and importing.

ATMP classification overview

The EMA sets four main classifications in Article 2 of Regulation (EC) No 1394/2007, which we will outline below alongside examples of use for each.



Subclassification of ATMPs

Gene therapy medicinal product (GTMP)

GTMPs contain or consist of a recombinant nucleic acid which must be of a biological nature and should be directly involved in the mechanism of action. GTMPs regulate, repair, replace, add to or delete genetic sequences. An example of a GTMP in action is found in a medicine known as Lexturna, used for the treatment of vision loss due to inherited retinal dystrophy linked to biallelic RPE65 mutation.

Somatic cell therapy medicinal product (sCTMP)

sCTMPs consist of cells or tissues subjected to either substantial manipulation or are not intended for their original function in the recipient and donor. This kind of ATMP is used to either treat, prevent or even diagnose disease through the action of its cells or tissues – this can be via pharmacological, immunological or metabolic action. sCTMPs are used in the medicine, Alofisel, which is used to treat complex anal fistulas in adults suffering from Crohn's disease.

Tissue-engineered product (TEP)

Like sCTMPs, TEPs consist of engineered cells or tissues subjected to substantial manipulation and are not intended for their original purpose in the recipient. The purpose of TEPs is to repair, replace, or regenerate human tissue. TEPs are used in the medicine, Spherox, which is used to repair defects within knee cartilage.

Combined ATMP

A combined ATMP must work as an integral part of, or must incorporate, one or more medical devices and a cellular or tissue component. The component must also contain viable (living) or non-viable (non-living) cells. An example of a combined ATMP in use is cells embedded in a scaffold used in tissue engineering.

To further understand what classification your ATMP is likely to be classified as – if at all – you can use this decision tree as published by the EMA. **(See overleaf).**

Advice for applying for ATMP classification

While ATMP classification is free and legally non-binding, there are a variety of factors that a developer must consider before applying. Although the procedure for ATMP classification is optional, a successful ATMP classification may help developers gain access to unique EMA services and incentives.

Documents required

When applying for ATMP classification, two documents are required for submission.

The first document is an administrative form that requests details including the product name, description of active substance, indication, company details and a date of submission.

The form (submitted as a single-tab Excel sheet) must also match the information on the second required document – the ATMP classification briefing document.

The briefing information document should contain information about the product, its development (such as quality and manufacturing details), and the outline of clinical and non-clinical development work. The scientific aspects of the application are broken down into the following steps:

1. Active substance: Description of active substance, additional substances, and medical device.
2. Finished product: Details on qualitative and quantitative composition, mode of administration, pharmaceutical form, plus the

description of the finished product when ready for clinical use.

3. Mechanism of action: Claimed mechanism of action, the properties of that action and proposed uses, including therapeutic, prophylactic, or diagnostic.
4. Summary of the status of the development of the product: Key elements of manufacturing aspects, including outlines of clinical and non-clinical development.

Procedure

Applications must be submitted on the EMA website before the allocated deadlines outlined on the Advanced therapy classification page. ATMP classification requests should be received by the EMA at least 15 days before the start of the procedure for inspection and the request for additional information if required.

Publication

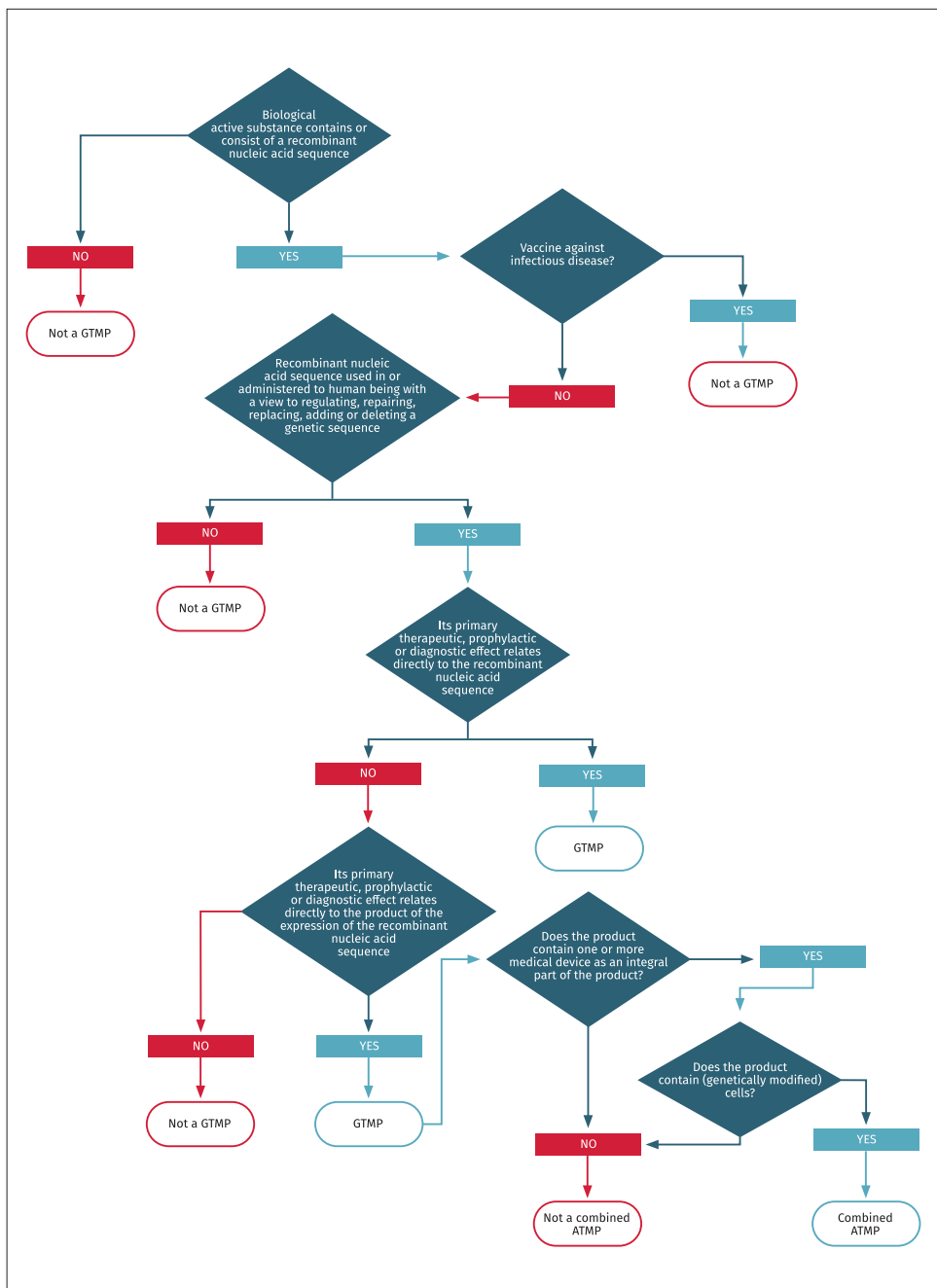
The Committee for Advanced Therapies (CAT) then initiates a draft preparation period where it meets to discuss the draft scientific recommendation. As a result of the meeting, the committee then delivers the outcome after consultation with the European Commission. In all, the procedure should be finalised no longer than 60 days after the receipt of the original request.

What does the future of ATMPs look like?

It is clear that ATMPs have high potential to be beneficial to patients' health and wellbeing in the future, but there is still significant work to be done to understand their full health impact.

Due to the wide range of applications that ATMPs could eventually be used for, there is already a lot of work going on to research and develop ATMPs fully, with positive results from clinical trials already resulting in significant investment and resources being allocated to this field.

Developing new ATMP products is just the start however. Taking the time to understand the classification and regulation of these products is just as important for businesses looking to get involved in this exciting field.



List of references

- <https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview>
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/directive-2001/83/ec-european-parliament-council-6-november-2001-community-code-relating-medicinal-products-human-use_en.pdf
- <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>
- <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF>
- <https://www.gov.uk/guidance/advanced-therapy-medicinal-products-regulation-and-licensing>
- https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-classification-advanced-therapy-medicinal-products_en-0.pdf
- <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification>

Estée Lauder

In this edition, **Kelly Rymenams will provide a brief insight into the Estée Lauder company. Who are they and what products do they make?**

Estée Lauder is an international cosmetic company founded by Madam Estée Lauder in 1946. In a time where not many women chased grand careers, let alone start their own company, she was a pioneer and role model. Her dream and dedication led to the birth of a global company which now holds 25+ different brands (including M·A·C, La Mer, Clinique, and Tom Ford beauty) which are sold in 150+ different countries. Worldwide, 60,000+ people work for it, with 900 situated in Oevel Belgium. These numbers are sure to rise more in the near future as an extension of the Oevel plant is currently being built.

At the moment, the Oevel plant consists of three different business units: the production plant, the EMEA hub and international services. In the production plant all ordered raw materials are transformed to skin care, parfum, make-up and hair care products. These products, from Oevel and from other plants, arrive in the EMEA hub for distribution

to other distribution centres or to the end users. 45% of all products sold worldwide pass through the Oevel EMEA hub! Besides these two, some international services are also present to support regional and EU wide support.

As the biggest facility in the EU, the Oevel plant has an important part to play to uphold Estée Lauder's worldwide reputation for elegance, luxury and superior quality.

Fun facts

The Oevel plant was built in 1965 as the first overseas factory.

75+ years later, second- and third-generation members of the Lauder family remain at the heart of the company, and still actively involved in company policy.

Estée Lauder started an innovation in the fragrance business. Before the 1950s, perfume was used sparingly as it was expensive. In 1953 she created a less expensive bath oil which doubled as a perfume, making it more affordable and accessible. This changed the way fragrance was sold and transformed the start-up company into a multimillion-dollar business.

With the development of the brand Clinique, they created the first dermatologist-created allergy-tested, 100% fragrance-free collection of cosmetic products.

Evelyn Lauder, co-created the now well-known Pink Ribbon, launched the Breast Cancer Awareness (BCA) Campaign and established the Breast Cancer Research Foundation in 1993.

Sources:

Who We Are – The Estée Lauder Companies Inc.
([elcompanies.com](https://www.elcompanies.com))

The Estée Story – The Estée Lauder Companies Inc.
([elcompanies.com](https://www.elcompanies.com))

Key Moments – The Estée Lauder Companies Inc.
([elcompanies.com](https://www.elcompanies.com))

<https://www.jobsbijesteelauderoevel.be/nl/wie-zijn-we>



SPOTLIGHT

Simona Cecchi

Project Engineer at Pfizer Puurs

Hi there! I am Simona, 28 years old, and started with SPGL in February 2020.

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

After I graduated in June 2019, I took a little break to travel before I dedicated myself to my career. I have had the time of my life travelling from one place to another including 12 different places around the world. I am so grateful to my parents for giving me the opportunity and I'm glad it was before Covid as it grounded travel plans for so many others. Thereafter, when looking for opportunities as a junior biochemical engineer, I was contacted by SPGL and immediately started to work as a Validation Engineer for Sanofi in Geel.

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

There was a click between SPGL and me from the very beginning. I did not hesitate to take the chance SPGL gave me to start a career as a consultant within the pharmaceutical industry. I have always been intrigued by research and development in the pharmaceutical and biomedical industry so it was a good fit. I have grown personally and technically in the past two years. I am grateful to SPGL for supporting me in my search for a more specific job in line with my studies and I am very much looking forward to starting at Pfizer in Puurs.



Getting to know Simona!

What is your favourite food?

I am a real PASTA addict!

What do you enjoy doing in your spare time?

I love to travel and be inspired by all the people and cultures along my path. I am a real foodie and love to cook for family and friends. I also have a passion for music and fashion.

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

This would be impossible; I grew up in a large and very close Italian family (with whom I am in contact with 24/7). To be clear, I am not going anywhere without them!

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

Home is where the heart is. I could adapt anywhere in the world as long as I have my loved ones with me.



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.



Daan Glas welcomes baby Mila

Daan Glas and his partner Annelies welcomed a baby girl in April named Mila.

Very many congratulations to Daan and his family from all of us at SPGL.



Maureen Hoengenaert Significant Contribution Recognition

We'd like to congratulate Maureen Hoengenaert on receiving significant recognition for her hard work and dedication in helping successfully release an important product for Pfizer, Puurs, Belgium. Well done Maureen on the tremendous feedback!



Benjamin Vanbel

Welcome to Benjamin Vanbel who joined us as an IT & System Engineer in January.



Ilke Van Reeth

Welcome to Ilke Van Reeth who joined us as Talent & Development Lead in August.

ANNOUNCEMENTS



Thomas Van Heupen

Welcome to Thomas Van Heupen who joined us as a Graduate Specialist in November.



Charlotte Mathys

Welcome to Charlotte Mathys who will join us as an Engineer Level 1 in December.



Filip De Smedt

Welcome to Filip De Smedt who joined us as a Specialist Level 1 in July.



Sarai Liekens

Welcome to Sarai Liekens who joined us as a Graduate Engineer in September.



Stef Vernelen

Welcome to Stef Vernelen who also joined us as a Graduate Engineer in September.

EVENTS

SPGL SPANISH EVENT SEPTEMBER 2022

A social gathering held at our Antwerp office where we enjoyed Spanish food and drinks, and a catch up with our colleagues.



SPGL SUMMER EVENT JUNE 2022

Our summer company event where our team enjoyed a golf tuition and a summer BBQ.





ACHEMA

On Monday August 22nd, the AACHEMA event in Frankfurt opened its doors to visitors. The AACHEMA is a five-day event during which countless manufacturers and service providers from over 50 countries present their products for chemical, pharmaceutical and biotech research and manufacturing.

I got the chance to visit AACHEMA with some of my J&J colleagues, to which we travelled by bus. We only visited the event for one day and of course that meant leaving early, at 4:30 in the morning to

arrive at around 9:00. The huge exhibition was stretched over 12 great halls and filled with all kinds of pharmaceutical, and sometimes functional equipment, such as a state-of-the-art fluid-bed granulator, tableting machines, dedusters, coating machines, containment devices, parts washers, etc. Evidently, every type of equipment being exposed came along with a sales representative or engineer explaining the detailed way of working. There was also the possibility of joining a virtual tour about a pioneering isolator with modules that can be exchanged

quickly and simply, with the main advantage of having greater flexibility and reduced batch-to-batch turnover time. After attending numerous different suppliers, we shortly relaxed, drank a beer and got back on the bus home. Halfway home, we stopped for food and to discuss the diverse range of equipment we saw during the day and which kind of technologies could be interesting to work with in the future. At around 22:00 in the evening, we got home; exhausted, drained, but evermore impressed with the advances in the pharmaceutical market and what kind of technologies are about to make their debut in the future.

In my opinion, AACHEMA should be attended by anyone wanting to get to know the industry more and is interested in expanding their knowledge of evolving technologies in the pharmaceutical market. Should you ever get the chance to go, I recommend you do, it's not only very interesting, but it's also a nice trip to get to know your colleagues.

Sam Vervliet
Validation Specialist

MANAGEMENT MEETING MAY 2022

The London office combined with our Belgium co-workers held the 2022 Management Meeting followed by a team outing of crazy golf and fabulous food.





Invites you and your partner to our

CHRISTMAS PARTY



Join us for the party of the year!
Red Carpet Entry, Welcome Drinks
Walking Dinner & Live Music!

Location - Former train station, converted into a party
location. La Gare 27, Damplein 27 2000 Antwerp.

LA GARE 27 | 9TH DEC | 7:30 PM

Dress Code: Formal Attire / Cocktail Party with lots of Glitz &
Glam!