spgl Managing Quality Improving Performance

December 2023

QUALITY TIMES

15 YEARS OF EXCELLENCE
STAFF ENGAGEMENT SURVEY
DRUG DEVELOPMENT JOURNEY
A GRADUATE'S PERSPECTIVE
SPOTLIGHT
ANNOUNCEMENTS
EVENTS
CHRISTMAS COMPETITION

15 Years of Excellence: Celebrating Our Journey

It just feels like yesterday that we were gathered in London, celebrating our '10 Year Anniversary'. In the blink of an eye, another five years have flown by, and here we are, marking our remarkable 15-year journey together.

Leading this group has been a privilege and witnessing the growth and development, especially of our people, has been truly inspiring. Our people are the heartbeat of our group, and I couldn't be more proud of the achievements and milestones we've achieved together. SPGL has been a significant part of my life, filled with challenges and invaluable lessons. Two decades, if I count the five years prior to our separation from Skanska, is quite a long time. So, what have I learnt that I can share with you all?

Courage: Whenever you take a significant step in business or your personal life, it takes real courage. Stepping out of your comfort zone and embracing new challenges can be daunting, but it's through conquering your fear that you realise your full potential. I vividly remember the courage it took to separate from Skanska in 2008 during a deep financial crisis. It was a scary time, but it was our courage that got us through and uncovered our hidden talents and allowed us to grow as individuals.

Focus is the Key to Success: I've come to realise that if we channel our energy into a single goal, not only does the goal become clearer, but we are more likely to achieve it. Without focus, our potential remains untapped, but with it, we can overcome almost anything and realise our ambitions.

Persistence: In both our professional and personal lives, there are times when giving up seems easier than pressing on. However, it's good old persistence, the "never give up and can-do spirit," that ultimately gets you through the other side. When faced with a brick wall, remember that there's always a way. If one door is closed, try another, or even create your own.

People and Relationships Matter: Taking the time to build good relationships based on open communication and trust is of paramount importance. Over the years, I've met countless people, and it's good relationships that has enabled me to resolve almost any issue or misunderstanding. Harnessing each other's strengths, allows us to achieve more and thrive.

Action/Reaction: Newton's 3rd Law reminds us that every action or choice has a consequence and it's these choices we make day-by-day, hour-to-hour, minute-to-minute, second-to-second, that truly shapes our life and destiny. In my experience, everything is interconnected and doing what you believe is right, even though it may not seem beneficial at the time, tends to work out better in the long run.

Life is a Function of Time and Energy: Time is the ultimate currency and it diminishes at the same rate for everyone, regardless of age. What differentiates us is the amount of energy we have and how we utilise it. The amount of energy one has depends on their mental/physical conditioning, so nourish your mind and body well. Time combined with energy is what truly propels life, so seize as much of it as you can.

Looking at the world today, I realise that it is changing at an exponential rate, especially with the integration of AI and quantum computers. The world is likely to be a very different place in the next decade. Who knows, robots and AI bots may become integral parts of our human experience, especially if they can mimic our consciousness. But until then, what matters most to me are our incredible people, after all we are a services business, and it's all about people.

Our success is a testament to your hard work, dedication, loyalty and passion. Thank you for 15 years of excellence and here's to many more!

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

Jay Lad Managing Director

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SPGL Staff Engagement Survey

By Lindsay Marsh
Administration & HR Associate Director

In 2022, SPGL embarked on a transformative journey by launching an extensive feedback survey. Our mission was to tap into the collective knowledge and experiences of our workforce in order to enhance our workplace environment. I am pleased to report that this initiative has exceeded our expectations, becoming a resounding success.

Invaluable feedback

Our inaugural survey delivered not only an outstanding engagement score but also invaluable feedback that inspired several remarkable initiatives. Fast forward to today, we've just completed our second survey, and the progress is evident. We're thrilled with the increased engagement score and participation rate, a testament to the positive impact of our follow-up actions from last year.

Our most recent survey featured a tailored set of questions, in addition to the standard ones and this customisation has provided us with deeper insights into specific aspects of our operations that we might otherwise have overlooked.

A culture of continual feedback

At SPGL, we are committed to continual improvement, consequently we analysed the suggestions and comments gathered from the survey and this has led us to identify three key areas to focus on. We firmly believe that by channelling our efforts into these critical areas, we will drive progress and bring about meaningful change.

The focal points that have emerged this time around are Communication, Company Purpose, and Client Feedback. While we take pride in our communication practices, we recognise the potential for improvement. Therefore, we plan to proactively enhance our communication efforts by disseminating general company information more efficiently, scheduling information sessions and increasing the frequency of updates through various channels.

Our purpose

Addressing our company's purpose is equally important and to illustrate this we released a video to define it at the end of last year. Although the video was a great success, it was not viewed by our entire workforce and therefore it will be relaunched in the near future. In addition, we have also developed and published our 'Purpose Statement' which truly encapsulates the spirit of our group and its people.

We extend our heartfelt gratitude to all our dedicated personnel who participated in this pivotal initiative. Your contributions have played an instrumental role in the remarkable success of this survey, and we genuinely value your input.

Furthermore, recognising the significance of client feedback, not just at the management level but also on an individual basis, we are diligently working on implementing a new and improved feedback system. Our objective is to foster a more streamlined and responsive environment, ultimately enhancing our client relationships and service delivery as well as providing individual feedback to our people.

Your contributions have played an instrumental role in the remarkable success of this survey, and we genuinely value your input.

An Overview of the Journey: From Drug Development to Approval

By Dr Layal Lutfi
Director Regulatory Consulting & Compliance

The development stages of a drug, from inception to receiving regulatory approval, typically takes between 10 to 12 years. However, this duration can fluctuate, largely depending on how similar the novel drug is to existing commercialised drugs, and the specific regulatory endorsement process it requires.

Despite appearing complex, here is an intriguing statistic: a mere 8 to 10% of drugs assessed in preclinical trials are eventually granted approval by the relevant Regulatory Authority (Figure 1). It is clear that securing approval is no easy feat!

Ultimately, the prime objective is to introduce drugs that promise utmost safety and efficacy for prospective patients.

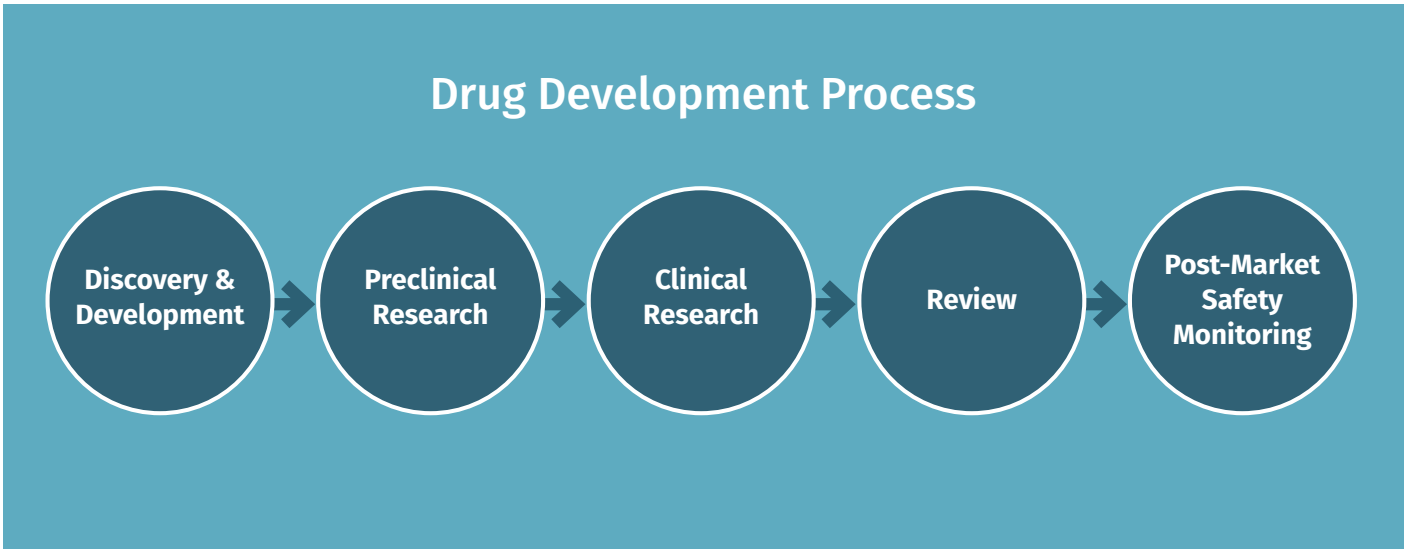

Figure 1: The New Drug Development Process: Steps from Test Tube to post market safety monitoring.

Step 1: Discovery and Development
In the Discovery stage, scientists in laboratories meticulously test thousands of potential compound candidates to identify those with the potential to become effective medical treatments. Only a select few compounds that show promise move on to the Development stage. Here, researchers conduct a comprehensive array of experiments to gather essential data related to the compound's characteristics. These tests cover various aspects, including absorption rate, distribution, metabolism, excretion, optimal dosage, potential adverse events (AEs), and efficacy in comparison to existing market drugs. It is during this stage that the groundwork is laid for the potential drug's journey through the approval process.

Step 2: Preclinical Research
Preclinical research is a crucial step in drug development that involves two distinct types of studies: In-Vitro and In-Vivo. These studies aim to provide comprehensive data on the investigational drug's proper dosage and toxicity levels. Adherence to Good Laboratory Practice (GLP) principles is essential during this stage to ensure the safety and

efficacy of the drug. The data collected during preclinical research is vital in determining whether the drug should advance to human clinical trials.

Step 3: Clinical Research Phase Studies
Clinical trials are the backbone of pharmaceutical breakthroughs. They are research studies designed to verify the safety and effectiveness of healthcare interventions, including experimental therapies, drugs, or treatments. Clinical trials are conducted in several phases:

- **Phase 1:** This initial phase involves a limited number of individuals and focuses on defining the safety profile of the investigational medicinal product (IMP), understanding its absorption by the body, establishing the correct dosage, and identifying any potential adverse events.
- **Phase 2:** In this phase, the IMP is administered to a larger group of individuals to monitor safety, assess effectiveness against specific diseases, and determine the most effective dosage.
- **Phase 3:** A broader population group receives the IMP in this phase, primarily to investigate safety and observe potential adverse events on a larger scale. The effectiveness of the IMP for specific diseases is also examined.
- **Phase 4:** This phase, if required, analyses the long-term risks, benefits, and Adverse Events (AEs) when the IMP is consistently used across a wider population.

Ensuring the safety of medicinal drugs and devices after they become accessible to consumers is a critical responsibility of regulatory bodies.

Clinical trials must adhere to various regulatory guidelines and standards, such as the ICH GCP E6 R2, ICH E8 R1 guidelines and relevant directives.

Step 4: New Drug (IMP) Application Submission, Review, and Licensing
Clinical trials are the backbone of submitting a New Drug Application (NDA) or an IMP application to regulatory authorities and is therefore a critical step. This application provides a comprehensive overview of the drug's journey, from preclinical data to Phase 3 trial data. It includes documents like proposed labelling, safety updates, drug abuse information, patent information, data from international studies, institutional review board (IRB) ethics compliance information, and directions for use. This information is crucial for regulatory authorities to make informed decisions regarding marketing license approval.

The review process involves a designated regulatory authority team thoroughly evaluating the application. Inspections at clinical study sites are also conducted to ensure data integrity. If the drug is deemed safe and effective, collaboration with the applicant ensues to create and enhance the drug's prescribing information.

Step 5: Post-Marketing Safety Surveillance (Pharmacovigilance)
Ensuring the safety of medicinal drugs and devices after they become accessible to consumers is a critical responsibility of regulatory bodies. While clinical trials provide valuable insights into a drug's safety, comprehensive information can only be obtained as the drug is used in real-world settings over time. Regulatory bodies oversee the safety of drugs and devices, scrutinising reports of issues and taking appropriate actions, such as issuing warnings or imposing stricter measures. Compliance with guidelines and regulations, such as EMA Good Pharmacovigilance Practices (GVP) Modules and FDA regulations, is essential during this phase.

In conclusion, the journey from drug development to regulatory approval is a multifaceted and stringent process that prioritises the safety and efficacy of pharmaceuticals. It involves rigorous scientific research, meticulous testing, and close collaboration between developers and regulatory authorities to bring safe and effective treatments to patients in need.

A Graduate's Perspective

Stef Vernelen
Graduate Engineer

Upon graduating as a Bioscience Engineer in August 2022, my exploration of opportunities in the Pharmaceutical Industry began. While I didn't have a specific interest or career path in mind, my encounter with SPGL at a job fair left a lasting impression on me. Despite being aware of larger consultancy firms, SPGL stood out for its personal touch. As I engaged in initial communications with them, that sense of personal connection only grew stronger. Unlike what I anticipated about entering the industry, I never felt like just another employee or sensed any hidden agendas. Right from the start, it felt like embarking on a unique and personal career journey.

However, my first project did not turn out to be the ideal fit for me. I promptly shared my concerns with SPGL, and they responded swiftly, making me feel valued and heard. We had regular discussions about available projects, exploring options, as well as assessing my aspirations and vision for the future. It genuinely felt like they were supporting and assisting me in achieving my goals.

Currently, I am working as a Turnover & Commissioning Engineer (T&C Engineer) at the newly constructed CAR-T facility of Janssen Pharmaceutica in Ghent. Although my educational background is in cellular and genetic engineering, my current project veers slightly away from the biological/ pharmaceutical aspect, but still maintains a focus on engineering. As a T&C Engineer, my responsibility lies in providing Janssen with the appropriate documentation. This entails supplementing the documentation provided by subcontractors with complementary documents. Additionally, I serve as a liaison between Janssen and the subcontractors, which requires frequent visits to the construction site to ensure proper installation of each system. Once confirmed, we proceed to test the systems to ensure their functionality. Despite being slightly distanced from the biological processes, my knowledge of laboratories, cleanrooms, and working in compliance with Good Manufacturing Practices (GMP) proves invaluable in this project.

Furthermore, being involved in a construction-oriented project has afforded me the opportunity to acquire practical skills that were not extensively

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covered during my studies. In the few months I've been part of this project, I have identified and addressed errors, raised necessary concerns, and followed up on them, requiring collaboration with diverse individuals. The extensive responsibilities have taught me effective task and time management, as well as overseeing the resolution of raised issues.

Reflecting on my discussions with SPGL regarding switching projects, my aspirations were clear: seeking more responsibility, a practical work setting that doesn't confine me to a desk all day, and a continued learning experience. I believe they have found a project that aligns with these desires and allows me to grow and develop further. I am genuinely excited about the next phase of my career at SPGL.

SPOTLIGHT

Sam Vervliet
Project Leader & Culture Team Lead

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

Tell us a bit about your background and what you did before you joined SPGL
I grew up in Schoten, and I have a twin brother; we attended the same school and learned to play soccer together. Over the last few years, our professional and soccer careers separated. Despite our different paths, we are still close and keep in touch on a daily basis.

After my graduation at the University of Antwerp, I joined SPGL about three and a half years ago and performed my first project at Pfizer in the cleaning validation department. For the last two years, I've been part of the cleaning validation department within J&J, where I now lead a team of two.

How do you find working for SPGL from a technical and personal perspective?
There was a click between SPGL and me from day one and I can honestly say that I never thought my degree in Biomedical Sciences would bring me here. I must say it's been an interesting few years so far and I have learnt a lot about the pharmaceutical industry. I continue to learn a lot throughout the projects I'm working on.

I highly value working with congenial and thoughtful colleagues here at SPGL. I know I can always ask them for advice, either at our desk in Berchem, through the Yammer page, or via a short call. Having colleagues in other projects also brings a different viewpoint that can help solve queries from a different angle.

Getting to know Sam!

What is your favourite food?
Must be something Italian like spaghetti or pizza.

What do you enjoy doing in your spare time?
I have soccer practice twice per week, along with one competition game. I also try to hit the gym twice per week. Obviously, I also like to grab a beer or a gin tonic with some friends.

If you were stuck on a desert island and you could have two people with you, who would they be?
My brother Kevin and my girlfriend Stephanie.

If you could live anywhere in the world, where would you choose?
I always thought that living and working in New York would be great fun.

ANNOUNCEMENTS

Welcome to **Eveline Pringels** who joined us as a Senior Project Leader in April.

Welcome to **Lars Van Belle** who joined us as a Graduate Engineer in February.

Welcome to **Laura Vanderwaeren** who joined us as a Engineer Level I in January.

Welcome to **Giles Willemsen** who joined us as a Graduate Specialist in October.

Welcome to **Dieter Vanherck** who joined us as a Graduate Engineer in October.

Welcome to **Eline Wils** who joined us as a Graduate Specialist in November.

“On behalf of everyone at SPGL we would like to express our heartfelt gratitude to Eric Moreels and Johan Boonen, two of our most dedicated and loyal team members, for their exceptional contributions to SPGL and the Life Sciences industry over the past four decades.”

EVENTS

SPGL marked its 15th anniversary in grand fashion with a special gathering held in Troyes, France, at the end of September.

The festivities encompassed a memorable trip to the Devaux Champagne House for a guided tour and delightful tastings, an adrenaline-pumping adventure navigating the treetops at Grimpobranches, and a joyous celebratory dinner hosted at our esteemed venue, Domaine de la Foret d'Orient.

We extend our heartfelt gratitude to all those who contributed to the success of this event, and we are pleased to share a curated collection of photos from this splendid weekend of celebration.

EVENTS

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Spot The Difference
Christmas Competition

It's that time of year again and we are celebrating with a 'Spot the Difference Christmas' competition!

Put your eagle eyes to the test, email Nicola **(nicola.tapp@spgl.eu)** with all the differences you spot by the 31/12/23. Whoever spots the most differences, in the quickest time, wins!

1st Prize – €100 gift voucher
2nd Prize – €50 gift voucher
3rd Prize – €25 gift voucher

Wishing you a Merry Christmas and a Happy New Year.