



# **A New Vision**

To navigate your product from molecule to market

# Innovative development plans and effective regulatory strategies.

## Introducing Triskel Integrated Services

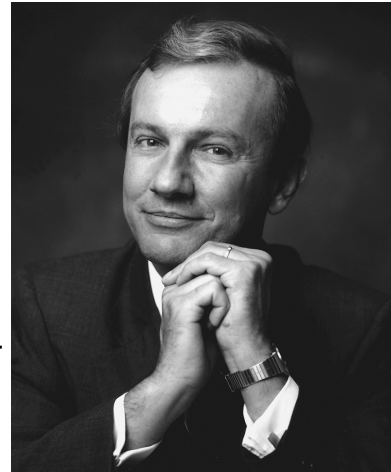


Competence  
Performance  
Innovation

Triskel Integrated Services SA, based in Switzerland, has rapidly become the reference international pharmaceutical consultancy in Europe. We assist high-tech and biotech companies to analyze, determine and implement the most timely, cost-effective and efficient strategies to steer a molecule from discovery to the market.

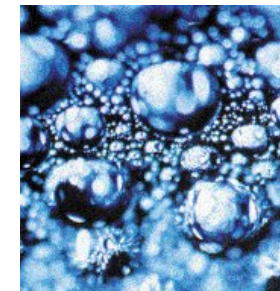
Triskel provides a strategic complement to CROs, contract manufacturers or other classical service providers. Based on a thorough understanding of cutting edge science and the constantly evolving regulatory environment, Triskel forges innovative development plans and pioneers effective regulatory strategies. Anticipating market trends, we have successfully developed first-hand regulatory and clinical expertise in areas as diverse as transgenic products, “generic” recombinants, and cell and gene therapies.

Our client portfolio, which has grown consistently, includes virtual and start-up companies, as well as large publicly-traded multinational pharmaceutical firms on both sides of the Atlantic.



Like explorers in uncharted territories, each Triskel team member contributes specific skills that strengthen the overall project for the benefit of our clients. **We can help you to bring out the best in your product in the most time-efficient way.** We look forward to discussing with you how we can address the specific needs of your company.

Jean-Yves le Cottonnec, M.D., Ph.D.

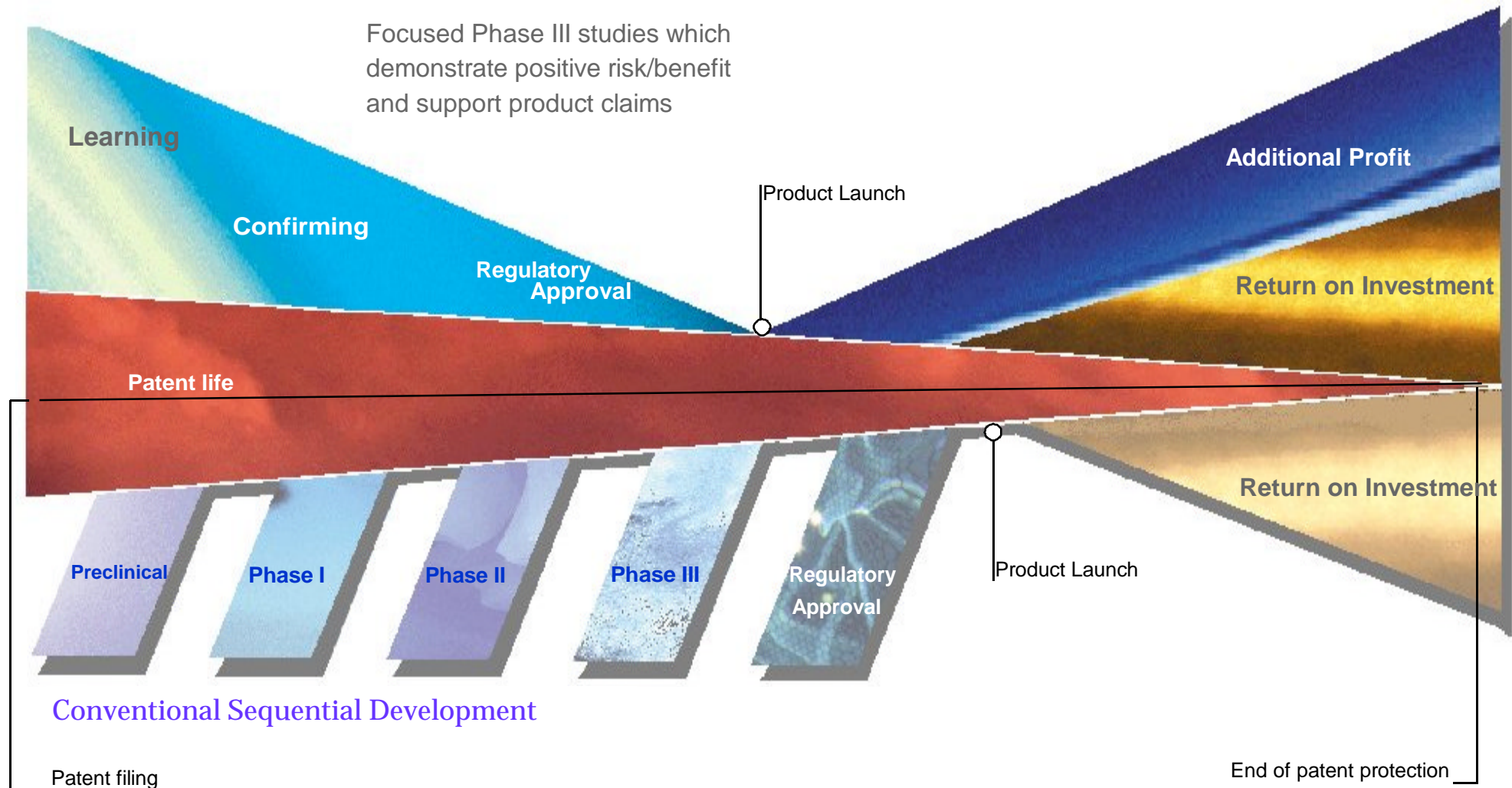


# Triskel's Innovative Approach to Drug Development :

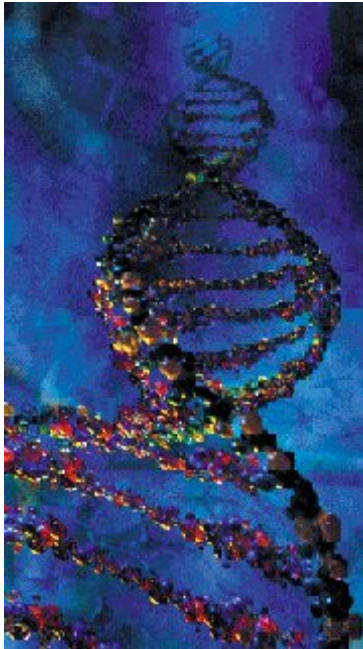
Focused Development → Faster Registration → Increased Return on Investment

Identify safety and efficacy  
dose response relationships  
and their source of variability

Focused Phase III studies which  
demonstrate positive risk/benefit  
and support product claims



# Competence, Performance, Innovation: three attributes that form the basis for the success of both Triskel and our clients.



## Mission

Triskel's mission is to **provide high quality, integrated and customised strategic expertise** to pharmaceutical and device companies to allow them to meet more expeditiously and efficiently the stringent regulatory requirements necessary to sell products on the worldwide market.

## Values

To provide integrated services of **high quality** to our customers

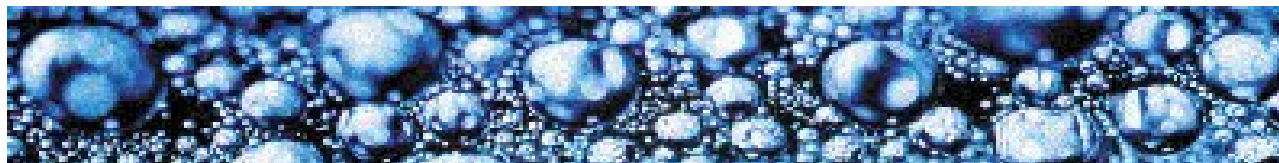
To keep a **focus on our client's** objectives at all times.

To stay on the **cutting edge of knowledge** in our various areas of expertise.

To maximize the benefit of each person's experience by **promoting teamwork**.

To be **flexible**, responsible and **strategic** in finding ways to help clients meet their goals.

To maintain **open communication** with our clients.



## Areas of Expertise

Antivirals/ Anti-Infectives, Cardiology, Hematology, Endocrinology, Gastroenterology, Gynecology and Obstetrics, Immunology, Nephrology, Nutritional and Metabolic disorders, and Oncology, both therapeutic and diagnostic.

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# Tailored and seamless scientific and legal strategic guidance from molecule to market.

## Competence



Since its creation in 1995, Triskel has grown consistently, fulfilling a market need for strategic services at the top level.

Unlike Clinical Research Organizations (CROs), we offer tailored and seamless strategic guidance for drug development. Our uniquely integrated services range from the **individual design of development strategies**, technology platform assessment, patent and trademark evaluation, Good Manufacturing Practice (GMP) and Quality Assurance (QA) reviews, design and full management of preclinical and clinical development plans, through **international registration and reimbursement** all the way to scientific design and the required review of marketing documentation.

**Acting as advisor, strategist and problem solver**, our scientific team **works closely with our clients** to produce hard data to convincingly support product claims, always keeping the strategic objectives of registration and marketing in view. In addition to medical and regulatory expertise, we have a body of scientific knowledge that encompasses molecular biology, virology, toxicology, toxicokinetics, manufacturing and QA, preclinical and clinical pharmacology.

Our practical experience has given us in-depth first-hand knowledge and understanding of recombinant proteins, peptides, peptidomimetics, cell therapy, allo- and xeno-transplantation, vaccines, blood products including hemoglobin therapeutics and new chemical entities. In addition, Triskel has extensive experience in pharmaceutical development, including immediate and sustained-release formulations, and in the medical device sector.

Triskel's lawyers provide a **seamless line of legal and public affairs services** to our clients in the pharmaceutical and device industries, covering intellectual property, monitoring regulatory licensing and distribution activities. Today, product portfolios must include strong patent positions. For example, centralized European regulatory licensure also presents a significant challenge in the trademark area. Our lawyers conduct intellectual property research on patent and trademark issues and work with our scientists to recommend the best routes for our clients.

**We lay the groundwork for the successful worldwide marketing of our clients' products using our knowledge of the political and socio-economic environment.** In Europe, reimbursement and price are still negotiated at the national level. Triskel reviews the specific health economics issues for optimal pricing and reimbursement and assists with those negotiations.

**Triskel is an internationally-oriented company**, with team members from various countries in Europe and North America. Our people have demonstrated adaptability, having successfully worked, often on a long-term basis, with large and small companies with different corporate cultures. We work in various languages and collaborate effectively with clients of several nationalities, all the while achieving outstanding results.

Today, we are recognized by the industry and regulatory agencies alike for our **high level of expertise and efficiency in the scientific and legal sectors** of drug development and registration.



# Increased return on investment is money well spent.

## Performance

The healthcare world is increasingly competitive and strictly regulated. Timeliness, anticipation of trends and emerging requirements, cost management and a clear view of regulations are all critical to remain at the vanguard of business.



In drug development, **Triskel's integrated team optimizes the potential of a product**, all the while monitoring evolving regulatory requirements in order to reduce development time and ensure optimal presentation of the product submission file to regulatory authorities.

We are a small, **flexible group**; we can work on projects for **niche markets** such as orphan drugs, which are important to our clients and to the community but which may be of little financial interest to large CROs.

Our international orientation allows us to integrate European Union (EU) requirements early in the drug development process. When done at the cloning or preclinical stage, it is easier to obtain a rapid and smooth registration in all European member states. Our track record includes a recombinant drug developed from the molecule to the market in 59 months.

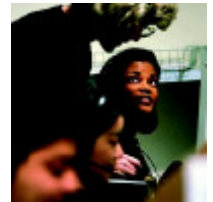
**We customize our services** to provide our clients with the key elements required **to successfully achieve European and US registrations**. Based on a thorough review of our client's manufacturing, GMP inspection, toxicology, preclinical and clinical development files, we prepare



**EU-specific** documents i.e. the three required Expert Reports, the summary of product characteristics (SPC), the labeling and the patient leaflet. For the US, we also assist our clients with FDA meetings (CDER and CBER) as well as prepare the **US-specific** IND and NDA/PLA documentation. Our track record includes the first successful centralized European registration of a human monoclonal antibody.

Our technical achievements range from the design and implementation of numerous successful drug development plans, the definition and execution of optimal regulatory strategies to achieve marketing authorization, to the delineation of healthcare policy and drafting guidelines with regulatory agencies. Our track record includes, among others, a four-month slow release formulation, two growth factors and a line of recombinant proteins.

Over the years, we have established strong links and an excellent reputation with both the European Medicines Evaluation Agency (EMA) for the centralized procedure of drug registration and national regulatory authorities in the different European countries for the decentralized mutual recognition procedure. **We have successfully steered our clients through the complex regulatory process**, e.g. the scientific advice of the Committee for Proprietary Medicinal Products (CPMP), nomination of rapporteur/co-rapporteur, and through all the subsequent stages of a successful European registration.



# Save time and resources through focused development and faster registration.

## Innovation

Forging innovative development plans and pioneering effective regulatory strategies, our role as trouble-shooter and problem solver requires us to consistently find creative means to help our clients achieve their goals.

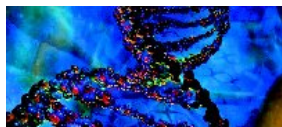


Our **scientific “learning/confirming” approach to drug development** presents a unique way to conceptualize and formulate the development of a product, which can help **save time and spearhead regulatory success.**

Triskel’s rational drug development is divided into two stages:

♦ **Learning:** Very early in development of the molecule, we integrate pharmacokinetic/ pharmacodynamic and population modeling methods to thoroughly and efficiently **identify the dose response relationships and their source of variability** both for efficacy and for safety. Thus, we can establish activity, indications, target population, efficacy and dosage parameters quickly and efficiently.

♦ **Confirming:** Having obtained hard data on the product, we can design efficient and successful Phase III studies which **demonstrate positive risk/benefit ratios and convincingly support product claims** and regulatory approval.



The ultimate benefit of this two step approach is that the **time to market is decreased** while the scientific integrity of the file is strengthened. More importantly, **risk is reduced** as expensive failures at the Phase III level are avoided.

In collaboration with the EMEA, we have drafted and proposed new EU guidelines, for example, for the

production of transgenic proteins, as well as for the regulation of human somatic cellular therapy. For the European Commission, we have participated in the elaboration of EU funding guidelines for AIDS vaccine development

Triskel’s proximity and access to the international organizations such as the World Intellectual Property Organization (WIPO), the World Health Organization (WHO), the International Standards Organization (ISO) and the World Trade Organization (WTO) allows our lawyers to provide early counsel and warning regarding changes in legislation, healthcare policies or standards.

For the medical device industry, Triskel offers insight into European legislation and a clear understanding of the scientific and legal issues necessary in order to obtain the best classification possible. We provide the **technical, clinical and legal guidance necessary for optimal results.** We can provide proactive analysis of the status of the device rather than waiting for the decision of the Notified Body at time of CE marking. A wide network of contacts with competent health authorities allows us to interpret data related to device classification in the best interests of our client.

We aim to push the boundaries of our know-how to benefit our clients as science moves into new areas of activity. These new frontiers will require new ways of working, which we shall continue to pioneer.

**Our entrepreneurial spirit, innovative thinking and sound knowledge base will forge our clients’ future successes.**



## Triskel's recent achievements

### Effective legal and regulatory strategies for:

- European centralized and national registrations
- CPMP and national scientific advice procedures
- FDA (CDER and CBER) pre-NDA meetings
- Development of new draft guidelines for EMEA and its Working Parties
- Patent strategies for clinical development of generics
- Establishment of legal justification for registration of autologous therapies
- Favorable classifications for complex medical devices

### Individualized development plans for:

- New & "generic" recombinant proteins, including transgenics
- New chemical entities
- Peptides, peptidomimetics
- Autologous cell therapy, allo- and xeno-transplantation, vaccines
- Blood products including hemoglobin therapeutics
- Immediate and prolonged release formulations
- Medical devices

## Integrated, Seamless, Registration-Focused Development



**TRISKEL** Intergrated Services S.A.  
The European high tech/biotech strategists

[www.triskel.com](http://www.triskel.com) – [info@triskel.com](mailto:info@triskel.com)