Our Services

Who We Are

www.swbxperts.com

"We provide you with the roadmap to get a brilliant GMO LBP idea up to pharmaceutical industry standards and assist you in this venture"

Our Services

Congratulations – you are part of an **exciting innovation: using a GMO LBP to prevent or treat disease**. Your idea is the foundation of a promising start-up, as an inventor, whether you're planning to invest in it or assist in its evaluation and execution. This journey, while full of potential, is often referred to (perhaps cynically) as 'walking across the valley of death.' Unfortunately, few of those who embark on it make it through.

We are among the very few who have navigated this path and we want to share that experience with you. Our goal is to help you cross the valley more quickly, cost-effectively, and with a significantly higher chance of success. To achieve this, we offer a tailored suite of support services.

Strategic thinking

Just as you have a brilliant idea – GMO LBP for medicine – we recognize that it's a rough diamond in need of refinement. Our expertise in scientific innovation, problem-solving, and strategic planning will help you polish that vision and turn it into reality.

- We guide you through scientific due diligence, identify gaps in your strategy, and work together to create a **solid development plan**.
- We partner with you to identify **the right targets**—and **the right indications**—for your unique capabilities and capacity. After all, your **development pipeline** is the heartbeat of your business.
- Together, we **design therapeutic strains** that are fit for human use, **the cornerstone of your innovative journey**.
- With you, we broaden your synthetic biology platform to meet your needs and to open perspectives.
- At your side, we facilitate seamless communication with authorities, investors, and stakeholders who need to fully understand your vision — from concept to product, from biological safety to deliberate release, from regulatory to CMC, IP, legal, and every 'near-impossible' question that may arise.

Compliant manufacturing

No matter how you approach it, you'll need a **rock-solid CMC strategy, led by an internal champion**, and **executed GMP, with precision**. Think of it like going to court—you can't assume you don't need legal representation just because the other party has an attorney. Similarly, expert CMC is essential for success on your road to **clinical trials according ICH guidelines**.

Contact and info: www.swbxperts.com

CMC: chemistry manufacturing and control; DP: drug product; DS: drug substance; GMO: genetically modified organism; GMP: good manufacturing practice; ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; IMPD: investigational medicinal product dossier; IND: investigational new drug; LBP: live biotherapeutic product; QC: quality control.

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- We **support your CMC activities**, including LBP Drug Substance (DS) and/or Drug Product (DP) design, manufacturing process development, and operational leadership throughout manufacturing and follow-up.
- We assist in **drafting CMC sections for IND** (Investigational New Drug) **and IMPD** (Investigational Medicinal Product Dossier) submissions, and support communications with authorities, investors, and other key audiences.
- We help to develop **analytical methods** for characterization, QC release, and stability testing of LBP DS/DP — including method development, validation, and tech transfer.
- We also **support QC release and stability data generation**. To enhance and secure your manufacturing process through all clinical stages and beyond. Further, we implement trending analyses across batches.
- And finally, **we support you throughout QA audits** conducted by stakeholders who need a clear and confident understanding of your development strategy.

So let us help you think and allow us to share our philosophy with you.

Inventors' noble life's dreams—to materialise their groundbreaking ideas
and help people regain and retain health—merit professional evaluation and assistance.

Sabine Neirynck and Lothar Steidler, Swartberg Experts®.

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As fresh PhDs in biotechnology, we started off with the plan to help people with intestinal inflammation by administering live, food-derived bacteria engineered to produce a natural anti-inflammatory. Over 2 decades later we look back on a journey full of inspiration, challenges, obstacles, errors and failures, eureka moments and victories, disappointment and regained enthusiasm, that led to a product platform which uniquely stands the requirements of pharmaceutical industry.

Our publication of 2 seminal papers (1, 2) led to the first ever GMO LBP intervention study (3), data of which have inspired us to help start ActoGeniX, a spin-off of VIB. Subsequently acquired by Intrexon, the company was renamed ActoBio Therapeutics. Acto conducted 4 clinical trials according ICH guidelines, across Europe and North-America. It was a sad experience to see Acto discontinued in August 2024, for neither technical nor scientific related reasons, soon after reporting a successful Phase 2 study in type 1 diabetes (4) and with 2 open INDs supported by a robust product platform.

We have learned along the road through scientific inventiveness, problem solving and strategic planning how to design and build GMO LBP. Scientific questionnaires, due diligence and gap analysis have shaped our understanding of the expectations thereof. We have established LBP DS and DP manufacturing, analytical method development, validation and tech transfer and wrote that down in CMC sections for IND and IMPD submissions.

This is how we have established the roadmap: hands on, the hard way. Now please take it from here, as no merits lie in going back to square one.

"*At Acto, we have led the elaboration of a synthetic biology platform for the carrier organism, crucial in swift strain construction. To fill an overt gap in the services landscape, we established a GMP accredited QC laboratory, an essential part in GMP manufacturing. Acto's great merit however lies in the overall establishment of a streamlined and powerful product and its CMC, which' development and operational lead was in our hands.*"

It is your life's dream to materialise your groundbreaking idea,
to help people regain and retain health. Truly a just, once in a lifetime opportunity.

Sabine Neirynck and Lothar Steidler, Swartberg Experts®.

More info: www.swbxperts.com

(1) L. Steidler et al., Science 289, 1352-1355 (2000). (2) L. Steidler et al., Nat. Biotechnol. 21, 785-789 (2003). (3).H. Braat et al., Clin. Gastro. Hepat. 4, 754-759 (2006). (4). C. Mathieu et al., Diabetologia, 67, 27-41 (2024).

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