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

Fantastic, you are part of **a great idea: to use a GMO LBP to prevent or treat disease**. Your idea materialises in a start-up, you plan to invest therein or you assist in the evaluation and implementation thereof, such a fascinating platform for clinical development. This fascinating journey is however often – slightly cynical - also called "the walk across the valley of death". Unfortunately, far fewer than those brave enough to actually walk, make it across in that metaphoric sense. We are amongst those very few and want to share the roadbook with you. We want to help you across that valley faster, cheaper, but more importantly, with largely increased probability of success. To do so, we offer a tailored suite of support.

Just like we once had, you have that brilliant idea: GMO LBP for medicine. But that rough diamond needs cutting and polishing and therefore we offer you our experience in scientific inventiveness, problem solving and strategic planning.

- We can assist your team with **scientific inventiveness, inventiveness, problem solving and strategic planning.** We can **prepare or execute scientific due diligence and gap analysis**, and assist with **questionnaires,** both inwards as well as outwards.
- Believe it or not, but we spent a lot of our time in **resolving "near to impossible" questions** from authorities, investors and many others, in matters covering assumed issues in the entire development path: concept, product, biological safety, non-clinical, clinical, regulatory, CMC, IP, legal... let us help you with that.

No matter how you turn it around, you will need **rock solid CMC, driven by an internal lead**, and you will need it very hard. You know, it is like going to court, you cannot just assume you do not need an attorney just because the other party has one. We offer support or even operational lead of CMC and establishment and maintenance of its required documentation.

- We can **support your CMC** with LBP DS/DP **product design, manufacturing process development and manufacturing lead and follow-up**.
- We can assist your team by **writing CMC sections for IND and IMPD** submissions and in the communication thereon with authorities, investors and so many others.
- We can assist with **analytical methods**: development, validation and tech transfer, for characterisation, release and stability testing of LBP DS/DP
- We can **support QC release and stability data** generation. To improve your manufacturing process and make it exclusively robust through all stages of clinical development and beyond, we can set up **trending analysis** of manufacturing,

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®.

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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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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