

# Bridging the gap between **academic** research and industry

BioArk, the biotech incubator from The Ark life sciences, hosts the Swiss Biotech Center, a cGMP pharmaceuticals production platform that is a key link in the innovation chain.

► **Located in the heart** of the industrial site in Monthey, BioArk is not really what you might call a conventional incubator. Indeed, beyond the dedicated facility to biotechnology activities and specific services proposed to the tenants like ExcellGene or Bioresearch & Partners, BioArk offers a cGMP production platform for biopharmaceuticals: the Swiss Biotech Center (SBC). Its mission is to bridge the gap between academic research and industry – a very critical gap in the innovation chain as once again recently underlined in a report published by a group from Toronto University in “Nature Biotechnology”.



*Dominique  
Perruchoud*  
Secretary  
The Ark foundation  
[www.theark.ch](http://www.theark.ch)  
[info@theark.ch](mailto:info@theark.ch)

Indeed, one aspect is missing: a core resource to enable rapid and cost-effective generation of products for clinical testing in this chain of scientific and economic value generation. At present, both the academic and

the small industry researcher reach a bottleneck in their respective activities (*see illustration “BioArk”, see also illustration article B. Dubuis Ecllosion*). On one side, in order to have truly major impact, academics must demonstrate a new therapeutic idea in a clinical setting, on the other, they have to integrate the recent legal developments into the domain: changes occurred in 2004 in regulations controlling clinical investigations that require all materials to be produced under cGMP, not as previously accepted under “cGMP-like conditions” in quality and purity. The Swiss Biotech Center proposes to bridge the gap between basic research and clinical development of biotechnological products by both developing and applying bioprocess technology to generating clinical-grade material under cGMP necessary to complete preclinical safety tes-



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ting, as well as clinical investigation of safety and efficacy.

## A dedicated exchange platform

Secondly, the Swiss Biotech Center provides a unique, dedicated environment, not only for research, development and production of small cGMP material quantities, but also for education in cGMP industrial-like environments where scientists and technical personnel (operators, process engineers, etc.) will exchange and acquire professional experiences (know-how transfer, on field education, etc.). SBC offers a dedicated exchange platform between industry and the different education pathways of academia (Swiss National Institutes of Technology, Universities of Applied Sciences, etc.) in biotechnology.

Regarding the problem discussed above and in order to deliver the best added value tailored to its customers' needs, the SBC design is based on the optimal use of flexible and disposable technologies like roller bottles, wave bag technology, disposable buffer bags, plastic tubing, etc. (*see illustration "Stedim Flexel"*).

The multi-product facility is designed for a fermentation volume of up to 100 litre working volume, specifical-

ly for protein synthesis based on bacterial processes or mammalian cell technologies.

SBC's strategy is focused on the one stop shop for the customer including

## Fertile ground for innovations

**P**hytoArk is a technology site without equal, entirely dedicated to the development of products made from intact plant cells or from molecules extracted from such cells.

PhytoArk is the heart of an ideal biological environment of incomparable know-how which accounts for 80% of Switzerland's production of alpine plants. Designed to make the innovations grow in fertile



ground, PhytoArk offers access to growers, research institutes, educational institutions and companies to promote the health of their projects.

Equipped with modular units around a biomanufacturing facility, PhytoArk is oriented to tomorrow's markets. It allows companies to test and prove a project's commercial potential already from laboratory concept development phase, if required. At the heart of a 26,000 m<sup>2</sup> site, it offers strategic, legal, commercial and administrative assistance with innovative action and solutions for project support, product development, market assessment, commercialization, coaching, funding, branding, marketing and benchmarking.

scale-up studies, process optimization, pilot runs, cell bank activities, development and validation of analytical methods, support for clinical trials and commercialization. SBC's customers benefit from the experience of a production core team specialized in the cGMP small-scale production of biopharmaceuticals, reduced production costs, high productivity and high production flexibility due to fast plant adaptation and short changes over time.

Thanks to the established network and the ideal location within the BioAlps cluster, SBC is not only able to perform the cGMP production itself, but is in a position to ensure the smooth transition between the different phases within the value chain of a biopharmaceutical.

## A broader look at The Ark life sciences

Beyond BioArk and the Swiss Biotech Center focused on biotechnologies, The Ark Life Sciences has a second site, the PhytoArk (*See side bar "Fertile ground for innovation"*). PhytoArk is dedicated to plant technologies, especially to the related APIs. It is located in Sion near several research, competences centers, institutes and associations (HEVs, PLAM-RAC Agroscope, PAMA, etc.). It is mainly focused on the development of plant-based products. Its technological platform is dedicated to the extraction of natural APIs, particularly for essential oils or nutraceuticals production. Company implantations are under discussion on PhytoArk's 26,000 m<sup>2</sup> surface. According to players in the sector, both the environment quality and the extraction platform proximity are key arguments for their business development.

The overall life sciences development in Valais is done by the Ark

## An effective facilitator

The Ark is an economic development project launched by Switzerland's Canton of Valais. Of a resolutely international scope, it combines several technology sites into one and the same entity. The Ark aims to make the Valais a true technology park with promise for the future and recognized as such in Switzerland and around the world. The Ark aims to nurture research and to foster the capacity for innovation among existing businesses. The Ark also facilitates the creation of new businesses and the relocation of others in the Valais.

### Life Sciences

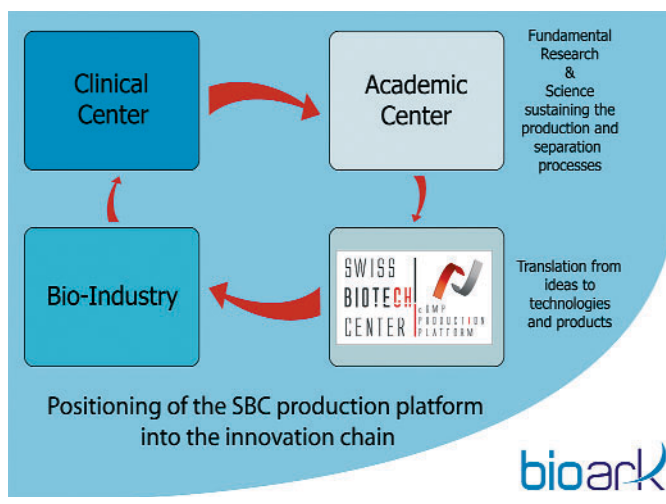
The Ark comprises two sites encompassing a multitude of businesses and multinationals, research institutes, institutions of higher learning and specialized companies. The BioArk at Monthey focuses on biotechnologies while PhytoArk at Sion is primarily dedicated to the development of products derived from intact plant cells or molecules extracted from such cells.

### Information Technology and Communication Sciences

High-tech fields of activity which have helped shape the region's international acclaim occupy two sites. Sierre's TechnoArk is home to information technology and Martigny's IDIAP focuses on artificial intelligence. They offer businesses a potential for innovation that is virtually inexhaustible.

### Services, Tourism and the Environment

With the Jungfrau, the Altesch Bietschhorn (JAB) region boasts the only alpine environment singled out by UNESCO as a World Natural Heritage Site. The Canton of Valais is Europe's biggest water tank and therefore also the most important renewable energy producer in Switzerland. The Ark intends to tap this opportunity to create a center for the development of new services of high added value. They would integrate the many possibilities offered by seemingly disparate activities such as nature, agriculture, tourism, energy and high tech.



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System for the  
handling and storage  
of biopharmaceutical  
sterile liquids.



foundation, in close coordination with regional, national and international initiatives. This foundation is supported by CimArk, its operational arm endowed with a multi-

skills team with strong experience in backing companies at all stages of development (start-up, existing, mature) and in assisting in the product/market strategies. The Ark is active through this operational arm within various life science and industrial networks at national (BioAlps, Swiss Biotech Association SBA, SwissbiotechNet, etc.) and international levels (EBN, ISPE, etc.).

### Nurturing project potential

The expertise used for supporting the enterprises in their development is based on systems' methods co-developed in international R&D projects. We can note in this respect the valorisation process developed and implemented with the University of Applied Sciences in Valais, targeting the valorisation of the technologies emerging from its research laboratories. Several projects, including licensing to major companies, are under development. ■

### Abstract

## Swiss Biotech Center: une approche flexible pour la production de matériel cGMP

**B**ioArk ([www.bioark.ch](http://www.bioark.ch)), l'incubateur biotech du domaine des sciences de la vie de The Ark ([www.theark.ch](http://www.theark.ch)) situé au coeur du site industriel de Monthey n'est pas un incubateur conventionnel. Il offre aux entreprises du site telles que ExcellGene ou Bioresearch & Partners, une infrastructure dédiée aux activités biotechnologiques ainsi que des services spécifiques. Le BioArk héberge le Swiss Biotech Center (SBC), une plateforme de production cGMP (current Good Manufacturing Practice) de produits biopharmaceutiques. Le Swiss Biotech Center ambitionne de combler le fossé situé entre la recherche de base et le développement de produits biotechnologiques. Il permet de générer par l'utilisation de

bioprocédés le matériel nécessaire à la réalisation des tests de toxicité pré-cliniques ainsi que les investigations cliniques de sécurité et d'efficacité et cela sous conditions cGMP.

Grâce à sa participation dans divers réseaux et son implication forte dans BioAlps, le cluster biotech de l'arc lémanique, le SBC est non seulement capable de fournir du matériel cGMP mais est également en position d'assurer une transition en douceur entre les différentes phases de la chaîne de valeur d'un produit biopharmaceutique. Son modèle de fonctionnement, véritable interface entre le monde académique et industriel, favorise la création et le développement de start-ups et de nouveaux produits.