Vitor SOUSA

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Vitor Sousa holds a PhD in Biochemistry and has been in CDMO industry for 17 years where covered roles in R&D, Manufacturing and now Business Development. Currently at Cerbios-Pharma SA as Director of Business Development, Vitor Sousa oversees the commercial activities related to the CDMO activities in the bioconjugate and biotechnology spaces. Holding a PhD in Biochemistry obtained at the University of Lisbon, Vítor moved to the CDMO business 17 years after pursuing a brief career in academic research. In the pharmaceutical industry he covered roles in Process Development, Manufacturing and recently Business development and participated in the development of more than 50 pharmaceutical products in areas of biotechnology, advanced therapies and ADCs.

Pushing boundaries in **ADC development**

Swissmedic has approved a new facility at the Lugano site of Cerbios in Switzerland dedicated to the manufacture of clinical and commercial HPAPIs, including cytotoxic linker-payloads for ADCs. LSKH asked the company to comment on current developments and future innovations.

Do you think the new generation of Antibody-Drug Conjugates (ADC) could be the making of Cerbios and its R&D Team in terms of innovation and pushing boundaries in the development and manufacturing of these new ADCs?
New products based on the ADC concept are evolving rapidly. These include antibodies conjugated with novel linker-payloads or new carriers such as nanoparticles or peptides conjugated with known linker-payloads. These new molecules indeed pose new challenges from the process and analytical standpoints. R&D plays an important role in developing and implementing new approaches and tools for suitable manufacture and characterise these next generation conjugates. For any new product in development, it is important to adopt new strategies necessary for better process control and understanding. There is no other place where this can happen than the R&D laboratories when combined with experience in developing and scaling-up processes transferable to the manufacturing plants.

Cerbios is rightly proud of its new Lugano-based facility. Could you comment on the facility's ability to produce complex cytotoxic linker-payloads for ADCs used in anti-cancer therapies? How will you build on this ability to best serve those involved in this specialised field?
Linker-payloads used for the manufacture of ADCs have evolved significantly over the last few years. The evolution targeting better stability, solubility, efficacy and tolerability have moved the chemistry away from the traditional organic chemistry introducing significant isolation steps, including chromatography. When designing the new facilities, our goal is to introduce flexibility in order to accommodate new technologies while addressing commercial manufacturing needs in terms of batch size. It should, of course, be underlined that facilities need operators to run processes. Highly-skilled and experienced employees are key for successful manufacturing, especially in early development when processes need to be continuously improved.

As a premier CDMO could you comment on just how much of an advantage Cerbios has in being able to develop and manufacture ADCs and all its components (mAb, linker/payload, conjugate) within a single site?
When dealing with manufacturing of ADCs, it means handling a quite complex supply chain that culminates in product with a high intrinsic added value. Our integrated approach providing mAb, linker/payload and ADC Drug Substance (DS) components in the same facility enables various advantages for our customers. This combination greatly simplifies the logistics without the need for shipments that in other configurations usually involve air transportation. Another advantage is related to the timeline due to the fact that activities related to the three components are performed in parallel leading to significant time compression and interactive product optimisation. Last but not least, communication and project management are centralised and synchronised among the different teams working in the different activities throughout the project life cycle.

Proveo extends Cerbios' capacity through the partnership with AGC Biologics and Oncotec. How do these partnerships aid in meeting the demands of small to large pharma companies, supporting their programs from early stage up to commercial supply for ADC and related components?
In PROVEO our goal is to further expand integration and provide large scale protein and Drug Product (DP) to our portfolio of services. With PROVEO, we are indeed addressing the entire supply chain for ADCs from gene to ADC DP for those clients that require the complete ADC supply chain for programs from early development to commercial manufacturing. In fact, PROVEO partners have extensive experience in supporting a range of customers from small biotech to established large pharma companies in successfully developing a wide variety of products, including ADCs. Independently from the customer size, important advantages are certainly regarding our experience in compacting timelines, optimising product quality, enabling integrated development and streamlining project management activities.

The complexity of an ADC project brings unique requirements, where each component or activity may require specific and diversified expertise. How does partnering with Cerbios ensure that the end-to-end solutions are seamless while streamlining each project phase?
Cerbios has been building intrinsic expertise and know-how in Highly Potent chemistry and biotechnology for more than 40 years. Merging these competencies that once were segregated into a combined approach for enabling high quality end-to-end solutions in ADCs was a spontaneous natural process. Our philosophy in build and maintaining multi-disciplinary teams composed of highly-skilled chemists, biotechnologists and analysts is certainly one of the keys to guarantee high standard services.

In recent years, Cerbios completed and received SwissMedic approval for several new manufacturing units. Additionally, further investment came in the form of a new R&D unit. Could you comment on how these commitments contribute to Cerbios providing best-in-class bioconjugation services for its worldwide partners?
Our commitment has always been to provide excellent services to our worldwide partners. Certainly, operating capacity in development and manufacturing is a key element to enable best-in-class services. In the last five years we have built bioconjugation and HiPo chemistry capacity to meet market demands in terms of capacity and technology. We have a portfolio of GMP facilities able to supply products from clinical to commercial supported by state-of-the-art R&D laboratories to assist our partners. Our overall capacity and structure is being continuously planned according to our business forecasts and market trends. In fact, as a result of our growth policy, we are now building additional HiPo chemistry and bioconjugation capacities that will be operational in the upcoming two years to provide additional commercial manufacturing preparedness.

Could you comment on Cerbios' Corporate Social Responsibility (CSR) and its role in evolving the company's Environmental, Social and Governance? Could you also comment on Cerbios' CSR initiatives that collect/separate exhausted solvents and its investment in photovoltaic panels and in recovering passive heat?
Our commitment has been to develop strategies that integrate ESG considerations into our core business operations. One of the focuses is certainly related to the reduction of environmental impact and of CO_2 emissions. The implementation of solvent recovery systems, photovoltaic panels and passive heat recovery are part of our ambitions plan in setting measurable ESG goals and designing initiatives that align with global objectives. Further initiatives have been recently launched and will further contribute to maintaining Cerbios' CSR contributing to a more sustainable and equitable future.

Finally, could you describe some of the innovations that you foresee in HPAPI/ADC and Cerbios' role in driving the technology forwards? What are the risks/benefits of implementing this new technology considering the ever-changing demands of pharma/biotech and the subsequent investments made by CDMOs in response?
The pharma industry is a continuously evolving world that is intrinsically correlated with innovation and scientific advances with the purpose of developing new treatments and therapies to improve patient lives. The recent advances in ADC outcomes and the hype around type therapy have changed completely over the last ten years and will certainly continue to evolve leading to safer and more effective products. It has been a path where many failed and many will succeed. Our approach as a CDMO is to carefully witness this evolution and appropriately build know-how and capacity for meeting future demands and be there when needed. We believe that implementation of technological innovations is a key for success for appropriately deliver success to our partners.