



Finding a partner for extracellular vesicles production

Overview

A pharmaceutical company has developed an exosome-based vaccine using mesenchymal stem cell-derived exosomes. The company is now seeking a production partner for GMP-compliant manufacture of exosomes at scale for clinical trials and potential commercialization.

Methodology and Solution

The team used the proprietary KnowEx™ platform¹ to identify GMP-compliant exosome production specialists with established and validated manufacturing capacity that would be able to deliver MSC-derived exosomes within set specifications.

Outcome

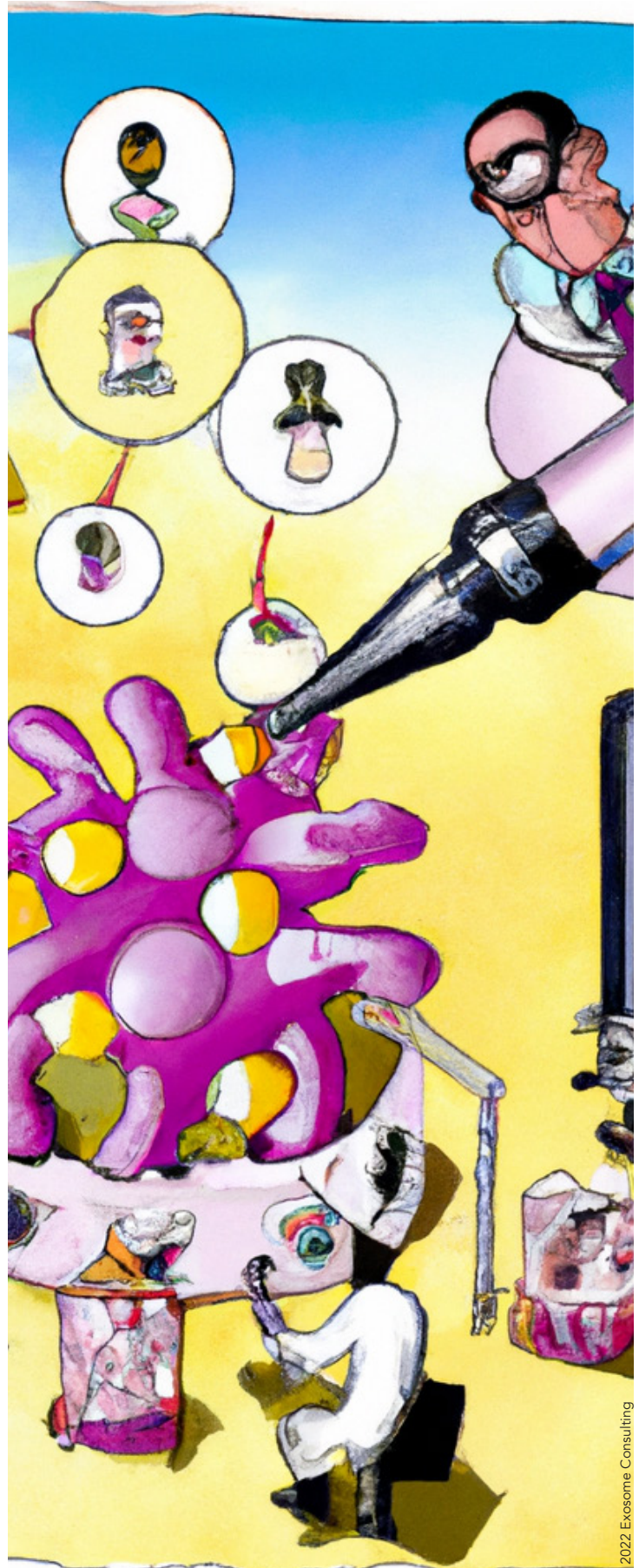
The team used the client's technical information to develop a list of criteria for evaluating potential partners, including experience in exosome production, capability to manufacture exosomes at scale, quality management systems and compliance with GMP, and research and development capabilities.

Next, by contacting potential partners to discuss their exosome production capabilities, capacity, quality control measures, experience with GMP, and costs, to confirm that analysis results and ranking of partners are within the specified parameters. With the help of SWOT analysis and MCDA of each partner, narrowed down the list of potential candidates.

After final discussions with the client of several potential partners, including the underlying technology, production costs, ESG framework, and logistics, the client selected a production partner with extensive experience in exosome production, including experience with GMP. The partner has a state-of-the-art production facility and a robust quality management system. The partner also has a strong track record of conducting research and development in the field of exosomes, which will be beneficial in optimizing the production process for the exosome-based vaccine.

Conclusion

The pharmaceutical company identified a suitable production partner with the expertise and capabilities to manufacture desired exosomes for vaccine clinical trials.



¹ - Read the INSIGHT02 white paper on the KnowEx™ platform and how it can help deliver the optimal solution for your needs.