

Insights into Global Antibody-Drug Conjugate Market 2023 – Cost Efficiency as a Major Challenge

BOSTON, US, May 17, 2023 /EINPresswire.com/ -- As they are a highly promising new class of biotherapeutics, the biopharma industry has set an intense focus in the development and production of [antibody-drug conjugates](#) (ADC). These novel drug substances are mainly used in cancer therapy, providing hope to millions of patients worldwide in the treatment of medical conditions like relapsed Hodgkin lymphoma or HER2-positive metastatic breast cancer.[1]

This is why several big players on the biopharmaceutical market are engaged in ADC technology, including companies like F. Hoffmann-La Roche, Gilead Sciences and Astellas Pharma. But although there has already been a third generation of antibody-drug conjugates, the considerable costs related to their development and production are a hurdle on their path of success that is yet to be overcome.[2]

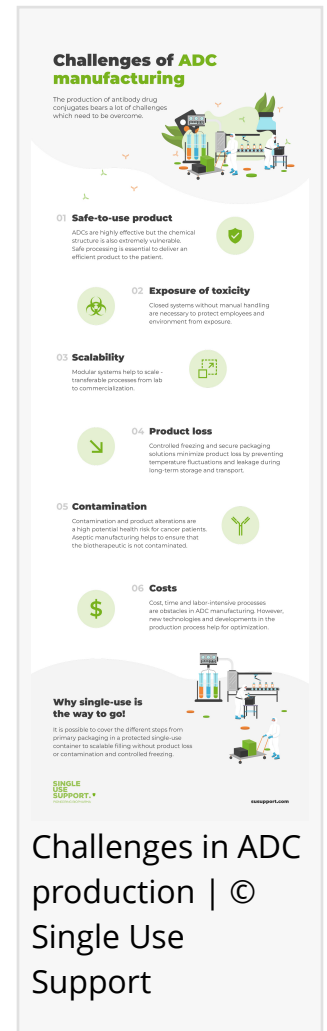
ADCs – a Milestone in Cancer Therapy

ADCs are therapeutic tools that are predominantly used in the treatment of several cancer types. They are structured as a compound of an antibody and a drug substance – a cytotoxic payload, conjugated with a linker. After an ADC is administered, the monoclonal antibody component detects and binds to specific cancer cells and releases their cytotoxic payload in order to damage malignant cells – a main advantage over traditional chemotherapy, as healthy tissue can be spared.

The history of ADCs dates back to the beginning of the 20th century, when approaches have been improved to have drug substances target specific cancer cells. After clinical trials of ADCs in the 1980s, the first approved antibody-drug conjugate was to be followed by the second generation of ADCs in 2011. As of April 2023, twelve ADCs are already FDA-approved.[3, 4]

ADC Market Growth to be Continued in 2023

ADCs have long become a globally investigated therapeutic approach, also driven by the



Challenges of ADC manufacturing

The production of antibody drug conjugates faces a lot of challenges which need to be overcome.

- 01 Safe-to-use product**
ADCs are highly effective but the chemical structure is also extremely vulnerable. Safe processing is essential to deliver an efficient product to the patient.
- 02 Exposure of toxicity**
Closed systems without manual handling are necessary to protect employees and environment from exposure.
- 03 Scalability**
Modular systems help to scale-transferable processes from lab to commercialization.
- 04 Product loss**
Controlled freezing and secure packaging solutions minimize product loss by preventing temperature fluctuations and leakage during long-term storage and transport.
- 05 Contamination**
Contamination and product alterations are a high potential health risk for cancer patients. Aseptic manufacturing helps to ensure that the biopharmaceutical is not contaminated.
- 06 Costs**
Cost, time and labor intensive processes are obstacles in ADC manufacturing. However, new technologies and developments in the production process help for optimization.

Why single-use is the way to go!

It is possible to cover the different steps from primary packaging in a protected single-use container to scalable filling without product loss or contamination and controlled freezing.

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predictably increasing incidence of cancer: It is estimated that, by 2040, 27.5 million cases of cancer will occur every year, driven by factors like obesity and smoking habits, but also an unhealthy diet and alcohol.[5]

Biopharma companies worldwide have therefore made heavy investments on the global ADC market, which already had an expected volume of 5.9 billion Dollars in 2022. But the growth on the sector is far from being over: With an expected CAGR of 22 %, the global ADC market volume is predicted to increase to 13.06 billion dollars by 2026.[5]

However, there are several factors that inhibit growth in the ADC sector: The war in Ukraine has had a major impact on the global economy, with disruptions in relevant supply chains and a significantly increased inflation. But also ADC technology itself is facing challenges that the biopharma industry is eager to overcome.[5]

Major Challenges Related to ADC Technology

ADC manufacturing is an extremely complex procedure, caused by the distinctive nature of their single components, but also to their sensitive structure once they are produced.

Monoclonal antibodies are temperature-sensitive and require advanced cold chain management. This also applies to the fully developed ADCs, while an additional focus has to be put on safety aspects.

High-potency active pharmaceutical ingredients (HPAPIs) are used as cytotoxic payloads in ADCs, enabling them to effectively fight specific cancer cells. However, an elaborate risk management is necessary to prevent staff and the environment from being exposed to these substances.

Further measures have to be taken in order to ensure product quality and safety, avoiding contamination and damaging variations in temperature. Additionally, the loss of targeted therapy can cause critical delays in a patient's therapy and is therefore to be avoided.

For manufacturers, all of these challenges result in a very cost-intensive ADC manufacturing process and the need for new solutions that help them increase efficiency in ADC production.

Cost Reduction in ADC Production – Necessary to Continue the Path of Success

Regardless of the considerable global ADC market volume and its expected growth, resources at manufacturing sites are limited. And with great discrepancies in the financial capabilities of healthcare systems around the globe, it is necessary for manufacturers to lower production costs in order to make ADCs as accessible as possible.

One cornerstone to achieve this is the use of specialized equipment that is suited for the unique conditions in ADC manufacturing. Many companies rely on systems based on single-use

technology, enabling them to process ADCs in varying amounts due to an increased level of scalability. Furthermore, pre-sterilized components can help meet cGMP standards and lower the costs for cleaning at the manufacturing facilities.[6]

In order to provide the highest possible level of process security, single-use based closed systems have been developed. With a reduced need for manual intervention, staff can be protected from being exposed to ADCs and their components. Moreover, automation is able to make biopharma processes more efficient and, thus, less cost-intensive.

However, these are only a few measures that have to be taken by the biopharma industry to ensure cost efficiency in ADC production. Nevertheless, the goal is to let cancer patients worldwide profit from a groundbreaking medical achievement.

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Christoph Mair
Klixpert.io / Media partner of Single Use Support
christoph@klixpert.io

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