DWK LIFE SCIENCES
DURAN WHEATON KIMBLE

CASE-STUDY UGA BIOPHARMA

OVERCOMING SUPPLY CHALLENGES AND EMBRACING SUSTAINABILITY WITH UGA BIOPHARMA

CASE STUDY OVERVIEW

Customer: UGA Biopharma

Project / Application:
Pre-culture of cells for inoculation of bioreact

DWK Life Sciences products featured:
DURAN® Culture Flasks and DURAN® Baffled Flasks

About the Company

UGA Biopharma is a biotechnology research company based in Hennigsdorf, near Berlin. The company focuses on the contract development of biologics and biosimilars, including all necessary steps from cell line development and bioprocess development to purification and analytical procedures. The company specializes in offering its customers so-called "ready-to-use" biosimilar cell lines.

Covid-19 and Supply Chain Disruption

Following the Covid-19 pandemic and the associated disruption to global supply chains, the UGA Biopharma team was faced with a shortage of sterile polycarbonate culture flasks used for the pre-culture of cells to inoculate bioreactors. While this represented a significant threat to a key process and the business itself, the team had already been considering a switch away from plastic culture flasks to glass alternatives where regulations and standard operating procedures would allow, as part of a more sustainable approach. This typically applied to the pre-culture stage, a crucial step in the organization's biopharmaceutical production process.

Laslo Eidt, Team Leader USP Operations at UGA Biopharma, began to explore alternative products but had to ensure they met several key criteria.

Laslo Eidt said: "As part of the core pre-culture / C-train batch processes, our flasks are placed in a shaker where they are held in position by sticky matts. Any alternative flask to the polycarbonate culture flasks would have to be compatible with this approach."

There were also concerns from the team of potential changes to cells under the shearing forces that might be more prominent in glass flasks, particularly those with baffles present. Additionally, switching the pre-culture process away from a sterile plastic product raised further questions about the viability of cleaning processes.

Laslo Eidt said: "Although we were already operating glass bioreactors and had established cleaning processes for these, a switch from plastic to glass culture flasks required a careful approach."

Replicating the Pre-culture Process with DURAN® Culture Flasks and Baffled Flasks

After a period of research, the team decided to test DURAN® Culture Flasks and Baffled Flasks as an alternative to polycarbonate culture flasks, which were still proving difficult to source.

To prevent contamination, an established cleaning process was used in which the bottles were washed and autoclaved. This has proven to be effective in eliminating cross-contamination between different experiments with various cell lines.

Discovering a Suitable and Sustainable Alternative

The transition from plastic to glass culture flasks showed promising results. The team observed no significant difference in precultures between plastic, glass unbaffled, and glass baffled flasks. While baffles are known to enhance oxygen transfer during shaking, the slow growth rate of CHO cells utilized by UGA Biopharma did not require such an advantage. There were no differences observed in cell growth, function, glucose consumption, or overall viability between the various flask types.

Laslo Eidt added: "Contrary to our initial worries, the glass flasks also adhered well to the sticky matts used in the shakers, even at 180 rpm. This meant that in addition to delivering an entirely suitable output, the adoption of the flasks fitted easily into our existing processes, without us having to adapt them."

"From an ergonomic point of view, our team also found that they particularly preferred the glass baffled flasks because of their larger opening. This allowed them to use serological pipettes without direct contact with the opening of the flask, further reducing the risk of contamination."

Following the initial tests and wider roll-out, UGA Biopharma successfully overcame supply challenges posed by the pandemic by introducing DURAN® Culture Flasks and Baffled Flasks. The transition not only solved immediate supply issues, but also offered sustainability benefits following the switch to a reusable glass alternative.

RESULTS

DURAN® Culture Flasks and Baffled Flasks have enabled UGA Biopharma to:

- Overcome supply chain issues, by switching to an alternative product that delivers the same pre-culture output, without the requirement for existing production processes to change
- Successfully manage a sustainable transition from plastic to more readily reusable glass laboratory products in a highly controlled biopharmaceutical production process

RESOURCES

- UGA Biopharma - https://ugabiopharma.com/index.php

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