ADCF & Serum-Free Policy

Media — Serum-Free Policy

All media are produced without the addition of human or animal serum.

Some of our media products may contain animal- or human-derived components. Such a material is only accepted if it represents no apparent health hazard and is compliant with TSE guidelines (EMEA/410/01), ICH Q5A and EP chapter 5.1.7 as applicable. When available and applicable, pharmaceutical grade materials are used.

All materials used in production are formally approved by QM. As part of the raw material control they are procured from reliable manufacturers and suppliers and their animal- or human origin is assessed before use.

If human, but no animal-derived materials are part of the media formulation, the product is designated "xeno-free". Human proteins that are part of the media formulation have been collected from healthy donors at the time of collection. All samples were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).

Serum-free media: CellGenix® GMP DC Medium

Serum-free & xeno-free media: CellGenix® GMP SCGM

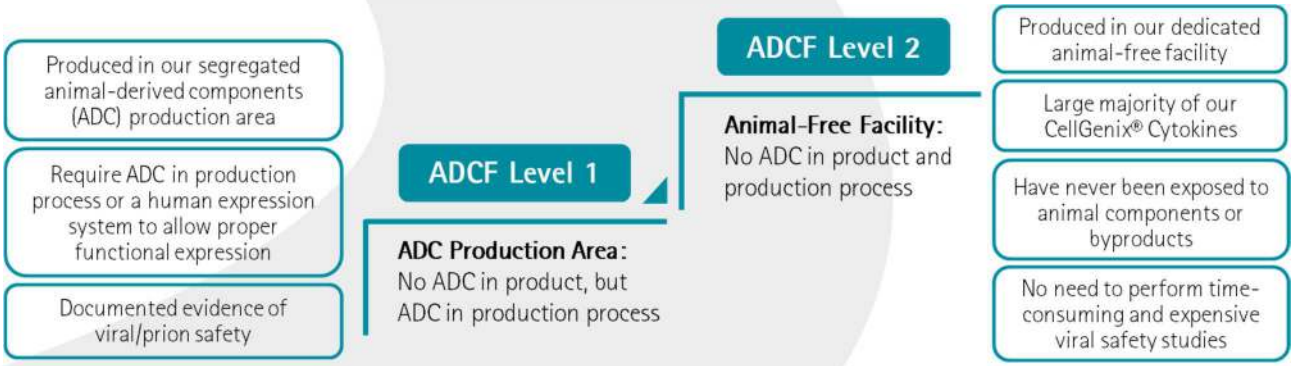
Cytokines — Animal-Derived Component-Free Policy

We follow a strict animal-derived component-free (ADCF) policy to ensure maximum safety of our preclinical and GMP cytokines. As a result no animal or human-derived components are part of any of our cytokine products.

The large majority of our cytokines is produced in our dedicated animal-free facility (ADCF Level 2). These cytokines have never been exposed to animal components or byproducts. They can therefore be safely used without the need to perform time-consuming and expensive viral safety studies, thereby bringing a significant economic benefit.

Those very few cytokines produced in our segregated animal-derived components (ADC) production area require either the use of ADC in the production process or a human expression system to allow proper functional expression (ADCF Level 1).

Our cytokine product portfolio is divided into two distinct ADCF levels:



ADCF Level 2 - No ADC in product and production process

The final cytokine product contains neither animal- nor human-derived materials. ADCF Level 2 cytokines are produced in our dedicated animal-free facility. No animal-derived components are used throughout the complete production process. All ADCF Level 2 cytokines are produced in *E. coli*.

By using only animal-free raw materials, equipment and lab supplies ADCF Level 2 cytokines have never been exposed to contamination by animal components or byproducts.

ADCF Level 2 cytokines

- CellGenix® rh OSM
- CellGenix® rh IFN-γ
- CellGenix® rh Activin A
- CellGenix® rh EGF
- CellGenix® rh Flt-3L
- CellGenix® rh GM-CSF
- CellGenix® rh IL-1β
- CellGenix® rh IL-2
- CellGenix® rh IL-3
- CellGenix® rh IL-4
- CellGenix® rh IL-6
- CellGenix® rh IL-7
- CellGenix® rh IL-10
- CellGenix® rh IL-15
- CellGenix® rh IL-21
- CellGenix® rh PDGF-BB
- CellGenix® rh SCF
- CellGenix® rh TNF-α
- CellGenix® rh TPO

ADCF Level 1 - No ADC in product, but ADC in production process

The final cytokine product contains neither animal- nor human-derived materials. They are derived from a human cell bank or an ADC is used during the production process. These cytokines are therefore produced in a segregated production area.

An ADC is accepted for use in the production process only if it represents no apparent health hazard and is compliant with Transmissible Spongiform Encephalopathy (TSE) guidelines (EMEA/410/01), ICH Q5A and European Pharmacopoeia chapter 5.1.7 as applicable. When available and applicable, pharmaceutical grade materials are used.

All cytokines produced in human cells are produced in a CAP® cell line[1]. The production cell line was derived from an extensively characterized human amniocyte cell line (CAP®) for which a Biologics Master File (BB-MF) was submitted to the U.S. Food and Drug Administration (FDA).

ADCF Level 1 cytokines

- CellGenix® rh HGF
- CellGenix® rh FGF-2
- CellGenix® rh TGF-β1

Raw Material Control

All materials used in the production process are formally approved by our quality management (QM). As part of our raw material control they are procured from reliable manufacturers and suppliers and their origin and impurity profile are assessed before use. The safety of the raw material is demonstrated by certificates of origin and validation reports. In addition, TSE certificates are provided for all our ADCF Level 1 and ADCF Level 2 cytokines.

In order to facilitate risk assessment by our customers we assess each raw material used for the production of our cytokines for the absence of ADC in its manufacturing process. Whenever possible, raw materials are used that themselves were produced without the use of ADC.

Safe | GMP Compliant | Reliable

[1] CAP® is a registered trademark of CEVEC Pharmaceuticals GmbH, Germany

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