

Proposed JPA action WG2

Replacement of serum to chemically-defined media - towards animal free cell-based effect-based methods

Lead:

Dr. Andreas Schiwy & Prof. Dr. Henner Hollert (FGU)



Peak serum: implications of serum supply for cell therapy manufacturing

“Current stocks and production rates of serum suitable for GMP manufacture may only be sufficient to support the production of one blockbuster cell therapy.”

KEYWORDS: biomanufacturing = bioprocessing = cell therapy = commercialization = fetal bovine serum = manufacturing = process optimization = serum

The cell therapy industry (CTI) is emerging as a distinct and competitive component of global healthcare, creating value for investors and providing life-changing therapies to patients [1,2]. Industry growth has necessitated an increased focus on large-scale manufacturing strategies to meet future demands [3,4]. One major challenge is the limited availability of some crucial raw materials used in cell therapy manufacturing – including bovine serum. Without a sustainable supply or viable alternatives to these components, the commercial-scale production of cell therapies will be impossible, halting the

serum, proteolytic activity within cell culture would ensue, resulting in reduced cell growth and proliferation [7].

There are several potential sources of serum, each with different compositions and characteristics. The most commonly used is fetal bovine serum (FBS) due to its strong growth-promoting capacity and relatively low immunoglobulin levels. However, as multiple calf fetuses are required to make a single liter of FBS, it is also the most expensive type of serum. Cheaper alternatives include new-born, calf, adult, donor calf or donor adult cattle serum [8]. It is also possible to

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Brindley DA, Davie NL, Culme-Seymour EJ, Mason C, Smith DW, Rowley JA. Peak serum: implications of serum supply for cell therapy manufacturing. *Regen Med.* 2012 Jan;7(1):7-13. doi: 10.2217/rme.11.112. PMID: 22168489.

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LETTER TO THE EDITOR

A plea to reduce or replace fetal bovine serum in cell culture media

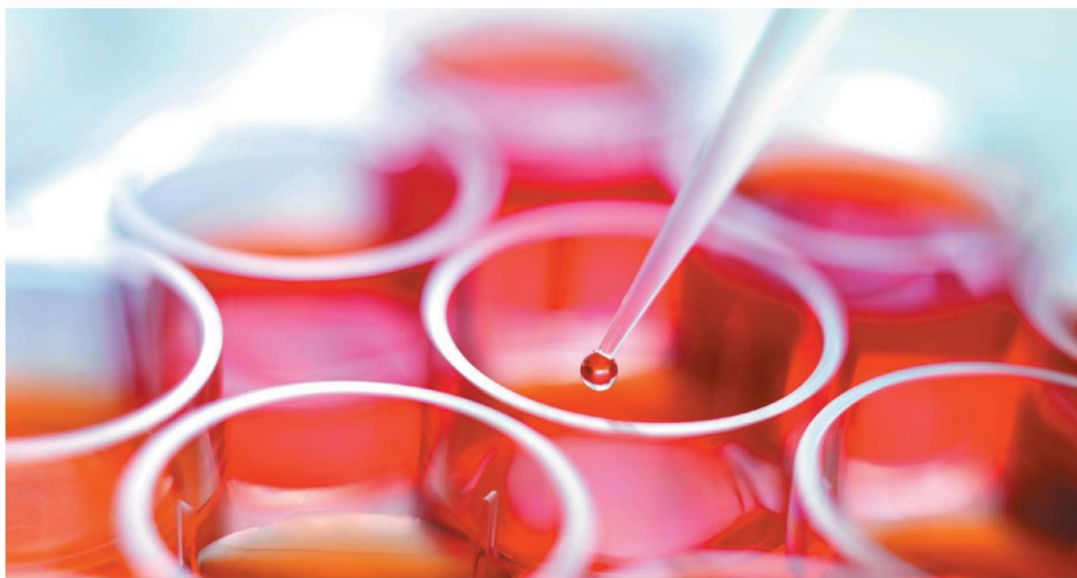
Gerhard Gstraunthaler · Toni Lindl ·
Jan van der Valk

Gstraunthaler G, Lindl T, van der Valk J. A plea to reduce or replace fetal bovine serum in cell culture media. *Cytotechnology.* 2013;65(5):791-793. doi:10.1007/s10616-013-9633-8

TECHNOLOGY FEATURE

REPRODUCIBILITY: RESPECT YOUR CELLS!

Numerous variables can torpedo attempts to replicate cell experiments, from the batch of serum to the shape of growth plates. But there are ways to ensure reliability.



TEK IMAGE/SPL

Subtle aspects of cell culture can wreck results. Researchers should check cell identity and behaviour, and carefully characterize reagents.



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ISO 21427-2:2006 (Water quality — Evaluation of genotoxicity by measurement of the induction of micronuclei — Part 2: Mixed population method using the cell line V79)

ISO 19040-3:2018 (Water quality — Determination of the estrogenic potential of water and waste water — Part 3: In vitro human cell-based reporter gene assay)

Task:

1. Development of a cultivation protocol for the ISO Guidelines based on chemically define media
2. Distribution of the chemically defined media and the cultivation protocol to partners
3. Compilation of results and publication of data

We are looking for partners! If interested in this JPA?

Please contact a.schiwy@bio.uni-Frankfurt.de and Hollert@bio.uni-frankfurt.de

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Potential partners:

- UFZ, KWR, University of Örebro, UBA, NIVA, EAWAG, VU, SLU, IWW & others