



To Whom It May Concern,

Vitro Biopharma is a biotechnology company based out of Golden, Colorado USA that manufactures and specializes in Umbilical Cord-MSCs. Our facility is registered with the FDA and is cGMP compliant to 21 CFR 810, 21 CFR part 210 and 211, 21 CFR part 600, 21 CFR part 1270 and 1271. Vitro Biopharma has a Quality Management System that is ISO 9001:2015 and ISO 13485:2016 certified. Our Chemistry, Manufacturing and Controls (CMC) have been authorized by the FDA under 21 CFR part 505. FDA has authorized AlloRx Stem Cells® to be studied in clinical trials.

Please find attached in the addendum of FDA notification of authorization and ISO certifications.

If you have any questions, please contact Tiana States, Chief Manufacturing Officer:

Tiana States  
Chief Manufacturing Officer  
[tiana@vitrobiopharma.com](mailto:tiana@vitrobiopharma.com)  
+1 (303)-999-2131  
Vitro Biopharma  
4621 Technology, Dr.  
Golden, CO 80403

## Addendum

**From:** Whitt, Nadia <Nadia.Whitt@fda.hhs.gov>  
**Sent:** Thursday, November 4, 2021 8:03 AM  
**To:** Caroline Mosessian <caroline@vitrobiopharma.com>  
**Subject:** IND 27853 | Study May Proceed

Dear Dr. Mosessian,

We have reviewed your IND 27853 and your study may proceed. This email should satisfy your IRB's requirement for written confirmation from FDA. As a reminder, please be sure to submit all documents that have been exchanged via email during the 30-day review period as an amendment to your IND. If there are any additional non-hold comments, you will receive them in a forthcoming e-mail.

Please acknowledge receipt of this

email. Warm Regards,

### **Nadia Whitt**

*Regulatory Project Manager*

Office of Tissues and Advanced Therapies  
(OTAT) Center for Biologics Evaluation and  
Research

U.S. Food and Drug Administration

Tel: 301-502-8368

[nadia.whitt@fda.hhs.gov](mailto:nadia.whitt@fda.hhs.gov)

### **COVID-19 CBER Regulated Biologics**

#### ***DRPM, Achieving Regulatory Excellence***

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## Certificate of Certification

*This is to certify the Quality Management System of:*

**Vitro Biopharma, Inc.**  
4621 Technology Drive  
Golden, CO 80403

*Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:*

**ISO 13485:2016**

*The Quality Management System is applicable to:*

**Vitro Biopharma is committed to development, manufacture and distribution of cell lines, cell culture media and investigational diagnostics to the entire regenerative medicine community and related research activities.**

*The Certification period is from*

**April 18, 2023 to December 5, 2024**

*This certification is subject to the company maintaining its system to the required standard, and applicable exceptions, which will be monitored by Orion.*

Client ID: 9452

Certificate ID: 1027012



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## Certificate of Certification

*This is to certify the Quality Management System of:*

**Vitro Biopharma, Inc.**  
4621 Technology Drive  
Golden, CO 80403

*Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:*

**ISO 9001:2015**

*The Quality Management System is applicable to:*

**Vitro Biopharma is committed to development, manufacture and distribution of cell lines, cell culture media and investigational diagnostics to the entire regenerative medicine community and related research activities.**

*The Certification period is from*

**April 18, 2023 to December 5, 2024**

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Client ID: 9452

Certificate ID: 1027013



  
Paul M. Burck, President      April 18, 2023  
Date

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