

other unwanted small molecules accumulate in the vessel with a potential to disrupt the cell growth, protein production, and the stability of the generated protein of interest. Second, necessary buffer exchange and/or cell concentration steps must be performed outside of the culturing vessel. These steps are more involved and increase the risk of contamination. Lastly, even with the addition of daily supplementation in the fed-batch process, there are limitations in length of time that the transfected cells remain viable and productive.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) developed a new transient gene expression (TGE) bioprocess using a perfusion system that resolves the current fed-batch limitations for influenza vaccine production. The major components of this technology are two-fold: the optimization of conditions for polyethylenimine (PEI)-mediated gene transfection in the bioreactor without the interference of microbubbles; and the implementation of a perfusion-based alternating tangential flow (ATF) system for single-system, prolonged cell culture, combining the steps of cell concentration, waste clearance, culturing/media replenishment, and protein expression within a single vessel.

The development of the TGE bioprocess included optimization of conditions for HEK293 cell growth in the bioreactor, optimized transfection mediated by PEI, and protein expression for an extended period to achieve reproducibility and high protein yield.

Due to high improvement in cell growth and protein production without external handling, this bioprocess could lead to substantial cost saving and other benefits in vaccine and drug manufacturing of clinical grade materials.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

- **Bioprocess**—A single-use protein production platform for transient gene expression (TGE) with potential applications in rapid protein expression as well as vaccine and drug manufacturing.

Competitive Advantages

The new transient gene expression (TGE) bioprocess for vaccine manufacturing has the following

features compared to commonly used related processes such as fed-batch:

- Robust, prolonged cell growth.
- High levels of protein production and reproducibility.
- Cost efficiency.
- Reduction in contamination risk.

Development Stage: Final Product.

Inventors: Jinsung Hong, Ph.D.

(NIAID); Jacob Demirji, Ph.D. (NIAID); Daniel Blackstock, Ph.D. (NIAID); and Joe Horwitz, Ph.D. (NIAID).

Intellectual Property: HHS Reference Number E-187-2018 includes U.S. Provisional Patent Application Number 62/751,204 filed 10/26/2018.

Licensing Contact: To license this technology, please contact Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov.

Dated: October 10, 2019.

Wade W. Green,

Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2019-25620 Filed 11-25-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: January 17, 2020.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Following opening remarks by the Acting Director, NEI, there will be

presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Eye Institute, 6700B Rockledge Drive, 1st Floor Conference Room, Bethesda, MD 20817.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700B Rockledge Drive, 1st Floor Conference Room, Bethesda, MD 20817.

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr. Ste 3400, Bethesda, MD 20892-9300, (301) 451-2020, aes@nei.nih.gov.

Information is also available on the Institute's/Center's home page: www.nei.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: November 21, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-25687 Filed 11-25-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Communities of Practice Webinar on Use of Animal-Free Affinity Reagents; Notice of Public Webinar; Registration Information

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar "Use of Animal-free Affinity Reagents." The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Interested persons may participate via WebEx. Time will be allotted for questions from the audience. Information about the webinar and registration are available at <https://ntp.niehs.nih.gov/go/commprac-2020>.

DATES:

Webinar: January 21, 2020, 11:00 a.m. to approximately 12:30 p.m. EST.