

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0644]

SEQC—The Sequencing Quality Control Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation.

SUMMARY: The Food and Drug Administration (FDA) is soliciting volunteers to participate in the SEQC (Sequencing Quality Control) project to objectively assess the technical performance of different next-generation sequencing technologies in DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) analyses and to evaluate the advantages and limitations of various bioinformatics solutions in handling and analyzing the massive new data sets. The SEQC project is a natural extension of the MicroArray Quality Control (MAQC) project (<http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/>) and is being coordinated by the FDA. This project is open to the public. Vendors of next-generation sequencing technologies and institutions interested in the generation, management, analysis, and interpretation of the resulting sequence data are welcome to participate.

DATES: Requests to participate in the SEQC project at the National Center for Toxicological Research (NCTR) should be submitted on or before 4:30 p.m., CST, January 9, 2009, or be postmarked on or before January 9, 2009.

ADDRESSES: Requests to participate in the SEQC project should be sent to Leming Shi, National Center for Toxicological Research, Food and Drug

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Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870-543-7387, FAX: 870-543-7854; e-mail: *leming.shi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA's Critical Path Initiative (<http://www.fda.gov/oc/initiatives/criticalpath/>) identifies pharmacogenomics as a key opportunity in advancing medical product development and personalized medicine. FDA has issued the "Guidance for Industry: Pharmacogenomic Data Submissions" (<http://www.fda.gov/cder/guidance/6400fnl.pdf>) to facilitate scientific progress in the field of pharmacogenomic data integration in drug development and medical diagnostics.

Microarrays represent a core technology in pharmacogenomics and toxicogenomics; however, next-generation sequencing technologies promise to provide some unique advantages in DNA and RNA analyses and are expected to be adopted by the pharmaceutical and medical industries for advancing personalized nutrition and medicine.

The SEQC project, with broad participation from scientists and reviewers within FDA and collaborators across the public, academic, and private sectors, is expected to help prepare FDA for the next wave of submission of genomic data generated from the next-generation sequencing technologies.

Dated: December 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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