

CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 034

Date of Recognition: 9/11/2024

SDO Name/Designation: ISO 24420

Year of Publication: 2023

Title: Biotechnology - Massively parallel DNA sequencing - General requirements for data processing of shotgun metagenomic sequences

Scope: This document illustrates the workflow of shotgun metagenomic sequence data processing of host-derived microbiome and environmental metagenomes. This document specifies the requirements for quality control of shotgun metagenomic sequence data processing for massively parallel DNA sequencing. This document provides guidelines for data directory, data archive and metadata for shotgun metagenomic sequence data. This document applies to data storage, sharing and interoperability of shotgun metagenomic sequence data. This document applies to shotgun metagenomic sequence data processing and analyses, but excludes functional analysis.

Extent of Recognition: Complete recognition

Rational for Recognition: This standard is relevant to gene therapies and is recognized because it is scientifically and technically valid and not in conflict with existing regulations and policies

Standard Development Organization: <https://www.iso.org/>

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm>