

April 5, 2021
Notice to the Public

The Food and Drug Administration (FDA) seek competitive offers which will be awarded via a purchase order.

Project Title

Purchase of Cryopreserved Hepatocytes

Statement of Work
Cryopreserved Hepatocytes

BACKGROUND:

FDA is conducting a research program to evaluate the usefulness of humanized mice (HM) for regulatory purposes. The HM are created by implantation of human liver cells (hepatocytes) into mice that have multiple genetic mutations that block the development of the mouse immune system at a very early stage. The absence of the mouse immune system allows the human tissues to grow and develop into functional human tissues without transplant rejection occurring. As part of this process DARS needs to acquire cryopreserved hepatocytes to humanize the liver.

For successful engraftment to occur the following quality characteristics have been experimentally demonstrated to be essential:

- Very young donor age (preferably pediatric, less than 10 years old)
- A minimum of 5×10^6 cells per vial
- Must be able to be plated and induction qualified

Even with these basic quality metrics met, it is still important to perform lot testing across as many lots as possible in order to identify which lot gives the best results.

The supplier will provide up to a total of 30 vials of cryopreserved human hepatocytes (liver cells) from up to two unique donors, providing at least 100 million hepatocytes from each donor, by the end of August 2021. Selection of the donor will be based upon their performance in mice humanized as tested by FDA, using samples (up to 6 different donors) provided to FDA at time of the award of contract.

1. REQUIREMENTS

Requirements for all cryopreserved hepatocytes:

1. Full (anonymous) donor information available and provided
 - a. Age
 - b. Sex

- c. Race/ethnicity
 - d. Cause of death
 - e. Tobacco/Alcohol or Substance abuse history
 - f. Disclosure of serious medical conditions affecting the liver (e.g. cirrhosis)
2. Tested negative for HIV, Hepatitis (B/C)
 3. Testing results available for CMV and EBV
 4. Must be from a single donor (not pooled)
 5. Must have minimum viability post-thaw of 85%
 6. Must be induction qualified
- Must be able to be plated

Salient Characteristics:

Description	Part/Product #	Quantity	Unit Cost	Total Cost
Male Human Cryoplateable Hepatocytes; min 5x10 ⁶ /vial	M00995-P	15		
Female Human Cryoplateable Hepatocytes; min 5x10 ⁶ /vial	F00995-P	15		
Shipping	FRTSHIPPER	1		
Total:				

2. DELIVERABLES / SPECIFIC TASK

- The hepatocytes will be delivered to:

US Food and Drug Administration
 10903 New Hampshire Ave, WO 64 Rm 2036
 Silver Spring MD 20993

Freight should be delivered to WO Bldg. 62 Loading Dock

SPECIAL CONSIDERATION

Deliveries must be coordinated with the Project Officer prior to shipment. No deliveries will be accepted without prior authorization from the Project Officer.

3. GOVERNMENT FURNISHED EQUIPMENT (GFE)/ GOVERNMENT FURNISHED INFORMATION (GFI)

NA

4. PERIOD OF PERFORMANCE

05/15/2021 – 05/14/2022

5. SECURITY AND PRIVACY REQUIREMENTS

NA

All quotes must be received by 10:00 a.m., Eastern Standard Time on April 8, 2021 via email to Linda Troutman at Linda.Troutman@fda.hhs.gov. Please include the RFQ number in the subject line of the email. The FDA intends to make an award immediately after the response date of this notice. The award will be made in accordance with FAR Part 13, Simplified Acquisition.