Regulatory Survey ION-5081

The data provided on this page is updated by the organisations.
The WMDA makes no representations or express or implied warranties regarding any information on this page.
Use of any information provided on this site does not and is not intended to create a contractual or other relationship.

General	
The information has been reviewed in year :	
Organisation name:	DKMS United States of America
Organisation ION:	ION-5081
Country:	United States of America
Year the registry started operations:	

Products		comment
Do you provide HPC, Marrow?		
Do you provide HPC, Apheresis?		
Do you provide HPC, Cord Blood?		
Do you provide MNC, Apheresis?		
Do you provide NC, Whole Blood?		

Product quantity		
Data valid for year		
Number of products	**National**	**International**
HPC, Marrow products:		
HPC, Apheresis:		
HPC, Cord:		

License	
Organisation is licensed/accredited by the Competent Authority:	
Comment:	
Name of Competent Authority:	
Date of last inspection:	
Link to website of Competent Authority:	
Can you provide the Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry ?	
Is your registry WMDA Certified, WMDA Qualified or WMDA Accredited?	
The registry is accredited by any other organisation:	
If yes, by which organisation?	

Affiliation	
The registry works with the following number of affiliated donor centres:	
The registry audits its donor centres:	
The registry works with the following numer of affiliated collection centres:	
Ther registry audits its collection centres:	
The registry works with the following number of affiliated Cord Blood Banks:	

The registry audits its Cord Blood Banks:	
The registry works with the following number of affiliated transplant centres:	
The registry audits its transplant centres:	
The registry works with the following number of affiliated IDM Testing Laboratories:	
The registry audits its IDM Testing Laboratories:	
The registry works with the following number of affiliated HLA/other DNA markers testing laboratories:	
The registry audits its HLA/other DNA markers testing laboratories:	
The registry would be able to provide a full list of name/addresses of each affiliated and their licence/accreditation status, on request:	
The Cord Blood Banks are FACT-NetCord accredited:	
If yes, the following Cord Blood Bank(s) are accredited:	
The registry is able to provide a copy of all the certificates:	
Affiliated centres comply with WMDA Standards and applicable national regulations:	
The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations:	
If yes, what are these requirements?	

Donor policy

All donors are unpaid volunteers:	
All donors are informed about donation process and associated risks:	
Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff:	
The registry has systems in place to protect and control access to donor/patient records:	
The registry maintains donor anonymity:	
The registry has detailed donor evaluation and exclusion criteria in place:	
The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines:	

IDM

IDM	Tested	Method	Days between test and sampling/workup
ALT/ASTALT/AST ratio, De-Ritis-Quotient	-		
ChagasChagas, T. cruzi	-		
CMV IgGCytomegalovirus (CMV) Antibody testing IgG	-		
CMV IgMCytomegalovirus (CMV) Antibody testing IgM	-		
CMV TotalCytomegalovirus Total	-		
EBV IgGEpstein-Barr Virus Antibody testing IgG	-		
EBV IgMEpstein-Barr Virus Antibody testing IgM	-		
HAV (NAT)Anti-hepatitis A virus nucleic acid testing	-		
HBV (NAT)Hepatitis B nucleic acid testing	-		
HBc AbHepatitis B core antibody testing	-		
HBs AgHepatitis B Surface antigen testing	-		
HCV (NAT)Hepatitis C nucleic acid testing	-		
HCV AbHepatitis C antibody testing	-		
HEV (NAT)Hepatitis E Virus nucleic acid testing	-		
HIV (NAT)Human Immunodeficiency Virus nucleic acid testing	-		
HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing	-		

HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing	-		
HIV p24Human Immunodeficiency Virus p24 antigen testing	-		
HTLV-IHuman T-Lymphotropic Virus type I testing	-		
HTLV-IIHuman T-Lymphotropic Virus type II testing	-		
MalariaMalaria	-		
HSVHerpes Simplex Virus	-		
STSSerological tests for syphilis	-		
STS FTA-ABSSerological test for syphilis	-		
ToxoplasmosisToxoplasmosis	-		
VZVVaricella Zoster Virus	-		
WNV-NATWest Nile Virus nucleic acid testing	-		
Other tests performed	-		

Testing

The physical and medical exam at donor workup is performed by a medical doctor:	
All donor testing (at workup) for infectious disease is performed in a laboratory certified/licensed by a Competent Authority:	
HLA typing for patient specific request is performed in an appropriately accredited laboratory:	
Sterility testing is performed on the adult donor product:	
Sterility testing is performed on the cord blood product:	
Screening questionnaire to exclude communicable disease:	
Screening questionnaire to exclude donors with 'high risk' lifestyles:	
Donor reliability identified by a medical doctor:	
Donor clearance to donate is confirmed by a medical doctor, following as a minimum the donor exclusion criteria in Annex 1 of EU Directive 2006/17/EC : The party providing the cell product must exclude donors when: • They are pregnant; • They are breastfeeding; • There is the potential for transmission of inherited conditions; • There is evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration *Donor travel and exposure history and local infectious disease prevalence*; • There is presence on the donor's body of physical signs implying a risk of transmissible disease(s); • There is a history of a disease of unknown aetiology; • There is a risk of transmission of diseases caused by prions; • There is systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated; • There is history of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the Cell Product; • There is recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist; • There is ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.	

Customs regulations

Are there any customs regulations to follow, or customs paperwork required, to import cell products into the organisation country? If yes, please specify:	
Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify:	
Are there any import regulations to follow, or paperwork required, to import cell products into the organisation country? If yes, please specify:	
Are there any export regulations to follow, or paperwork required, to export cell products from the organisation country? If yes, please specify:	

Reporting of Serious Adverse Events

Please indicate which of the following schemes for reporting Serious Adverse Events relating to either the Donor or the product the Registry participates in:

- Mandatory National Reporting Scheme	
- Voluntary National Reporting Scheme	
- WMDA SEAR/SPEAR Reporting Scheme	
The registry will notify the receiving Registry within 24 hours of receiving information relating to any serious adverse event that could be considered to affect the patient receiving the product:	

Quality management

The registry does maintain Standard Operating Procedures for your work:	
The registry would be willing to provide these to WMDA or another registry upon request:	
The registry would be willing to provide WMDA or another registry, on request, with copies of any packaging the HPC product will arrive in:	
Donor records relating to the medical exam and HPC collection process are the following number(s) of year(s) retained:	