

BMTSAA Newsletter

Easter Edition 2004

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Editorial

I am still having trouble with material for our newsletter. If one looks back at the previous issues you may note I seem to be managing only one issue per year now, in place of the promised three issues per year.

Sorry, this is a reflection of the amount of material supplied by the membership. Of course we all seem to be bogged down with the extra duties imposed on us with our profession. Come on gals and guys, how about some more news and material from the membership!

David Ford
Editor



PRESIDENT'S REPORT 2003.

I was unable to attend last year's meeting in Adelaide, but from all reports it was a very successful and informative meeting. My thanks to Pam Dyson for putting the meeting together and arranging speakers at very short notice. Also thanks to Dianne Tucker and Gail Lazzaro who accommodated for my absence.

It is a time of accelerated change for scientists within the cellular therapy field. Our work has now clearly crossed the boundary between experimental therapy and standard care. It seems that we no longer process cells for individual patients, but provide a 'manufacturing' service! There is no doubt that mandatory federal regulation of our labs is imminent. Despite my own resistance to such a fate, there is a definite indication from both the licensed labs and the TGA that such licensure does improve on the already high standards, and should be attainable by all current BMT labs.

Under a NSW Department of Health initiative, BMT centres in NSW have recently been networked. This network covers all 14 clinical transplant sites and 8 laboratories and is primarily focussed on adoption of common clinical, laboratory and nursing protocols to attain a uniform standard of care. We are also aiming to take a common approach to meeting the requirements for gaining a TGA licence for each site. The history of networking and support amongst BMT scientists gained after the

formation of the BMTSAA has facilitated the rapid formation of a cohesive group amongst the NSW scientists. This is a good reminder of how much the BMTSAA has already achieved and how effective the group is.

I would like to extend my thanks to our corporate sponsors:

Baxter Healthcare, CSL, Gambro, Merck Sharp and Dohme, and Nat Tech

My thanks also to the following BMTSAA members:

- Sue Carnoutsos for organising the Christchurch meeting. I know that Sue has put a lot of time and energy into bringing together a both a quality program and a full social day.
- Nancy Messino for her continuing role as Treasurer, and for attracting sponsorship that provides grants to our members and subsidises our Annual Meeting.
- Scott Ragg for maintaining the BMTSAA website and David Ford for producing the BMTSAA Newsletter.
- Gail Lazzaro for her hard work and continued enthusiasm as the BMTSAA Secretary. This is without doubt the most demanding job of any group, and Gail fulfils this role in an excellent manner.
- All members who presented or attended the BMTSAA scientific meeting.

Annette Trickett
President



THE BONE MARROW TRANSPLANT SCIENTISTS ASSOCIATION OF AUSTRALASIA

MINUTES OF THE ANNUAL GENERAL MEETING OF THE BONE MARROW TRANSPLANT SCIENTISTS' ASSOCIATION OF AUSTRALASIA HELD ON SUNDAY 19th OCTOBER 2003 AT THE CHRISTCHURCH CONVENTION CENTRE, CHRISTCHURCH, NEW ZEALAND AT 5.00 PM.

1. WELCOME TO MEMBERS

The President, Annette Trickett welcomed all members to the Annual General Meeting of The Bone Marrow Transplant Scientists Association of Australasia.

2. PRESENT

Vicki Antonenas, Lisa Barrow, Sandra Brockie, Sue Carnoutsos, Annabella Chang, Graeme Chapman, Pam Dyson, Helen Hanlin, Chris Hicks, John Ivey, Audrey Kill, Gail Lazzaro, Noor Parker, Scott Ragg, Mark Simmerson, Colin Story, Marian Sturm, Annette Trickett, Dianne Tucker, Emilia Varga, Dominic Wall, Glennis White, Geordie Zaunders.

3. APOLOGIES

Simon Bol, Kerrie Clerici, Nicole Egan, David Ford, Loretta Huckstepp, Cheryl Hutchins, Jesper Jensen, Michael Kersten, Lia Kubala, Nancy Messino, Heike Mumford, Emanuel Raniolo, Bill Smits, Rosanna Soares-Mendes, Nicole Wright.

4. REGISTRATION OF PROXIES

None Received

5. CONFIRMATION OF THE MINUTES OF THE ANNUAL GENERAL MEETING OF THE BONE MARROW TRANSPLANT SCIENTIST'S ASSOCIATION OF AUSTRALASIA HELD ON SUNDAY 8TH DECEMBER 2002 AT THE ROBSON LECTURE THEATRE, ROYAL ADELAIDE HOSPITAL, ADELAIDE, AUSTRALIA AT 2.00 PM.

Scott Ragg moved that the members accept the minutes as being true and correct. Seconded by Colin Story. Carried.

7. PRESIDENT'S REPORT

Annette Trickett presented the President's report for 2003. This report was to be published in the next edition of the Bone Marrow Transplant Scientists Association Newsletter.

8. TREASURER'S REPORT

Scott Ragg read the financial summary for 2002-2003 on behalf of the Treasurer.

"It is with great pleasure that I announce that the BMTSAA have had another efficient financial year. We finished the financial year with \$21,744.93 in the account held with the Commonwealth Bank. This amount is not inclusive of membership dues and sponsorship banked after 30th of June 2003. All paperwork was audited by an independent accounting firm Pavano and Company.

*Nancy Messino
Treasurer*"

9. MEMBERSHIP COMMITTEE REPORT

There was no Membership Committee for the year 2002. The small number of new applications made it practical for direct review by Council. Gail Lazzaro read the recommendations of Council.

10. RATIFICATION OF NEW MEMBERS

The following applicants were ratified by the meeting as members of the Bone Marrow Transplant Scientists Association of Australasia.

Scientific Members

Neil McNamara Royal Prince Alfred Hospital, NSW

Associate Members

Vanessa Buchan Canterbury Health Laboratories, NZ
Francis Garvin Westmead Hospital, NSW
Loretta Huckstepp St Vincent's Hospital, NSW
Mark McKechnie Crown Scientific, NSW
Rose Wong St. George Hospital, NSW
Kon Zarkos Royal Prince Alfred Hospital, NSW

Reclassification to Scientific Membership

Mary Brun Canberra Hospital, ACT
Christine Hicks St. George Hospital, NSW

Sustaining Member

Chris Olsen Chart Australia Pty Ltd (Bio-Medical)

11. BUSINESS ARISING FROM PREVIOUS MINUTES

• ISHAGE Affiliation

Annette Trickett advised that the ISCT E-Membership was available and that some members had already registered. The cost is significantly lower than active full membership (US \$75 per year) with most of the benefits including access to Cytotherapy and Telegraft. This membership is not exclusive to BMTSAA members but was established as a result of requests from our organisation and other groups outside the United States.

• CD34 QAP Expert Panel

Annabella Chang advised that the Expert Panel was active and would be consulted in the near future for additional advice related to issues associated with the CD34 QAP.

CD 34 Expert Panel

Annabella Chang
David Ma
Graeme Chapman
Scott Ragg

• ABMDR Courier Guidelines

Gail Lazzaro advised that an ABMDR meeting would be held late in October to review the guidelines. Members were asked to indicate their requirement for a copy.

• Colony Assay Workshop

A number of external events had prevented the workshop from being conducted in Christchurch. Despite the lengthy delay in conducting this workshop, considerable interest for it to run was demonstrated by the members in a show of hands. Dianne Tucker indicated that she would request a facilitator from Vancouver for the Melbourne meeting in 2004.

12. APPOINTMENT OF AUDITOR

The Treasurer moved that Pervano and Company (Certified Practising Accountants) be appointed auditors for the 2001-2002 financial year. Seconded by John Ivey.

13. COMMITTEE APPOINTMENTS

Nancy Messino had been participating in planning meetings for the Annual Scientific

Meeting in 2004. Additional volunteers were called for.

The following Committee was appointed:-
Annual Scientific Meeting Committee 2004

Nancy Messino (Chair)
Dianne Tucker
Annette Trickett
Dominic Wall

14. NOMINATIONS FOR COUNCIL 2003

THE COUNCIL

President Annette Trickett
Vice President Cheryl Hutchins
Secretary Gail Lazzaro
Treasurer Nancy Messino
Editor David Ford
Councillors Scott Ragg
Sue Carnoutsos
Vicki Antonenas
Dianne Tucker
Annabella Chang

15. GENERAL BUSINESS

• TGA Discussion Paper

Annette Trickett advised that following the circulation of the TGA Discussion Paper in May, responses were combined in a letter to Rita Maclachlan, Director, Office of Devices, Blood and Tissues. The content of the discussion paper was more applicable to tissues. Haemopoietic progenitor cells are now being considered under the code for blood and blood components thereby rendering the discussion paper obsolete. There were no more comments from the floor.

• BMTSAA 2004

Dianne Tucker read a letter from Nancy Messino inviting all members to Melbourne for the ASM to be held between the 16th and 20th October 2004. All members were assured of a very warm welcome.

Suggestions and comments were called for. Gail Lazzaro requested that a discreet meeting be considered to avoid overlap with the HSAZ program and to enable any excess registration funds to be channelled back into the organisation. It was acknowledged that the advantages of this model compared with one organised within the main meeting varied enormously from year to year and depended on the arrangements with the organising committee in the host city.

Dianne Tucker asked for comments and views on the ideas of a social function such as a bus trip

POSITION	NOMINATED	SECONDED	NOMINEE
President	Annabella Chang	Lisa Barrow	Annette Trickett* Bone Marrow Transplant Network, NSW
Vice President	Annette Trickett	Dianne Tucker	Cheryl Hutchins* Royal Brisbane Hospital, Herston, QLD
Secretary	Annabella Chang	Lisa Fava	Gail Lazzaro* Australian Red Cross Blood Service, Perth, WA
Secretary	Annette Trickett	Dianne Tucker	Gail Lazzaro*
Treasurer	Dianne Tucker	Annette Trickett	Nancy Messino* Peter MacCallum Cancer Institute, Melbourne
Treasurer	Lisa Fava	Annabella Chang	Nancy Messino*
Editor	Lisa Fava	Vicki Antonenas	David Ford* Prince of Wales Hospital, Randwick, NSW
General Councillor	Heike Mumford	Dianne Tucker	Scott Ragg* Royal Hobart Hospital, Hobart, TAS
General Councillor	Scott Ragg	Heike Mumford	Sue Carnoutsos* Canterbury Health Laboratories, Christchurch
General Councillor	Annette Trickett	Dianne Tucker	Vicki Antonenas* Westmead Hospital, Westmead, NSW
General Councillor	Scott Ragg	Heike Mumford	Dianne Tucker* Royal Children's Hospital, Parkville, Vic
General Councillor	Gail Lazzaro	Judy Calcei	Annabella Chang* Royal North Shore Hospital, St Leonards, NSW

prior to the meeting and tours of local GMP facilities in Melbourne at The Peter MacCallum Cancer Institute and The Royal Children's Hospital.

Sponsors 2003

Scott Ragg thanked the generous sponsors for the 2003 meeting
Baxter Healthcare, CSL, Gambro, Merck Sharp & Dohme, Nat Tech.

Travel Grants

Gail Lazzaro advised that the Association had been in a position to offer travel bursaries to assist with travel to the 2003 meeting. All those who applied for a bursary received some funding. Gail also reminded members of the generous Baxter Travel Grant and urged everyone to apply to make the most of this special opportunity. Applications close on 30th November 2003.

Acknowledgements

On behalf of all members, The President thanked Sue Carnoutsos sincerely for her enormous effort in organising the Christchurch meeting.

The meeting closed at 1802.

*Gail Lazzaro
Secretary*

*Annette Trickett
President*

**Financial Report for
2002-2003**



ABN 91 681 340 671

CREDITS

Balance Cheque Acc. (June 2002) \$10,836.33

MEMBERSHIPS RECEIVED

Membership 2003 banked up to 30.06.03 \$560.00

SPONSORSHIP RECEIVED \$12,250.00

Acknowledgements

Baxter Healthcare

Gambro

MSD

Nat Tech

INTEREST

Cheque Account \$36.15

TOTAL CREDITS

Cheque Account \$23,682.48

EXPENDITURE

Details in attachment \$1,937.55

TOTAL DEBIT

\$1,937.55

CHEQUE ACCOUNT BALANCE

\$21,744.93

OPENING BALANCE for 2002-2003

Cheque Account \$21,744.93

Thanks to our sponsors;

Baxter Healthcare

CSL

Gambro

Merck Sharp & Dohme

Nat Tech

*Nancy Messino
Treasurer*

shown by the BMTSAA scientists and send everyone their regards.

Via Anabella Chang



The recipients of the **Baxter Travel Grant** 2003 were:

Sue Carnoutsos
Kerrie Clerici
Peter Gambell
Congratulations!

Off the Web



Acronyms and abbreviations

<http://www.chemie.fu-berlin.de/cgi-bin/acronym>

The Institute of Chemistry in Berlin has posted an

acronyms and abbreviations database with more than 12 000 entries. Although geared towards chemistry and spectroscopy, the database offers plenty of other potentially relevant, interesting results. This site could be especially useful if an unfamiliar acronym pops up while one is doing web research.

Some of you have already heard of GMTT from San Adelaide meeting last August. I did hope to have an article about this NSW Health inceptive group in this NL however it did not reach me in time for this issue.

Others outside NSW may like to look at the website as PowerPoint lectures will be posted from monthly teleconferences start to get underway.

Prof. Tony Dobbs give a general lecture on the use of BMT in adults only days before this NL went to press. Hopefully this will be posted by the time you have a look?

"The Bone Marrow Transplant Network New South Wales (BMT Network) is an initiative of the Greater Metropolitan Transition Taskforce. This Ministerial Advisory Committee was established in 2001 to implement the recommendations of the Greater Metropolitan Services Implementation Group (GMSIG) Report (NSW Health).

The BMT Network comprises a network of clinicians - Consumers, Nursing, Allied Health, Medical, and Scientific staff, as well as hospital administrators, - from 14 different hospitals, linked together to work toward the common goal of improved patient care and health outcomes." <http://www.bmtsw.com.au/>

David Ford



The Grapevine

Carlos Lee and Myrlena loved the sights and sounds of New Zealand and the sincere friendliness of the Kiwis and the Australians. They had a wonderful time, loved the hospitality

From: Tissue Engineering [tisseng@unsw.edu.au]
Subject: Tissue Engineering Initiative Update #1
Dear Colleagues,

For many of you, this email will be the first evidence of the follow-up promised at the Workshop last Wednesday. Firstly, for those of you who participated at the meeting, I hope you found it as enjoyable and stimulating as we did. For those of you who were not able to attend, hopefully this will keep you in the loop as to what happened and what's planned.

The email list of participants and other interested parties has now been set up. I'm going to refer to everyone as members of the tissue engineering initiative from now on, for simplicity's sake.

As one outcome, UNSW has agreed to host a web-based 'capability database' listing the skills and interests of our members. Just as important, Anthony Jones at ANU has kindly offered his programming skills to help set it up. As Anthony says: "As I understood from Wed, we should have searchable database, with fields such as name, address, institution/company, position, skills (something a bit more specific?). Maybe the ability to create and update profile?" So if you have comments or suggestions as to how you'd like to see this set up, please let us or Anthony (acj110@rsphys1.anu.edu.au) know.

At the meeting there was unanimous agreement that we should have a national rather than a regional focus. So if you have colleagues from around the country who you feel would benefit from joining, please encourage them to contact us at tisseng@unsw.edu.au to be added to the member list.

We're putting together the presentations from the breakout groups, and will hopefully send them out to everyone tomorrow, as promised.

We agreed to put together a small working party (5/6 people) to progress matters. Given that we're now looking nationally rather than within NSW, it's important that this group represents a cross section of disciplines, institutions and locations, so that it can reflect the views of the membership. If you have any nominations for this group please send them to us by July 10. You can self-nominate, and nominees don't have to have been present at the meeting: the key issue is to get a representative group together.

There was considerable enthusiasm for putting together an application for ARC Network funding (http://www.arc.gov.au/grant_programs/centres_networks/research_networks.htm). Given the tight deadlines this is going to represent a fair amount of work, but we are happy to move on this if our members are supportive: let us know what you think.

So in essence, we're up and running, and would value your feedback on the following:

Nominees for the working party (by July 10)

A possible ARC Network application (by July 11)

Structure of the capabilities database (by July 14)
Colleagues who would like to become members
Any other issues you'd like to raise

This has been a very positive and encouraging start: thank you all for your enthusiasm and support, and let's keep working together to keep this exciting initiative moving forwards.

Regards

Clive and John

Graduate School of Biomedical Engineering,
UNSW

CRICOS Provider Number 00098G

Our group are investigating the setting up of a teleconference series, similar to the ISCT where the Laboratory Practices Committee are hosting discussion sessions. The first teleconference was on Cleaning and Decontamination Practice. The next subject will be ABO incompatibility – lab. procedures that will be run sometime mid March. As these sessions are probably out of the reach for us, (about 70 North American centres called in on the last session, the ISD cost and time difference), we are hoping to try and run something similar over here. We hope to run with an 1800 number for all to join in. Nancy M who seems to have the gift of procuring money from supply companies is working towards this for us. Best of luck Nancy.

David Ford



ABSTRACTS FROM THE CHRISTCHURCH SCIENTIFIC MEETING 2003

Rate Control Freezing Vs -80°C Dump Freezing of Autologous Peripheral Blood Stem Cells

Garvin F, Antonenas V, Bradstock KF
The Blood and Marrow Transplant Laboratory, Westmead Hospital, Sydney, Australia
Background and Aim: The traditional cryopreservation method of haemopoietic stem cells involves controlled-rate freezing with 10% DMSO and use of a rate-controlled freezer. In recent years, there have been several groups who have reported successful cryopreservation of stem cells using a mechanical -80 degrees C freezer (not controlled rate frozen, otherwise known as the dump freezing method). In this study, we summarize our validation data of 20 patients who underwent autologous PBSC using the -80 degrees C dump-freezing method (due to mechanical malfunctions of rate control freezers, or time constraints). The dump frozen samples were compared to the controlled rate PBSC samples. Method: Autologous stem cells were harvested from patients via peripheral blood and cryopreserved by the traditional method involving 10% dimethyl sulfoxide (DMSO) and 20% autologous plasma. Sixty six patients had their stem cells cryopreserved in a programmed rate control freezer, with a cooling rate of 1-2°C per minute to -80°C, then the cryopreserved cells were transferred to a liquid nitrogen, vapour storage tank. The remaining 20 patients had their stem cells dump frozen in a -80°C mechanical freezer, for a period of 16 to 20 hrs, prior to being transferred to the liquid nitrogen, vapour storage tank. The samples were compared according to type of freezing method, the CD34 yield (x10⁶/kg), CFU-GM colonies, % viability, and engraftment dates (ANC >0.5x10⁶/L) were evaluated.

Results:

Parameters	Rate Controlled Samples N=66	Dump Frozen Samples N=20
CD34x10 ⁶ /Kg	9.1 (1.4-35)	9.9 (2.2-55)
CFU-GMx10 ⁶ /Kg	46.2 (2.5-208)	57.2 (13-144)
Viability	80.7 (55-100)	85.1 (75-92)
Engraftment Dates	11.4 (5-19)	12 (9-24)

Above values represent the mean followed by the range of values, shown in brackets.

Conclusion: These results demonstrate that in the context of achieving engraftment after an autograft, there is no observable difference between rate control freezing and dump freezing of stem cells. The -80 degrees C technique is

suitable and useful for cryopreservation of haemopoietic stem cells, and serves as an alternative backup method to the use of rate control freezers.

Evaluation of a Dry Thawing Device for Cryopreserved Peripheral Blood Stem Cells

Sturm MJ, Egan N, Herrmann RP
Department of Haematology, Royal Perth Hospital, Perth, WA
Haemopoietic stem cells that have been cryopreserved are most frequently used for autologous transplantation and are often used for allogeneic transplantation. Thawing of the cryopreserved products occurs in a waterbath at 37 °C, by submerging the bags and massaging the contents until an ice-free state is observed. This practise has several disadvantages including that of being a wet system with the possibility of microbial contamination. The Sahara-TSC (Sarstedt Australia) is a new device that uses dry warming to thaw stem cells. We evaluated the thawing of stem cell products using the Sahara-TSC device and compared it to our standard wet thawing practise, using paired cryopreserved products from the same apheresis procedure. Eighteen cryopreserved PBSC products that had been stored in liquid N₂, were thawed at discard, one after the other, using the Sahara-TSC device or in a waterbath (37 °C) as per routine practise. The thawed products were immediately assessed for nucleated cell viability using the trypan blue exclusion method and for colony forming ability (CFUGM) using methylcellulose (Methocult QF H4534, Stem Cell Technologies). The volume of PBSC products ranged from 25-120mL (mean 65 + 6mL (SEM)). The mean thawing time using the Sahara- TSC device was 3.4 + 0.2min. Cell viability was 84.5 + 1.6% (range: 72.4-96.0%) using the Sahara TSC device, higher than using the waterbath method (76.4 +1.8%, range: 64.6-

Collection bag	Collection volume (ml)	Pre TNCC x 10 ⁸	post TNCC x 10 ⁸	Yield (%)	post CD34 x 10 ⁶
Maco Pharma	104.3 ± 30.3	14.8 ± 6.1	12.1 ± 4.2	76.8 ± 5.7	4.6 ± 3.8
Baxter	93.5 ± 26.6	13.2 ± 5.1	9.5 ± 3.6	72.3 ± 6.4	2.3 ± 1.3
p value	0.14	0.27	0.012	0.006	0.15

87.9%, p=0.0016). However, there was no difference in colony forming ability of the products thawed by either method (24 + 3 vs 20 + 4 colonies/plate respectively, p=0.12). Our results indicate that dry thawing of haemopoietic stem cells compares favourably with the waterbath method in current practise and is in support of a recent report (Rollig et al., 2002). The enhanced viability of nucleated cells observed using the Sahara TSC may indicate a more gentle agitation of cells than the manual massaging of cells that is performed with the waterbath method. Both

techniques take a similar time to perform, however, the main advantage of the dry thawing procedure is the reduced potential of microbial contamination.

Further, the dry thawing device has added advantages over the waterbath method in being physically easier, less labour intensive, easier cleaning and in providing documentation of thawing, indicating thawing time and temperature. As well, the device alarms when the cryopreserved product reaches an ice-

free state. The disadvantage of adopting the dry thawing technique is the requirement of a specialised instrument with the inherent cost. Rollig et al (2002): Cytotherapy 4 (6), 551-555.

A bag specifically designed for the collection of cord blood: An advancement in cord blood banking

Jessica Stylianou I, Marcus Vowels, April Goodear, Leigh Mison, Sue Brooke
The Australian Cord Blood Bank, Sydney Children's Hospital, Randwick
Cord Blood (CB) has traditionally been collected into collection bags designed for peripheral blood collection. However, CB banks have been exploring the use of collection bags specifically designed for collection of cord blood. A triple bag designed for the collection of cord blood and licensed for use in Australia (Maco Pharma Industries: MP), which has two large gauge needles to enable a fast flow and double sampling and an anticoagulant pack to minimise risk of clotting in the collection line, has been investigated and compared to the traditionally used Baxter triple bag (Baxter). Preliminary evaluations were carried out on 20 CB collections using the MP bags to establish the optimum centrifugation time, temperature and speed and also to establish the optimum setting for volume reduction / buffy coat preparation using the Fenwal-Optipress II, these evaluations had previously been performed on the Baxter bag. CB units (n=30) were collected into MP bags by obstetricians trained and competent in the collection of cord blood, using identical collection methodology to control samples (n=30) collected in Baxter bags at the same collection centre. These were weighed, centrifuged, volume reduced, separated. Their collection volume, total nucleated cell count (TNCC), CD34 count and yield recorded. The data was analysed using the heteroscedastic Student T-test.

The average volume of CB collected, pre-processing TNCC and post processing CD34 were 10.7 ml, 1.6 x 10⁸ and 2.3 x 10⁶ higher for the MP bag compared to the Baxter bag respectively. These were not statistically significant. The average post-TNCC and yield were 2.6 x 10⁸ and 4.5% higher for the MP bag compared to the Baxter bag respectively, and these were statistically significant (p= 0.012 and 0.006 respectively). As well, there were less donation volumes lower than 60ml (MP =10%, Baxter = 33%) and a similar frequency of clots (MP =0%, Baxter = 3%). Both these latter issues are relevant to rejection of a cord blood donation. Our findings indicate that a bag specifically designed for collection of cord blood has advantages over a bag designed for large volume

No Lyse, Viable CD34 Assay for the Enumeration of Thawed Haemopoietic Stem Cell Products

Antonenas V, Sartor M, Garvin F, Bradstock KF
The BMT Laboratory, Westmead Hospital, Sydney, Australia
Quantitation of human CD34⁺ cells is now an established method for the enumeration of haemopoietic stem cells (HSC) performed by

flow cytometry. However, similar methods for the enumeration of viable CD34⁺ cells post cryopreservation has proven more challenging due to cellular fragmentation, dead cells, debris and effects of DMSO and lysing agent on post thaw samples with time. We describe a simple absolute CD34⁺ cell counting protocol suitable for post- cryopreserved samples using TRUCOUNT tubes and a modified ISHAGE gating strategy. The method includes no wash, no lyse and a viability dye 7- AAD to exclude dead cells. The threshold was set on CD45 FITC expression and counting was ceased when a minimum of 100 CD34 events and 3000 beads were collected. A comparison of our IN-HOUSE no lyse CD34 assay to the dual platform ISHAGE method was performed. 7 samples of PB from patients undergoing PBSC mobilisation and 14 samples from PBSC harvests were analysed by both methods. Absolute numbers of CD34 cells ranged from 7.7 to 22,000/ul. Results showed excellent precision, linearity and correlation with the dual platform reference method (slope 1.00, intercept 0 and r2 0.99). There was no significant difference or bias between the two methods. Our IN-HOUSE NO LYSE method was applied to 10 cryopreserved PBSC products. The absolute numbers of viable CD34⁺ cells/ul were compared pre and post cryopreservation. A mean of 90% viable CD34⁺ cells were recovered from cryopreserved/thawed samples. This IN-HOUSE viable CD34 assay gave equivalent results to the dual platform reference method for both whole blood and PBSC harvests. The method is simple and requires no lysis and can be readily applied to the standardization of viable CD34⁺ cell enumerations in post-cryopreserved PBSC products. Further evaluations are being performed to validate this protocol on bone marrows and cord bloods.

Designing and Building A GMP Facility – "oh, the places you'll go!"¹

Tucker D

Division of Laboratory Services, Women's and Children's Health, Melbourne

In 2002, funding was finally approved to build a GMP laboratory to house the BMDI Cord Blood Bank, Cell Therapy Laboratory and other cell therapeutic activities at the Royal Children's Hospital. After many years of debating and discussion we felt elation at the project finally beginning. In the great words of Dr Seuss, "Congratulations! Today is your day. You're off to great places! You're off and away." This paper describes our experiences during the continuing journey in an attempt to satisfy the requirement of cGMP and the regulatory bodies. Specifically it discusses:

- Reasons why the facility was required and the purpose of each lab in the facility;
- The importance of defining terms and a having a clear understanding of the regulatory requirements;
- The processes we followed in the embryonic stages of the project; outlining the validation processes and the approach we took to define our path;
- How and where we found the information for what we had to do;
- The mistakes we have made and the 'wins' we've had.

We acknowledge that we are not the first laboratory in the country to build such a facility but felt that with the issue of regulation so topical, an account of our experiences (particularly in relation to planning and development) may be of benefit to other people about to embark on a similar journey. We are still

in the building process and are yet to meet the regulators.

1. "Oh, the places you'll go". Dr Seuss, 1990 Dr. Seuss Enterprises, L.P.

Development of a Database for a GMP Cell Processing Laboratory

Greenstein V, Ford D, Hession E, Lindeman R
Department of Haematology, Prince of Wales Hospital, Randwick NSW Australia
A comprehensive "in house" database was developed by the Bone Marrow Transplant Laboratory at Prince of Wales Hospital to assist the laboratory to perform in the environment of GMP (good manufacturing practice). The system, built from Microsoft Access, allows for easy entry, storage and retrieval of information concerning all aspects of haematopoietic stem cell collection, processing, cryopreservation and reinfusion. Pre and post-transplantation clinical events are also recorded allowing for easy communication with both national and international transplantation registries for outcomes analysis. The system is flexible enough to store details concerning multiple collections from multiple donors resulting in multiple infusions from any stem cell source (peripheral or cord blood, bone marrow and donor lymphocytes). A wide range of laboratory procedures may be accommodated within the system. The database provides on-screen views on any aspect of collection, processing or transplantation event. Reports can be generated to allow storage of a "hard copy" of transplant-critical information. A bar-coding system allows collection and monitoring of information on batches of all materials and reagents used during processing. Cryopreserved units are labelled in accordance with Foundation for the Accreditation of Cellular Therapy (FACT) regulations and are individually barcoded to allow the specific contents of each unit to be monitored and stored. The system releases individual cryopreserved units for subsequent infusion and updates the inventory storage details. Several set queries have been established to allow for easy up-dating and summarising of collection and transplantation details, while other specific queries may be easily designed to access the stored information. For more detailed statistical analysis, the data may be readily exported to other software packages.

Networking of the NSW Haemopoietic Stem Cell Transplant Laboratories

Trickett A, Antonenas V, Bradstock K, Marshall G, Trotman J, Tiley C
NSW BMT Network, Sydney

In November 2001, the NSW Health Department established the Greater Metropolitan Transitional Taskforce (GMTT) to provide patients with equity of access and outcome to specialist medical services. Clinicians and allied health workers in the targeted fields were directed to achieve this equity by (a) provision of core services at locations close to the community, (b) provision of expensive & complex services by a small number of appropriately resourced centres, and (c) establishment of clinical networks. Haemopoietic stem cell transplantation (HSCT) was included as a targeted speciality. The specific GMTT goals in this area were to increase the number of centres providing autologous transplantation, reduce the number of units undertaking allogeneic transplantation, and to network all centres with the view to achieving common clinical and laboratory protocols. The perceived potential benefits of such networking include evaluation of practices across the

network, definition and adoption of 'best practice' within the group, and standardization of protocols. In the laboratory setting, standardization of protocols and procedures could have substantial benefits in reducing the time spent by laboratory personnel on preparation of documentation for accreditation and on method validation, as well as providing a uniform base for performing research trials. Further adoption of a common quality management system may also be the most efficient means of approaching accreditation with the Therapeutic Goods Administration. Activities of the networked NSW HSCT laboratories to date include determination of the workload, range of procedures performed, staffing levels, current facilities and equipment. This information is being used to identify the most urgent requirements and apply for State funding to address these needs. Such information has also been beneficial for establishment of the four new autologous HSCT units. Negotiations have taken place with a courier company for a state-wide contract for transportation of stem cells between centres, and the networked group is currently working together to develop and validate a common method for viable CD34 cell determination. A Quality Manager has recently been appointed to coordinate adoption of common protocols and a common quality system across laboratories in NSW.

Report of the RCPA Haematology CD34+ QAP results

Chang A1, Ma D2

1PaLMS, Royal North Shore Hospital, Sydney, 2St Vincents Hospital, Sydney

To fulfil the need for an external quality assessment of CD34⁺ cell enumeration required for the accreditation of stem cell transplant laboratories, an Australasian CD34⁺ quality assurance program (QAP) has been established as a module in the RCPA Haematology QAP to compare CD34⁺ cell results and methods. Samples for the CD34⁺ QAP consisted of mobilised peripheral blood or leukapheresed peripheral blood stem cells (PBSC). To provide adequate samples for distribution to participants, cells were diluted in fresh frozen plasma (FFP), then sent for testing within 24 hours. For the white blood cell count (WBCC) results, instruments using similar technologies were grouped together. Results for the %CD34⁺ cell were divided into lyse-no-wash (LNW) or lyse-wash (LW) methods. Absolute CD34⁺/ml results were divided into dual platform (DP) or single platform (SP) methods. Statistics were calculated for all submitted results as well as for each method group for comparison. During 2001-2002, the number of participants increased from 36 to 43 institutions. There were 6 surveys consisting of 12 samples. The median CV for the WBCC was 15%, and showed 2 sources of variation, one between results within the same instrument group, and the other between results from counters belonging to different groups, one of which showed significantly lower results. This latter difference was not observed if FFP was not used as diluent. For %CD34⁺ cell results, the LNW method showed tighter CV than the LW method. The absolute CD34⁺/ml results consistently showed lower CV for the SP method (median 13.3%CV), compared with the DP method (median 23%CV). The methods used by participants for CD34⁺ cell enumeration have reached near consensus for the gating strategy, the antibodies and fluorochromes used, with an increasing number using LNW and SP method. Data suggest that the presence of citrate in the diluent is a probable cause of the WBCC

variation obtained by different instrument groups. The QAP results showed that the tolerable degree of imprecision (10%CV) was achievable by the SP method, but not by the DP method. While citrate could be avoided in future QAP samples, it cannot be avoided in PBSC harvests, which contain citrate as anticoagulant during leukapheresis, and the effect of citrate on the WBCC may impact on the CD34+ cell counts obtained by the DP method.



Please note the two letters from TGA have been pasted without the official TGA letterhead to allow their content to be placed in this newsletter.

**From
Blood and Tissue Products Unit
Office of Devices, Blood and Tissues
TGA**

Dr Jeffrey Szer
President

Bone Marrow Transplant Society of Australia and New Zealand

Dr Annette Trickett
President

Bone Marrow Transplant Scientists Association of Australasia

Re: Regulation of haematopoietic progenitor cells (HPCs)- Meeting at TGA on 21 January 2004

I thank you for attending a meeting at TGA to discuss the issues arising from the Therapeutic Goods' Committee's resolutions regarding standards and oversight of HPCs. As agreed, I am writing to seek your confirmation of the TGA's understanding of the discussion and outcomes of this meeting.

We agreed that with the increasing involvement of the TGA in the bone marrow transplant area, appropriate channels of communication with the sector were crucial. Therefore, while the TGA would continue to engage individual experts from the sector and the area as a whole in its regulatory and consultative process, your respective organisations would constitute the official stakeholders for progressing regulatory outcomes. In this regard, we agreed that a committee would be formed under the chair of the Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ) which would include yourselves, a TGA nominee from the Manufacturing Assessment Section (MAS) and other members as you consider appropriate, including for example the Australian Bone Marrow Donor Registry and the apheresis nurses area. This committee would be charged with developing appropriate mechanisms for managing the introduction of the FACT standards for HPC's as adopted and adapted by the TGA. In particular, the committee would be mindful of the need to ensure that oversight of the Standard is open, transparent and accountable while maintaining the capacity of the BMT sector, particularly those areas currently unregulated and not seeking licensure as manufacturing facilities by the TGA. The TGA will provide this committee with appropriate background papers.

We also discussed other issues of concern to the sector. The TGA maintains that the licensure of laboratories performing quality-related testing on products is an essential part of GMP. However, it is recognised that facilities in the lowest tier of oversight in the HPC sector will not be seeking licensure but will be operating to the FACT standard. The TGA will therefore consider the position of tests performed for such laboratories.

I trust this captures the spirit of our discussions. The TGA looks forward to continuing to work with your Societies in this important area.
Albert Farrugia
22 January 2004



Dear Members
As you can see from the attached letter from Albert Farrugia at the TGA, the presidents of the BMTSAA and the BMTSANZ were invited to the TGA for a meeting regarding regulation of haematopoietic progenitor cell transplantation. The January 21st meeting involved preliminary discussions regarding implementation of the FACT standards. A brief summary of the major topics of conversation follow:

- Use of "FACT Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation" and/or "Australian Code of Good Manufacturing Practice – Human Blood and Tissues". Since both documents outline the requirements of a quality system, it was felt that adherence to one document would be less cumbersome but equally effective. The FACT document is more relevant to the field of HPC, and hence (pending removal of irrelevant sections) seems the more appropriate document.
- Committee to develop mechanisms for managing the introduction of the FACT standards. It was agreed that the BMTSANZ and BMTSAA would each have 1 – 2 representatives on the committee. It was proposed that a representative from the Apheresis nursing sector, the ABMDRR, and the Transplant Coordinators be included in addition to the TGA representative.
- Classification of HPC according to degree of manipulation. It was suggested that the classifications used in the document entitled "Circular of information for the use of cellular therapy products" (available on the ISCT website) be adopted. In this document plasma reduction, RBC reduction, buffy coat preparation, density gradient separation, cryopreservation, and CD34 selection are classed as minimal manipulation, regardless of the source of HPC (marrow, PBSC, cord blood). Major manipulation includes processes that expand or change the function of the cells.
- The requirement for laboratories testing HPC products to be licensed by the TGA. It was stated that it will be extremely difficult for HPC processing labs to exclusively use TGA licensed laboratories to test their products. The necessity for rapid results makes it unrealistic to use centralised licensed testing laboratories and the small workload exerts little encouragement for each testing laboratory to gain a license.

I will try to keep everyone up to date on the outcome of future meetings.

With regards,
Annette Trickett a.trickett@unsw.edu.au



**From
Blood and Tissue Products Unit
Office of Devices, Blood and Tissues
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Dear Sir/Madam

Banked cord blood manufactured under non-current conditions of licensure

This communication is being sent to agencies licensed or applying for a license to manufacture

and release banked cord blood for therapeutic use. Specifically, this communication addresses banked cord blood manufactured and stored under conditions deviating from those required for approval at the time of product release. These conditions currently include the requirements of TGO 66/66A and the code of Good Manufacturing Practice for Human Blood and Tissues (the Code), but may include other requirements in the future. Included in these conditions is the requirement to test for certain blood borne pathogens using methods based on validated and currently accepted scientific principles, including methods for viral detection with nucleic acid technology.

The TGA recognises that products that have been held in inventory during periods of technological change, including the introduction of new selection/screening measures, present difficulties when conformance to current provisions is required. As a principle, the TGA will be using a process of risk management in assessing such provisions. The TGA will be using the principles described in the AS/NZS 4360:1999 Risk Management and would expect agencies requesting exemption from current provisions to follow a similar approach in their submissions.

1. Establishing the context.

- Cord blood banked for eventual haematopoietic reconstitution is a valuable therapeutic resource for patients suffering from a number of severe diseases. These include malignancies, cellular aplasias and congenital conditions such as thalassaemia.
- Infectious disease testing for blood borne pathogens is an essential component of the blood safety framework. Serological testing for the immunological markers of blood borne viruses has been supplemented in recent years with nucleic acid testing (NAT) which seeks to shorten the testing window of infection during which laboratory markers are absent while infectious virus is already in the blood.

2. Identifying the risks

- Death or severe morbidity as well as prolonged hospitalisation are the risk of withholding transplant therapy from the severely ill patients which are the subjects of this therapy. This is apparent from long-standing medical practice as reflected in the peer-reviewed literature.
- Infection by blood borne pathogens is the risk of inadequate screening of the products used for transplantation therapy. The pathogens which can be screened by NAT as of the date of this communication are human immunodeficiency virus (HIV) and hepatitis C virus (HCV). Both infections lead to life threatening illnesses as well as to chronic disease states requiring extensive medical intervention and impacting severely on the quality of life.
- Risks arising from poor observance of the principles of Good manufacturing Practice, such as inadequate process controls, handling, labelling, inappropriate temperature monitoring and cross-contamination.

from the provisions of TGO No 66A and the Code in relation to the following areas:

3. Analysing the risks

- The following table quantifies the risk of mortality from the various conditions treated with banked cord blood transplant¹.

Disease	Disease mortality	
	No transplant	With transplant
ALL CR2 - relapse within 30 months of diagnosis	>85%	35%
ALL CR1 - high risk	70%	70%
ANLL CR2	>85%	>35%
CML	>90%	>40%
Severe aplastic anaemia	>90%	>40%

- The risk of infectious disease transmission through cord blood transplanted without the performance of testing depends on the level of testing performed and the virus in question. Using accepted models for estimating the residual risk of such products²:

Risk per million procedures = viral incidence per 10⁵ person years X window period in years

The viruses tested using NAT are HIV and HCV.

The relevant parameters for these viruses are :

Virus	Incidence / 10 ⁵ person years ¹	Window period (years)	Risk/million transplants (%)
HIV	5.8	0.06	0.35 (0.000035)
HCV	8.5	0.16	1.4 (0.00014)

In each instance worse case scenarios are used for the estimates

4. Evaluating the risks

On the basis of the analysis in ³, the TGA judges the risk of actual HIV and HCV transmission by cord blood units not tested by NAT to be outweighed by the risk of withholding the product to an extent that the risk-benefit balance results in a decision to issue cord blood units not screened by NAT during manufacture. The TGA estimates the risk as acceptable. The TGA considers that release of these cord blood units can be subjected to an appropriate level of monitoring and review. In this instance, the review should include testing of the recipients of banked cord blood for the markers of HIV and HCV infection pre and post the transplant of these non-NAT tested units, and the development, by the agencies involved, of appropriate plans for assessing causality in the event of a post-transplant infection having occurred.

The TGA will also require that agencies with cord blood units eligible for this exemption will demonstrate adequate compliance with the principles of Good Manufacturing Practice which will ensure the minimisation of cross-contamination as specified in 2.

5. Treating the risks

The TGA will require agencies with cord blood units eligible for this exemption to ensure that patients or their relatives subject to transplant of non-NAT tested cord blood are informed of the risks involved in the procedure and sign an appropriately worded document indicating informed consent. Appropriate wording of currently used informed consent forms will be sufficient to satisfy the TGA's requirements in this regard.

Therefore, for the purposes of sub-section 14(1) of the Therapeutic Goods Act 1989 ("the Act"), I hereby grant consent for the release of banked cord blood by licensed agencies to be exempt

Performance of NAT testing for HIV and HCV. The conditions for this consent under sub-section 15(1) of the Act are that

- This exemption applies to cord blood units

banked before 1 October 2003. All units banked subsequent to that date require adherence to all the relevant provisions to date.

2. Patients transplanted with units covered by this exemption are to be tested for the markers of HIV and HCV infection pre and post transplant using appropriate protocols and a protocol for assessing causality in the event of infection is to be developed. All such protocols are to be made available for review by the TGA by 1 May 2004.

- An appropriate consent form for these units is to be developed and submitted for the TGA's approval by 1 May 2004.
- A protocol for

demonstrating the adherence to good manufacturing principles so as to minimise cross-contamination between cord blood units subject to this exemption and NAT-tested cord blood units is to be submitted for the TGA's approval by 1 May 2004.

Albert Farrugia

¹Barker JN, Weisdorf DJ, DeFor TE, et al. Rapid and complete donor chimerism in adult recipients of unrelated donor umbilical cord blood transplantation after reduced-intensity conditioning. *Blood* 102:1915-1919, 2003

²Schreiber GS et al (1996) The risk of transfusion transmitted infections. *NEJM* 334:1685-90

³HIV/AIDS, virally transmitted hepatitis and sexually transmitted diseases in Australia. Annual surveillance report 2003. National Centre in HIV epidemiology and clinical research.



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Comparison of Standards

Summary prepared by Annette Trickett

	<i>FACT 2002 (Processing section)</i>	<i>Australian code of GMP - blood & tissue (Excluding donor selection)</i>	<i>ISO17025 (Relevant sections)</i>
Facilities	D2	Section 3	5.3
Space & design	2.1 Adequate	300 Protect product, reduce error. 302 Protection from weather & pests.	
Specific areas	2.2 Defined	301 Appropriate & specified. 320 Processing area: easy cleaning. 324-7 Donor interview & cell collection areas.	5.3.3 Prevent cross contamination.
OH&S	2.3 SOP for infect control, biosafety, chemical safety, accident management, waste disposal, hazard exposure, protective clothing	321-3 Hand wash facilities, protective clothing, no eating etc.	
Equipment	2.4 Adequate	304 Emergency power	
Housekeeping	2.5 SOP	312-6 SOP for cleaners, disinfectant storage & use. Avoid particle-generating equipment. Waste disposal.	5.3.5 Ensure good housekeeping.
Security	2.6 No unauthorized personnel	303 Check & supervise visitors/contractors etc	5.3.4 Controlled access.
Environment		305-8 Control mandatory for processing. Critical material storage areas monitored. Open processing in clean space (microbial & air control records). Lab access via corridor or other manufacturing area.	5.3.1-2 Facilitate correct performance. Documented requirements. Monitor & control as required.
Floors, walls & fittings		309-11 Smooth, non-porous, non-slip, resistant to cleaning agents. Sealed surfaces (not wood) & floor-wall joints.	
Personnel	D3	Section 2	5.2
General	3.4 Processing staff requirements	200-6 Organisational chart, names, job descriptions, deputies.	5.2.4-5 Job descriptions, authorization.
Lab director	3.1 Requirements & responsibilities	110 Controls product manufacture	
Medical director	3.2 Requirements & responsibilities	107 Ultimate responsibility for QMS.	5.2.1 Management to ensure staff competency.
Quality manager	3.2 Requirements & responsibilities	109, 111 Independent from production manager. Must have practical experience in manufacture of blood products, in accordance with GMP requirements.	
Training		207-12 Documented & on-going, trainer & trainee competency assessment.	5.2.2 SOP
Records		213-5 Learning programs, timeframes & assessments. Register of signatures.	5.2.5 Authorisations, competency, qualifications, training, experience.

	<i>D4.1 & 4.5 & 4.6</i>	<i>Section 1</i>	<i>4</i>
Quality Management			
System	4.1 Establish & maintain	100-6 Quality policy, organizational structure. 114-5 Documentation of QMS 116 Change control 123-5 Management review	4.1 Organisational structure/responsibilities 4.2 QMS stated in quality manual 4.14 Management review.
Document control	5.21 Standardized format. Document numbering system.	507-9 Authorized, unique id, version & page #, distribution, ensure current, changes.	4.3 All docs: review, approve, control, id, changes.
Validation of significant procedures	4.11 SOPs, review & approval		5.4.5 Data, range, accuracy.
Audits	4.12 Review & approve	118-20 Internal audits.	4.13 SOP for schedule & procedure.
Improvement	4.5 Review of processing records. Document investigation, resolution, & outcome. 4.61 Detect, evaluate, document & report all errors, accidents, (suspected) adverse reactions, product deviations, complaints & corrective actions.	117 Continuous improvement SOP. 121-2 Corrective action. 611 Documented system. 910 Record of all deviations & corrective actions.	4.8-4.11 Complaints, non-conformance, corrective & preventative action.
Engraftment times	4.13 Document & review		
Product testing	D4.2		
General	4.21 Permanent record of results		5.10 Report accurately & clearly.
QC	4.22 Records for all tests	909 SOP & records.	5.9 SOP & records.
Testing lab requirements	4.23 Required tests performed in licensed lab	828 Mandatory screening tests in TGA licensed lab. 840-2 Contract.	4.5 Subcontractor complies with ISO17025, written contract, list of subcontractors.
Nucleated cell count	4.24 SOP		
Microbial testing	4.25 SOP, timely review of results & notification of positive cultures.	905 Periodic sampling. Record of corrective action.	
ABO & Rh testing	4.26 At time of cell harvest. Compatibility if indicated.		
Communicable disease testing	B6.17 Prior to harvest (<30 days) HIV-1/2, HBV, HCV, HTLV-1/2, syphilis, CMV (unless previous positive).	828 Negative for HIV-1/2, HBV, HCV, HTLV-1, syphilis or documented authority for release if positive.	
Other testing	4.27 Evaluation of target cells before & after processing		

Supplies & reagents		D4.3	Section 7	4.6
Qualification	4.31 All significant products: equipment, reagents, labels, containers, packaging, computer systems. 4.36 Sterile if contact with product		702-4 Record of receipt. QC specifications.	
Reagents for processing	4.32 Appropriate grade & sterile		715-6 Record of conformity & QC. Sterile & for therapeutic use.	
In-house reagents	4.33 Validated			
Examination	4.34 Inc seals, colour, expiry date		701 SOP for assessment of critical materiel. 713 Record of checks.	4.6.2 Not used until inspected. Record of check.
Storage	4.35 Safe, sanitary & orderly		317-9 Temp monitored. Segregation & labelling (705) of quarantine & release. Documented receipt & storage. 706 According to manufacturer's instructions.	4.6.1 SOP for storage.
Usage	4.37 According to manufacturer			
Suppliers			707-11 Written approval, defined specifications & rejection criteria, regular review, conformance to quality standard.	4.6.4 Evaluate, then list approved suppliers.
Purchasing			712 Clear description of materiel ordered.	4.6.1 SOP for selection & purchase.
Equipment		D4.4	Section 4	5.5
General	4.41 Clean & orderly		400-5 Suitable, good repair, unique id, movable to permit cleaning, SOP for cleaning, back-up.	5.5.1 Ensure internal & external equip comply with this std. 5.5.3-4 Operated by authorized personnel. Unique id.
Calibration	4.42 Regularly as per SOP & manufacturer		413-7 SOP's, records, acceptance range, tag with last date & due date. Accuracy of calibrating device.	5.5.2 Meet accuracy requirements, comply with specs, calibration program. 5.5.8 Label with details.
Sterilisation equip	4.43 Must ensure destruction of microbes			
Fridge/freezers	4.44 Only used for specimens, HSC, blood & reagents		419-20 Control, monitor, & review temps. Clean & defrost regularly.	
Bar coding & readers			422-3 Ensure accuracy.	
Qualification			406-10 Formal commission (IQ, OQ, PQ).	5.5.2 Comply with specifications.
Maintenance			411-2 Stated regular intervals & documented.	5.5.6 SOP
Records				5.5.5 Id, manufacturer, location, instructions or location of manual, calibration, maintenance.
Loans				5.5.9 Function check on return
Documentation		D5	Section 5	4.3
General	5.3-4 Available to appropriate staff. Followed.		502-3 No superfluous data. When & who to use.	5.4.2 Use of appropriate methods & procedures, preferably published.
Scope of SOPs	5.1 Processing, emergency action, donor & pt confidentiality, QM, deviation & corrective actions, training, competency assessment, outcome analysis, audits, labeling, storage, transport, expiry dates, product release, waste disposal, equipment & suppliers, maintenance, cleaning, disaster plan.		501 All processes in manufacture of product.	5.4.1 Sampling, handling, transport, storage, equipment instructions,
SOP manual to include	5.21 Preparation, implementation & review of procedures.			
SOPs to include	5.22 Purpose, equipment, supplies, objectives, acceptable endpoints, range of expected results, references, approval history, examples of completed forms.			5.4.4 Id, scope, description, test parameter, equipment, reference stds, environmental conditions, procedure, approval/rejection criteria, data analysis & presentation.
Implementation & revision	5.5 Documented review & training		506 Commission & train	
Archival	5.6 Indefinite		510-2 Documented, secure, defined.	
Deviations	5.7 Documented			
Processing		D6	Section 9	
Validation	6.1 Use of validated procedures. Performance monitoring for procedures & instruments.		906-8 All critical processes. Re-validation after change.	5.4.7 Checks on calculations, computers, automated equipment used for data capture.
Processing	6.21-6.24 Written request. Performed to SOP using aseptic technique.		901 SOPs. 727-8, 912 System & SOP to ensure quarantine until release criteria met.	
Release criteria			829 SOP detailing screening tests & acceptance/rejection criteria. 913 Minimum = medical assessment, donor infectious disease status.	
Worksheets to include	6.25 Signature for each significant step, lot #/expiry dates, key equipment details, deviations.		612 Date (time). Id of person performing & authorizing significant steps.	
Record review	6.26 By lab director. Inform Tx physician if end-points not met.		911 Regular.	
Complex processing	6.27 Need written informed consent from recipient?			
ABO incompatibility	6.28 SOP			
Cryopreservation		D7		
Samples	7.1 Cryopreserved & stored under same conditions as product			

SOP to describe	7.2 Freezing criteria of specific product, cryoprotectant & its concentration, container, volume range, NC concentration range, cooling rate, endpoint temperature, storage temp range.	
Cooling rate	7.3 Validated & each run recorded.	
Labels D8		
Labelling	8.1 Strategy to prevent mislabeling, check printed labels, discard obsolete labels, legible & use moisture-proof ink. Proper name of product & modifications	719-25 Retain file copy. Specified adhesive. Check for errors (inc bar codes). Record errors. 1002 Processing status of product.
Product identification	8.2 Unique # for product. Identifier for each of multiple containers. Must ensure traceability.	726 System to ensure no repeat of unique numbers.
Label content	8.3 Stringent requirements. Partial label OK on product.	
Product issue D9		
Inspection	9.1 Labeling & integrity check by 2 trained staff. Lab director to authorize if requirements not met.	614 Record of inspection.
Return	9.2 Requirements: container integrity & temperature range, documentation or lab director authorization.	734-7 Recall procedure?
Infusion	9.3 SOPs for use, indications, contraindications, side effects, hazards, dosage & administration.	
Forms	9.4 Completed form to include name & identifier of pt, proper product name & identifier, initials of medical staff receiving product.	

Storage D10		
Conditions	10.1-2 SOP for duration, temp, conditions & indications for discard. Pts/donors to be informed of policy prior to cell harvest.	1001 SOP for conditions.
Product safety	10.3 Materials that may adversely affect product not to be stored with product. Minimisation of cross-contamination in liquid nitrogen.	418 Not used for other purposes. 1005 Quarantine SOP.
Monitoring	10.4 Record temp \leq 4 hours. Ensure liquid nitrogen level.	731 SOP to ensure control. 732 Conditions monitored.
Alarms	10.5 Continuously active alarm on storage devices. Checked periodically. Audible signal. Remote alarm if <24 hour staff. Written instructions for device failure. Backup storage device.	
Security	10.6 Located in secure area.	418 Secure product storage.
Inventory control	10.7 Records to include location of product & samples, donor id, patient name & id, product id & proper name, date of collection, storage device id, dates of issue, disposition.	
Transportation D11		
General	11.1 Must protect integrity of product & safety of personnel.	730 Ensure integrity & status of product. 1001, 1007 Documented system.
Packaging (non-frozen)	11.2 Product container to be sealed in plastic bag	
Off-campus	11.3 Appropriately labeled, thermally insulated container that can withstand leakage, shocks, pressure change. Dry shipper for frozen products. Temperature specified & monitored.	1009 State: address & contact name for origin & destination sites, contents. 1012 Validation data.
Method	11.5 Minimize transport time. Hand carrier by informed courier if recipient already received high-dose therapy. Alternative transport plans. No X-ray.	
Records	11.6 Traceability: date, time of shipping & receipt. Id of sending & receiving facility & courier. Problems & delays.	1010 Container id, product id, number of products, signature of authorized person responsible for dispatch.
Disposal of HSC D12		
Required documents	12. SOP, agreement between patient & storage facility, pt death, discard record.	1006 SOP for disposal. Record including reason.
Approval	12.5 Lab Medical director & pt's Tx physician.	
Legal requirements	12.6 Must meet all relevant requirements.	

Records D13		Section 6	4.12
General	13.1 Confidential, traceable, legible, responsible persons, test results, lot numbers, manufacturers, etc	600-4 Complete history from donor to release of product. Documented traceability system. 612 Inspection checks, QC, equipment. 616, 625-6 Secure, accessible. 618 Pest control records for paper records.	4.12.1 SOP for id, collection, indexing, access, filing, storage, disposal. Protect from damage, secure.
Retained indefinitely	13.2 Processing, storage & distribution, compatibility, errors, accidents, adverse reactions & complaints.	617 Documented archival system. 624 Corrective actions.	4.12.1.2 Specify retention times.
Retained for 10 years	13.3 Temp charts, reagent preparation, storage & performance, equipment, aseptic technique, proficiency testing, inspection & accreditation, training,	615 Documented disposal system.	4.12.1.2 Specify retention times.
Electronic records	13.4 Long term retrieval, alternative system, SOP for use, QA, validation, modifications, unique identifiers, etc	627-41 Written conformance to ISO9001 by software vendors. Flow diagram for software development. Documented development, implementation, validation & operation. Back-up, accuracy, security, etc.	4.12.1.4 Protect & back-up.
Divided responsibility	13.5 Extent of responsibility.		
Donor		605-10 Consent, signature of med history reviewer, donation record (factors affecting product quality). 621-3 Donor deferral.	