

## ISHAGE 2000 Meeting - San Diego, California, USA



The Sixth Annual Meeting of ISHAGE was held at the Hyatt Regency in San Diego, California June 15th through 18th, 2000. There were over 400 attendees, the majority from the USA (71%), Europe (18%) and Canada (5%). Attendees also came from Australia, Asia, the Middle East and South America.

### An Extensive Program

The organizing committee, led by Malcolm Brenner, as well as the committee members and ISHAGE Head Office staff put together an extensive program that included the latest developments in cell and gene therapy, such as the biology and therapeutic applications of mesenchymal stem cells. The plenary and parallel sessions, workshops and poster sessions also



Dr. Malcolm Brenner, ISHAGE 2000 Welcome Reception

covered hematopoietic progenitor cell biology, graft manipulation and transplantation, immunotherapy as well as minimal residual disease and cell expansion. Results of the attendees' evaluations of the program are summarized in the accompanying article, "Did You get the Most from the Annual Meeting?" (page 2), from Ineke Slaper-Cortenbach, Chair of the Educational Affairs Committee.

In brief, the presentations were well received, but it is evident that the workshops need to be reengineered so that they are more technical in orientation.

The social highlight of the meeting was held the evening of June 17 at the San Diego Wild Animal Park, a pioneer in zoo design. Attendees enjoyed a delicious buffet dinner as well as scenic monorail tours around the perimeter of the park. During dinner, there was the opportunity to meet some of the denizens of the park "up close and personal".

### Other Committee Meetings

In addition to the scientific discussions, a significant amount of society business was conducted in San Diego. ISHAGE's nine scientific committees, Advisory Board, Executive Committee, Educational Affairs Committee as well as the Cytotherapy and Telegraft Editorial Boards all met in San Diego during the course of the meeting. In addition, planning committees for the GMP 2000 workshop and the ISHAGE 2001 meeting convened.

The next meeting will be held in historic Québec City, Canada, from June 14<sup>th</sup> through 17<sup>th</sup>, 2001.

J'espère vous rencontrer a Québec l'année prochaine!

Iain Webb



L-R: Dennis Van Epps, Nexell Therapeutics; Gilles Clappison, Lyon France; Assia Eljaafari, Lyon, France

## What's Inside

ISHAGE 2000 Meeting - San Diego, California, USA .....	1
"Did You get the Most from the Annual Meeting?" .....	2
More ISHAGE 2000 Pictures .....	3
From the President's Desk .....	3
From the Editor's Desk .....	4
Stem Cell Transplantation Symposium Moves to Heidelberg .....	5
Meeting Announcement .....	5
United States DHHS Press Release Concerning Protections for Human Research Subjects .....	6
DHHS Public Meeting .....	7
Regulation of Blood Products in Australia .....	8
Good Clinical Practice (GCP) Explained .....	9
Upcoming Meetings .....	10
Tech Talk .....	11
ISHAGE 2000 Election Results .....	12
Cytotherapy Editorial Board Reviews the Journal's First Eighteen Months .....	13
Just the FAHCTs .....	14
Contributing Authors & Telegraft Editorial Board .....	15
ISHAGE GMP 2000 Workshop .....	17
Employment Ads .....	18

# “Did You get the Most from the Annual Meeting?”



Thanks to the help of the ISHAGE Head Office, we did get some information on the views of the participants at our annual meeting in San Diego. And without hesitation, I think that we can start with the conclusion that the meeting was a great success, both in attendance and ratings.

## High Ratings for the San Diego Meeting

Despite the evaluation forms being “somewhat” extensive, due to the character of the CME accreditation system, 45 participants took the time to give their personal opinion. The speakers in the plenary sessions, technical breakfasts, workshops and simultaneous sessions were all rated excellent to outstanding! Moreover, the overall quality of the program was rated 4.3 on a scale from 5 (= excellent) and 1 (= poor). The quality of the hotel and conference rooms also scored high: 4.45. This greatly reflects the rumors in San Diego of a general feeling that the participants were very appreciative of the annual meeting, which was very well organized: “Chapeau pour ISHAGE-Head Office” (“Are we going to Quebec in Canada next year)? Moreover, the general program did meet their objective (4.3), so they did get the most out of the meeting!

## Suggested Improvements

Of course, one can argue that only the very satisfied participants were ranking the sheets, since only the “happy” few worked their way through the evaluation sheets. But, you know better than that; people who are unhappy generally grab the opportunity to let their negative energy flow. Were there no general remarks to help us improve the meeting? Yes, the

most overwhelming theme in the comments appeared to be the need to break the workshops into smaller interactive and more lab-based, technical sessions. I personally think that that is the challenge for the next meeting. Some participants regretted the lack of outlines from a considerable number of speakers, I would say, no problem, consider it done! Others would like to see improvement in the quality of the posters; a comment made for the membership to work on! However, the overall quality of the oral presentations was more than excellent.

## ISHAGE Best Abstract Award

The selection of the ISHAGE best abstract award was this year again a tough task for the committee members. Out of 9 nominations selected by the scientific committees, we finally selected Scott Burger from the University of Minnesota, USA for an outstanding presentation entitled: Thymidine kinase transduction and expansion of allogeneic T-lymphocytes for management of graft-versus-host disease. This study in the field of gene therapy and cell selection showed the way to go in cytotherapy; it was a lot of work, but necessary to bring research into the field of clinical application.

So, for the next ISHAGE meeting, it will be a difficult task to exceed the success of this year’s meeting, but that is also a challenge. You can help by sending excellent papers to the journal and contribute by submitting new “hot” data for the Quebec meeting. Maybe you will win the best abstract award this time.

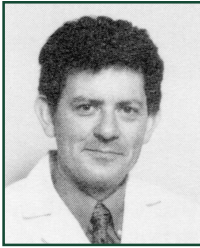
*Ineke Slaper-Cortenbach*

## More ISHAGE 2000 Meeting Pictures



### Captions:

1. ISHAGE 2000 delegates enjoying Nexell tour.
2. Malcom Brenner and Jean Winter
3. ISHAGE 2000 Registration
4. Malcolm Brenner and Edwin Horwitz
5. L-R: Chris Chun, Scott Merryweather, Steve Konings, Doug Padley, Barb Davies, Mary Molter, Kevin Bundy, Erin Merryweather
6. L-R: Joan Garcia, Gunnar Kvalheim, Klaus Pantel



## From the President's Desk

Malcolm Brenner, MB, PhD

*As outlined below, Dr. Malcolm Brenner has resigned as ISHAGE President. Dr. Robert Negrin, President Elect, has now become President. A new President Elect will be selected in an upcoming election. Comments from the outgoing and incoming Presidents are included below.*

### From Dr. Brenner's Desk

This is my last column as President of the Society, as I am handing over this position to Rob Negrin, who also comments below.

This has been an exciting year for our field and for the society. The increasing realization that marrow derived cells can potentially contribute to a multiplicity of non-hematopoietic tissues means that the practice and applications of stem cell manipulation will likely undergo major changes over the next decade. This shift has led us to begin pursuing the adoption of a new name for the society that more accurately reflects these changing circumstances. The new name, *The International Society for Cytotherapy*, would also mirror the name of the society's own new journal, *Cytotherapy*, edited by Nancy Collins and Adrian Gee. After some start-up distribution problems, *Cytotherapy* is now hitting its stride and by publishing a range of original and review articles and meeting summaries, we plan that it will keep our

members fully abreast of all that is relevant. We have also extended the society's interests in *ex vivo* gene therapy. This is an area that has received a considerable boost with the successful treatment of immunodeficient patients in France, and the appreciation that *in vivo* gene therapy may be more hazardous than anticipated. I believe that all these positive developments were well reflected at our annual meeting in San Diego. Although I helped organize this event, and so cannot be considered a disinterested observer, these new developments seemed to generate a genuine atmosphere of excitement and optimism – that was not exclusively fuelled by alcohol or Prozac!

Our society still faces formidable challenges, however. Continuing litigation with Mary Ann Liebert Publishers remains a financial drain, while increased regulatory demands and oversight is placing an ever-growing burden on our members, and will stifle

innovation if unchecked. Dealing effectively with these issues requires a substantial time commitment. In June of this year, I became President-elect of the *American Society of Gene Therapy*. While this has in the past been a largely ceremonial post, the problems of clinical gene therapy have made this a much more high profile and demanding position. After extensive consideration, we decided that the *International Society for Cytotherapy* deserved an experienced President who would not be distracted by major obligations to any other society. Under the circumstances, Rob Negrin graciously agreed to assume the Presidency a year earlier than usual. I know that Rob shares my vision of the society's future, and I look forward to continuing to work with him, with the Executive Committee and with the membership as a whole to ensure the continued success and expansion of the International Society for Cytotherapy.

### From Dr. Negrin's Desk

Our Society has benefited greatly from the energy and insight of Malcolm Brenner during his tenure as President of ISHAGE. The meeting in San Diego set the standard for future meetings of our society. New and exciting directions in cellular therapeutics were identified as well as comprehensive coverage of our field. Clearly, our society faces critical challenges, yet will continue to serve a central role in the dissemination of new knowledge, ideas, techniques

and information necessary to the field of hematopoietic cell transplantation and cellular therapy. Cytotherapy and the Telegraft have become established voices, organization of the next general meeting of the Society in Quebec City from June 14-17, 2001 as well as satellite meetings of other topics throughout the year are well underway. I look forward to my time as torch carrier for our Society and value all of your input with respect to new ideas,

directions and comments. I am personally grateful to Malcolm for his wonderful leadership not to mention good humor during the past year. Please join me in thanking Malcolm and we look forward to his continued participation in our Society. I am personally more than ever committed to the goals of the Society and look forward to working with all of you to broaden our horizons and further our collective mission.

## A New President and a New Name

Dr. Malcolm Brenner, who was to remain President of ISHAGE for another year will be unable to complete his term. Dr. Brenner is also the incoming President of the American Society of Gene Therapy. In the wake of the gene therapy related issues at the University of Pennsylvania last year, the demands of this position have increased to such a level that Dr. Brenner cannot be President of both societies. Consequently, he has handed the reins over to Dr. Rob Negrin, the ISHAGE President Elect. Dr. Negrin, based at Stanford University Hospital in California, has worked with the society for many years and is sure to make this a smooth transition. Congratulations and best wishes to Dr. Negrin and thanks to Dr. Brenner for all his hard work.

This transfer is being made at a pivotal time for the society. At the ISHAGE meeting in San Diego, it was decided to pursue changing the name of the society to the International Society for Cytotherapy. A new slate of officers was recently elected and the journal has survived its growing pains and is ready to flourish. Behind the scenes, many individuals contribute their time and energy to carry out the business of the society. Without them, things would grind to a halt. Further information about the new officers and committee members, as well as the journal, are provided in the election report and Cytotherapy Editorial Board report in this issue.

However, despite all the positive changes and progress, obstacles to success still persist. The litigation launched by the publisher of the society's previous journal remains the main burden that we continue to bear. We will do so, but it will take the continued efforts of our new President as well as the many others that give of their time to the society to get the society past this significant problem.

## Telegraft Editorial Board Membership

Joan Garcia from Barcelona, Spain has agreed to become the newest member of the Telegraft Editorial Board. He is joining as Moya Berli from Oslo, Norway is leaving our group. I am looking forward to Joan's contributions and will miss Moya's. Please join me in thanking Moya for her excellent work these past few years. Moya will continue her extensive involvement with ISHAGE in other areas.

## After the Meeting

The program of this year's ISHAGE meeting demonstrated that the activities and interests of our members are becoming increasingly diverse. As outlined in the annual meeting reports in this issue, significant scientific advancement is being made and was shared with all attendees in a variety of sessions with different formats. In particular, the sessions on mesenchymal stem cells generated much interest and discussion both during and after the meeting. Attendees went away from the meeting



and returned to their own facilities with a sense of excitement stemming from these developments.

## Regulations Evolve

In San Diego, when not discussing the progress in the field, attendees were often found discussing the regulations surrounding these advances. In the United States, the increasingly rigorous application of regulations and review of clinical trial practices continue. FDA and NIH are continuing to discuss more stringent regulations concerning not only gene therapy, but all cell and tissue related procedures. Similarly, the Department of Health and Human Services has announced its intention to review and strengthen the protection of clinical trial participants through renewed attention to Good Clinical Practices (GCPs). Particular attention is being paid to potential conflicts of interest. In this issue we have reproduced a relevant press release from May of this year and notification concerning a public meeting this month, both addressing this issue. No summary of this meeting was available when this issue went to press. Further discussion of GCPs is included in the article from Marlies Van Hoef.

Other steps are being taken that impact our laboratories in a more immediate way. According to a Chicago Tribune story on August 9<sup>th</sup>, FDA's proposed rule requiring registration of cell and tissue processing establishments will come into effect early in 2001. All labs would need to register and report their activities every six months. The original federal register notice of this proposed rule may be found at the following internet address: <http://www.fda.gov/cber/genadmin/tissuepro.pdf>. Not surprisingly, the regulatory framework for cellular therapy is also in evolution in other countries. For example, as outlined by Miles Prince in this issue, new regulations are also being proposed in Australia.

As the field continues to move forward and new advances in cellular therapy are discovered, we will continually have new challenges, obstacles and regulations to deal with. With the continued efforts of our new President and the society officers, committee members and head office staff, the International Society for Cytotherapy will be prepared to meet these challenges.

*Iain Webb*

# Stem Cell Transplantation Symposium Moves to Heidelberg

The 8<sup>th</sup> Annual International Symposium entitled Recent Advances in Hematopoietic Stem Cell Transplantation was held in Heidelberg, Germany from May 4-6, 2000. The office for Continuing Medical Education of the University of California San Diego provided arrangements for obtaining CME credits as well as excellent administrative and organizational support. Dr. Edward D. Ball, Chief, Division of Blood and Marrow Transplantation and Dr. Ping Law, Director, Stem Cell Laboratory, University of California San Diego, chaired the Organizing Committee with Dr. Anthony Ho, Chairman, Department of Internal Medicine V, Heidelberg University.

## Various Topics Discussed

While the first seven symposia were held in San Diego, the Meeting became truly international with this year's venue in Heidelberg, Germany. As expected, the meeting drew a heavier participation from European scientists and clinicians. The scientific content of the conference was provided by internationally

renowned experts, and included basic research as well as clinical applications. The efforts and contributions of each member of the organizing committee resulted in smooth and open discussions on all topics. The most up-to-date research data on hematopoietic stem cells, such as molecular control mechanisms, plasticity of pluripotent stem cell surface phenotypes, as well as homing and self-renewal of pluripotent and committed stem cells, were presented and discussed. Discussion of clinical applications of hematopoietic stem cells had been broadened to include immune competent components such as T cells and dendritic cells, as well as novel methods and procedures to harness the therapeutic potential of the immune sequelae of allogeneic transplantation. The strength of immune ablation, doses of different cell types, and the degree of chimerism were important topics. Disease specific controversies in autologous and allogeneic transplantation were discussed using latest clinical results. Updates of transplantation using alternative sources of hematopoietic

stem cells, such as cord blood and mismatched related donors, were provided. The application of hematopoietic stem cell transplantation in autoimmune diseases also received special attention in this meeting.

## Next Year's Symposium

The sunny weather of Heidelberg during the Symposium was enjoyed by everyone. The history and medieval atmosphere of the city greatly enhanced the meeting. The Mayor of Heidelberg gave a welcoming speech to all participants at the general reception the first evening, beginning a successful conference. Next year, the 9<sup>th</sup> Symposium will again be held in San Diego from March 29-31, 2001. Conference information will be available later this year from UCSD CME office and on their website. We look forward to the participation of everyone in the various areas of hematopoietic stem cell research and clinical applications.

*Anthony Ho*

## Meeting Announcement

Somatic Cell Therapy Meeting & Workshop; May 3-6, 2001. South Seas Plantation, Captiva Island, FL. Conference Chair: Dr. Stephen J. Noga. For further information contact John Hopkins University, Office of Continuing Medical Education at 410.955.2959 and watch for more details on the ISHAGE website: [www.ishage.org](http://www.ishage.org)

# United States DHHS Press Release Concerning Protections for Human Research Subjects

HHS Secretary Donna E. Shalala today announced several new initiatives to further strengthen protections of human research subjects in clinical trials, including those involving gene transfer. The department's actions are designed to heighten government oversight of biomedical research and to reinforce to research institutions their responsibility to oversee their clinical researchers and institutional review boards (IRBs). "In the last few years, we've seen dramatic advances in the effort to find new therapies for cancer and other diseases, and we've taken new steps to protect the safety of patients in clinical trials," Secretary Shalala said. "But the explosion in biomedical research has also brought new challenges, as more researchers are becoming involved in commercial ventures that may create new ethical dilemmas. Today's actions are designed to further strengthen government oversight of all biomedical research, including gene transfer research, and to reinforce institutions' and researchers' responsibility to follow internationally accepted ethical standards and federal guidelines."

The actions taken by HHS today focus on expanding education and training for all clinical investigators and IRB members and staff; enhancing the informed consent process and ensuring more vigilant monitoring and oversight; ensuring that researchers understand and comply with federal conflict of interest regulations; and pursuing efforts to provide the Food and Drug Administration (FDA) with additional enforcement tools to enhance its oversight role. They also respond to a request from President Clinton to examine ways to ensure patient safety and increase public confidence in clinical trials.

## Supporting IRBs is Essential

Secretary Shalala also stressed the responsibility of the leaders of universities and academic medical centers to oversee IRBs. "Recent reports of problems in gene transfer trials have highlighted the new pressures facing researchers, IRBs, and research institutions themselves," she said. "Protecting patient safety, and ensuring informed consent, is a shared responsibility. I want to urge university presidents, leaders of our academic medical centers, and others involved in biomedical research to take a hard look at oversight of clinical trials, their partnerships with the private sector, their own ethical guidelines, and the support and guidance they give their IRBs. Public confidence in clinical trials is essential to the continued advances in medicine we all hope to see in the next century."

"We must ensure that patients are well protected and

properly informed when they choose to enroll in a clinical trial," said FDA Commissioner Jane E. Henney, M.D. "By maintaining high standards and requiring that all investigators adhere to them, we can be sure that the nation's biomedical research enterprise will continue to earn the trust of research subjects."

"We are constantly exploring new and effective ways to enhance systems to strengthen protections for human research subjects without unduly burdening IRBs," added Ruth Kirschstein, MD, acting director of the National Institutes of Health (NIH). "These new initiatives should significantly improve communication among researchers, patients and the IRBs."

## Issues Addressed

Today's announcements address the following issues:

- **Education and Training.** HHS will undertake an aggressive effort to improve the education and training of clinical investigators, IRB members, and associated IRB and institutional staff. NIH, FDA and the Office for Protection from Research Risks (OPRR) will work closely together to ensure that all clinical investigators, research administrators, IRB members and IRB staff receive appropriate research bioethics training and human subjects research training. Such training will be a requirement of all clinical investigators receiving NIH funds and will be a condition of the NIH grant award process and of the OPRR assurance process.
- **Informed Consent.** NIH and FDA will issue specific guidance on informed consent, clarifying that research institutions and sponsors are expected to audit records for evidence of compliance with informed consent requirements. For particularly risky or complex clinical trials, IRBs will be expected to take additional measures, which, for example, could include third-party observation of the informed consent process. The guidance will also reassert the obligation of investigators to reconfirm informed consent of participants upon the occurrence of any significant trial-related event that may affect a subject's willingness to participate in the trial.
- **Improved Monitoring.** NIH will now require investigators conducting smaller-scale early clinical trials (Phase I and Phase II) to submit clinical trial monitoring plans to the NIH at the time of grant application, and will expect investigators to share these plans with IRBs. The NIH already requires investigators to have such plans and they also require large scale (Phase III) trials to have Data and Safety Monitoring Boards (DSMBs). For research on medical products intended to be marketed, FDA will also issue guidelines for DSMBs that will delineate the relationship between DSMBs and IRBs, and define when DSMBs should be required, when they should be independent, their responsibilities, confidentiality issues, operational issues and qualified membership.

*Continued on page 7*

*Continued from page 6*

- **Conflict of Interest.** NIH will issue additional guidance to clarify its regulations regarding conflict of interest, which will apply to all NIH-funded research. HHS will also hold public discussions this summer to find new ways to manage conflicts of interest so that research subjects are appropriately informed, and to further ensure that research results are analyzed and presented objectively. In addition, these public discussions also will focus on clarifying and enhancing the informed consent process. Based on these public forums, NIH and FDA will work together to develop new policies for the broader biomedical research community, which will require, for example, that any researchers' financial interest in a clinical trial be disclosed to potential participants.
- **Civil Monetary Penalties.** HHS will pursue legislation to enable FDA to levy civil monetary penalties for violations of informed consent and other important research practices-up to \$250,000 per clinical investigator and up to \$1 million per research institution. While FDA can currently issue warning letters or impose regulatory sanctions that halt research until problems are rectified, financial penalties will give the agency additional tools to sanction research institutions, sponsors and researchers who do not follow federal guidelines. As an interim step, NIH, OPRR and FDA will work more closely together to enforce and target existing penalties.

### **Improving the Informed Consent Process**

For more than 50 years, HHS agencies have been committed to protecting individuals from possible abuse or harm in clinical trials and to ensuring that prospective and enrolled participants understand the potential risks and

benefits, if any, of being a research subject. In 1972, OPRR was created as part of NIH to ensure the safety and welfare of people who participate in research sponsored by HHS. In 1981, FDA followed up by revising its regulations to require written informed consent in all studies of products that FDA regulates. Today, FDA, NIH and OPRR continue to play important and complementary roles in overseeing research and protecting the human subjects involved. More resources may be needed to fully implement these responsibilities in the years ahead.

These agencies work with IRBs to ensure that people who agree to participate in studies fully understand the nature of the research and willingly consent to participate. This "informed consent" process requires that potential participants be given an explanation of purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed and their potential risks and benefits, and identification of any procedures that are experimental. Research institutions such as academic health centers and universities have the ultimate responsibility to ensure that clinical investigators adhere to this informed consent process.

Note: For other HHS Press Releases and Fact Sheets pertaining to the subject of this announcement, please visit our Press Release and Fact Sheet search engine at: <http://www.os.dhhs.gov/news/press/>.

*DHHS Press Release - Tuesday, May 23, 2000*

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# **DHHS Public Meeting**

The department of Health and Human Services will hold a two-day public meeting August 15-16, 2000, to discuss the issue of financial conflict of interest and human subject protections in clinical research. The meeting will emphasize the informed consent process and how it might be clarified and enhanced in dealing with issues related to financial conflict of interest. This conference responds to one of the five main actions outlined by HHS Secretary Donna E. Shalala in her May 23 announcement of steps being taken to strengthen human subject protection during clinical trials.

The conference will provide information on current Public Health Service and Food and Drug Administration regulations, guidelines and guidance, and will include examples of how the issue of financial conflict of interest has been handled by a number of institutions, Institutional Review Boards, and clinical investigators. The conference also will solicit public comment on the issues of surrounding financial conflict of

interest and human subject protections. The input received during the meeting will provide information for HHS to develop additional guidance to implement current regulatory requirements.

The meeting will be held in the Natcher Conference Center on the Bethesda, MD, campus of the National Institutes of Health. The Office of the Secretary, HHS, NIH, the Food and Drug Administration, and the Centers for Disease Control and Prevention are the sponsors of the meeting. Additional information about the conference is available at the following website: <http://www.aspe.hhs.gov/sp/coi/index.htm>. You may register on-line at the website, or you may contact Mark Brown by phone at 240-632-0519, by fax at 240-632-0519, or by e-mail at [mbrown@masimax.com](mailto:mbrown@masimax.com).

*DHHS Press Release - Monday, August 7, 2000*

# Regulation of Blood Products in Australia: A New Approach in the Making

## Background

In Australia the licensing to produce Pharmaceutical products falls under the Therapeutic Goods Act 1989 which is overseen by the Therapeutic Goods Administration (the closest equivalent to the FDA). This is a Commonwealth Act to which all individual States must comply. A central principal of this Act is the requirement to license manufacture of any 'Therapeutic Goods'. Human Tissues fall within this Act and in 1991, it was determined that any blood collection centre supplying plasma to a fractionation centre for further manufacture required such a license.

To obtain such a licence from the Therapeutic Goods Administration (TGA), Codes of Good Manufacturing Practice (GMP) must be followed and until recently, two Codes existed: one for 'Blood and Blood Products' (1992, 1995) to regulate plasma destined for processing and the other for 'Human Tissues' (1995). Currently, all blood collection centres and tissue banks must be licensed and are regularly audited for compliance.

## Motivation for Change

The Australian Government has determined the need to eradicate the inconsistencies within the current regulations which only cover certain tissues (plasma, viable tissues stored in tissue banks) and has taken the approach that all fresh blood products and stored viable tissues should be regulated. This change is (not unreasonably) driven by a need to broadly improve the quality (and consequently safety) by which all blood and tissue products are obtained, stored and distributed. Furthermore, there is a recognition of the need to develop appropriate standards in-line with those overseas (e.g. Council of Europe Guidelines).

## Implementation of Change

Although the Therapeutic Goods Act is vague, the critical regulatory requirements are set out in a list of regulations which can be modified from time-to-time by approval of Parliament and subsequently ratified by the Minister for Health and Aged Care. Very recently, the Regulations relating to blood products have been modified to not only include plasma for fractionation but all fresh blood products. Furthermore, the regulations for human tissues have also been modified and extended to include various levels of manipulation from minimal to highly manipulated products.

The primary document to incorporate these regulatory changes is the new Code of GMP for 'Human Blood and Tissues' which will supersede the two previous Codes.

The approach of the TGA is one of 'Risk Management' and will be targeting its efforts, in the first instance, to upgrading the licensing of blood collection centres.

## Impact of Change on Blood Collection Centres

The only blood collection service in Australia is the Australian Red Cross Blood Service (ARCBS) which is a not-for-profit organisation. There are no private collection centres. A number of not-for-profit cord blood banks also exist. As the ARCBS is already GMP-licensed for plasma collection, and given the normal method of processing of fresh blood to obtain such plasma, the impact of these changes will be relatively modest compared to the anticipated changes required by hospitals.

## Impact of Change on Hospitals

The new Regulations and Code encompass most activities of blood and tissue collection and storage within hospitals. The changes have the potential to impact in three broad ways: **1) Storage of Products:** Currently in Australia all public and private laboratories wishing to store blood products must be accredited by an independent self-regulating authority (NATA). The TGA is currently determining if this NATA accreditation meets the appropriate quality standards determined by the TGA. It is widely anticipated that in most instances it will not and most laboratories will need to upgrade their quality systems to meet any new requirements negotiated between NATA and the TGA. Alternatively, another accreditation body may be utilized to undertake this not insubstantial task; **2) Collection of Blood Products** (red cells, platelets, blood/marrow stem cells, granulocytes): fortunately, the new Regulations specifically exempt the collection of 'autologous or directed blood products' at non-ARCBS centres. Consequently, little change from current practice is anticipated; **3) Manipulation of Cells/Tissues:** in this instance, regulation will depend on the 'level' of manipulation of the cellular product.

The cost of implementation will not be inconsiderable and to date, there has been no indication as to how this will be resourced.

In practical terms, it is anticipated that hospital issues will be addressed in turn after TGA audit and licensing of the ARCBS blood collection centres (commencing in late 2000) and subsequently, cord blood banks. However, we understand

*Continued on page 9*



*Continued from page 8*

that hospitals intending to process highly-manipulated blood/tissue (i.e. purging, ex vivo expansion and gene therapy) will come under scrutiny by the TGA very soon and be expected to be GMP compliant. The new Regulations relating to blood (including stem cells) have recently been gazetted and the Regulations relating to viable tissue are soon to follow. However, when licensing and auditing is to commence remains unknown, although we are informed that the TGA will adopt a flexible approach in order to ensure compliance to GMP.

In regards to Gene Therapy (Very High Level Manipulation), all trials must comply with the Gene and Related Therapies Research Advisory Panel regulations (RAC-like equivalent) and will be subject to full regulation

by the TGA including Technical Master Files and Clinical Trial Exemption (CTX) certification. In regards to *ex vivo* cell manipulation, each clinical trial must be submitted to the TGA on an individual trial basis and obtain a Clinical Trial Notification (CTN) or CTX certification.

### Summary

No one would disagree that the objective of these changes is to improve the quality of blood and tissue products. In broad terms they are necessary to address the inconsistencies that currently exist. However, the process will be slow and ultimately must be appropriately resourced, an issue that to date has been inadequately addressed.

*H. Miles Prince*

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# Good Clinical Practice (GCP) Explained

The last issue of the *Telegraft* discussed GCP guidelines. GCP guidelines apply to all clinical studies conducted in the scope of biopharmaceutical product development. The gene therapy related death at the University of Pennsylvania last year has renewed FDA's attention to safety in clinical research and study conduct according to GCP. In this article the background, content and goals of GCP are briefly explained and the value of application of GCP in product development-related and investigator-initiated clinical research is addressed.

## Introduction

GCP is the terminology for guidelines that describe processes for clinical research and data generation in biopharmaceutical product development. Such regulations differed in the past substantially between the various countries as well as the three market regions Europe, Japan and the United States. This resulted in duplication of clinical research related to product development and non-economic use of animal, material and human resources. In 1992 regulatory and industry representatives of these market regions agreed to harmonize the standards during a process called the International Harmonization Conference (ICH). This resulted in 1997 in acceptance of the ICH GCP by regulatory agencies of the three markets. The ICH GCP describe operational aspects of clinical research related to product development. These guidelines are not equal to product development regulations, neither do they guarantee scientifically sound clinical research, nor do they offer a meaningful tool to evaluate best treatment strategies.

## Founders of the ICH Process

The founders of the International Conference on Harmonization of Good Clinical Practice are in Europe the European Commission and the European Federation for Pharmaceutical Industry Associates, in Japan the Ministry of Health and Welfare and the Japan Pharmaceutical Manufacturers Association and in the USA the Food and Drug Administration and the Pharmaceutical Research and Manufacturers of America.

## Goal

The ICH GCP guidelines intend to prevent inefficient use of trial resources on a global basis. These standards unify design, conduct, recording and reporting of trials that involve human subjects such that data generated in one region can be used for product registration in another region. They intend to streamline processes in clinical research to enhance safety and efficacy. The guidelines provide recommendations for Institutional Review Board (IRB) or Independent Ethics Committee (IEC), investigator, sponsor, clinical trial protocol content and amendments, investigator brochure content and essential other documents for conduct of a clinical trial. They support the logistics of product development-related clinical trial conduct, data generation and data collection and harmonize processes for: informed consent; compliance with protocol; adverse event reporting; study audits and study monitoring.

*Continued on page 10*

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## Restrictions of the ICH GCP

The value of the guidelines are restricted to logistics as they do not guarantee development of quality products, explain regulations for product development/approval in the various regions/countries, imply scientifically meaningful clinical research, guarantee efficient use of resources or protect against deceptive business practice. The ICH GCP emphasize the *endpoints* (trial process/data generation) but not the *start points* of logical, strategic and efficient product development.

## Impact of ICH GCP on Academia

The ICH GCP guidelines provide standards for quality assurance and control of clinical research related to product development at study sites. These standards can be used to develop standard operating procedures (SOPs). Clinical research according to the ICH GCP guidelines and adherence to the SOPs might not only be of benefit to quality assurance in clinical research related to product development but might also facilitate investigator-initiated study conduct. Implementation of SOPs and compliance with the standards by a study site might offer the site the advantage of becoming a preferred study site above centers not complying with study conduct according to the ICH GCP guidelines. The FDA will put emphasis on trial conduct according to the ICH GCP guidelines to enhance safety and quality assurance of clinical trials and to reduce the risk of medical errors. The European Parliament recently released an amended proposal for implementation of GCP in clinical research involving human beings according to ICH. The process of SOP development according to the ICH GCP guidelines should be centralized as well as education of centers in implementation of SOPs. The transplant community should take charge of this effort. To achieve that goal central organization of clinical research in blood, marrow and cell transplants on a continental basis would be of tremendous support (BMT 1999; 24:1265, the Hematology Journal, in press).

## Conclusion

The ICH GCP guidelines have been established to reduce duplication of clinical research efforts involved in data generation for biopharmaceutical product development in the market regions Europe, Japan and the USA. The ICH GCP guidelines support harmonization of protocol outlay, study conduct, reporting and recording of study results. The ICH GCP guidelines do not guarantee quality product development neither scientifically sound clinical research, but facilitate quality assurance and control to improve safety in clinical research. Development of SOPs according to the ICH GCP guidelines, implementation and compliance to these SOPs may

not only benefit logistics in clinical research related to product development but also logistics in investigator-initiated clinical research. Central organization of clinical research in blood, marrow and cell transplants is in progress and will facilitate this effort (BMT 1999; 24:1265, the Hematology Journal, in press).

*Marlies Van Hoef*



## Upcoming Meetings

28th World Congress of the International Society of Hematology (ISH). August 26-30, 2000. Toronto, Ontario, Canada. Contact: ISH 2000 Secretariat, 275 Bay Street, Ottawa, ON, Canada, K1R 5Z5. Tel: 613-238-9998; Fax: 613-236-2727.

"Cell Culture and Separations for Cell and Gene Therapies". September 25-28, 2000. San Diego, California, USA. Co-sponsored by The American Society of Mechanical Engineers (ASME) and the International Society for Hematotherapy and Graft Engineering (ISHAGE). Limited Participation. Contact: David Delucia, BioSynergy. Phone: 603-448-4908; E-mail: delucia@sover.net.

25th International Symposium on Blood Transfusion. October 4-6, 2000. Martinihal, Groningen, Netherlands. Contact: Blood Bank Noord Nederland, P.O. Box 1191, 9701 BD Groningen, NL. Tel: 31-50-369-5555; Fax: 31-50-369-5556. E-mail: srbnn@worldonline.nl

ISHAGE GMP 2000 Workshop. November 30, 2000. San Francisco, California. Contact: ISHAGE Head Office, 777 West Broadway, Suite 609, Vancouver, BC, Canada, V5Z 4J7. Tel: 604-874-4366; Fax: 604-874-4378. E-mail: ishage@malachite-mgmt.com; Website: www.ishage.org

42nd ASH Annual Meeting. December 1-5, 2000. San Francisco, California. Contact: The American Society of Hematology, 1900 M Street NW, Suite 200, Washington, DC, USA, 20036. Tel: 202-776-0544; Fax: 202-776-0545; E-mail: ASH@hematology.org, Website: www.hematology.org

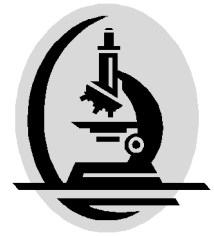
3rd International Symposium on Minimal Residual Cancer. February 16-18, 2001. Hamburg, Germany. Contact: CPO Hanser Service, PO Box 1221, D-22882 Basbittel. Tel: +49.40.670.88.20; Fax: +49.40.670.32.83. Email: hamburg@spo-hanser.de; Website: www.mrc-symposium.de.

The 9th Annual International Symposium on Recent Advances in Hematopoietic Stem Cell Transplantation. March 29-31, 2001. San Diego, California.

Somatic Cell Therapy Meeting & Workshop. May 3-6 2001. Captiva Island, Florida. Contact: Office of Continuing Medical Education, Johns Hopkins University School of Medicine, Turner 20, 720 Rutland Avenue, Baltimore, MD, USA, 21205-2195. Tel: 410-955-2959; Fax: 410-955-0807. Email: cmenet@jhmi.edu; Website: www.med.jhu.edu/cme.

7th International ISHAGE Annual Meeting. June 14-17, 2001. Quebec City, Quebec, Canada. Contact: ISHAGE Head Office, 777 West Broadway, Suite 609, Vancouver, BC, Canada, V5Z 4J7. Tel: 604-874-4366; Fax: 604-874-4378. E-mail: ishage@malachite-mgmt.com; Website: www.ishage.org

# Tech Talk... Validation and Qualification - Initial and On-going



Process and method validation and instrument qualification, like other elements of GMPs, have become central concepts for cell engineering laboratories, helping reveal or prevent operational problems. Validating a new procedure or instrument can be a rigorous undertaking, however, and once completed it is tempting to consider the matter closed. However, on-going qualification is also an essential aspect of laboratory control, as an abstract presented at the recent ISHAGE annual meeting demonstrates.

## LN2 Vapor Shippers

Alonso, Regan and Wall, of the St. Louis Cord Blood Bank, described their experience in transporting cryopreserved umbilical cord blood units using LN2 vapor shippers (*JMF Alonso III, DM Regan, DA Wall. Importance of ongoing qualification as well as validation of liquid nitrogen shippers used for interinstitutional transport of frozen hematopoietic stem cells. ISHAGE 2000*). LN2 vapor shippers are widely used for transporting cryopreserved cells and tissues by commercial package shipping services. Umbilical cord blood banks, and other centralized cell engineering laboratories, rely on vapor shippers to transport cryopreserved grafts to transplant centers.

The length of time a vapor shipper maintains an appropriately low temperature is obviously critical. Shipping cryopreserved grafts within the United States typically involves one day or more of transit time, while transport overseas may require several days. After transport, vapor shippers sometimes are used to store cryopreserved grafts for additional days prior to transplant. The vapor shippers used by the St. Louis Cord Blood Bank, and numerous other cell engineering laboratories, are specified by their manufacturer to maintain cryogenic temperatures for 7-10 days, which would seem more than adequate for transport.

In their abstract, Alonso *et al.* described using five LN2 vapor shippers to transport over 120 cryopreserved cord blood units. All five shippers were validated to hold their LN2 charge and temperature for at least five days. In practice, the authors found that products shipped within the United States involved transit times up to 48 hours, and up to six days for products sent internationally.

## Initial Validation is not Enough

The sentinel event in this case was a product that arrived at its destination thawed after only 24 hours in transit - well within the five-day validated storage period. In response, the laboratory began on-going qualification of the vapor shippers upon their return to the bank. Surprisingly, three of the five vapor shippers maintained the target transport temperature for less than 48 hours.

Alonso *et al.* noted that "To visual inspection from the top and inside, there was no visible container damage. However, compromised shippers exhibited dents to the exterior, flaring at the base, a more concave shape to the bottom's interior, a widening of the bottom's perimeter, and bubbling on the surface of the LN2 after charging was completed". As one would expect, the compromised shippers also demonstrated unusually rapid decrease in weight after being filled with liquid nitrogen.

Evidently, damage sustained in shipping compromised the integrity of the interior chamber. LN2 leaking from the chamber would have accounted for the bubbles observed after filling, the subsequent rapid decrease in overall shipper weight, and the shorter effective cryopreservation period.

## On-going Qualification is Required

It is sobering to consider that these shippers -which are intended specifically for the rigors of transporting cryopreserved grafts- had undergone a careful initial validation, and yet had failed after seemingly little use. Experiences like this one teach a healthy skepticism, though. Having learned not to accept a manufacturer's assurances at face value, we validate, and rely on our data. However, even this is not enough - weeds creep into any untended garden, however orderly it may once have been. Instruments drift out of calibration, and devices can be subtly damaged. The reassuring data from six months ago cannot reflect more recent events. The laboratory must be vigilant, using calibration and qualification in an on-going effort to prevent and detect operational problems.

*Scott Burger and Kathy Loper*

# ISHAGE 2000 Election Results

Two hundred and forty-two ISHAGE members cast their votes in the 2000 election campaign. Final results were tallied and announced at the annual meeting in San Diego, CA, USA. The following election winners are to be congratulated, and deserve our support as they carry out their duties.

Office	Name	Affiliation
Secretary	Rob Ploemacher, PhD	Erasmus University, Rotterdam, Netherlands
Australasia Regional VP	David Ma, MD	University of Sydney, St. Vincent's Hospital, Sydney Garvan Institute, University of New South Wales
Japan Regional VP	Yasuo Ikeda, MD	Keio University School of Medicine
Advisory Board Rep (MD/PhD)	Scott Burger, MD	University of Minnesota. Fairview Medical Center
Advisory Board Rep (Tech)	Carlos Lee, BSc	Baylor College of Medicine, Houston, Texas
Europe Regional VP Elect	Wolfram Brugger, MD	University Medical Center Tuebingin, Germany

A special welcome to Savatore Siena, who is a new face on the ISHAGE executive committee. Salvatore has served the past two years as regional Vice President Elect. A special thanks to those who have served their term to completion. We thank you for an excellent job and look forward to seeing you all in leadership roles again. Members who have completed their terms this year include:

Gunnar Kvalheim, MD, PhD  
Shigetaka Asano, MD  
L. Bik To, MD  
Diana Worthington-White  
Diane Krause, MD, PhD  
Donna Rill, MT (ASCP)  
Karen Schepers MS, MT (ASCP)

Europe Regional V.P.  
Japan Regional V.P.  
Australia Regional VP  
Secretary  
Elected member of ISHAGE advisory board  
Elected member of the ISHAGE advisory board  
Elected member of the ISHAGE advisory board

A few of the candidates were interviewed and this author is pleased to share excerpts with our members:

If Carlos Lee, who enjoys all kinds of outdoor activities, could change one thing about cellular and tissue engineering, he would "shift the focus of the field from GMP type facilities to improvements in documentation, process/equipment improvements and development." If he could change one thing about the ISHAGE society, he would "have a strong program for staff training, development, and credentialing; provide more technical workshops, audioconferences, and a help/support/resource desk!"

Scott Burger happily reports that he has become an avid cyclist and though this is a new obsession, he recently broke 1000 miles on his bicycle! One thing that is really important to Scott is that our society strives to firmly establish *Cytotherapy* as a real foundation and premier resource of all cellular therapies.

*Kathy Loper*

# Cytotherapy Editorial Board Reviews the Journal's First Eighteen Months

A meeting of the *Cytotherapy* Editorial Board was held Friday, June 16, 2000 to review the status of the official ISHAGE journal after the first 18 months of publication. The issues of *Cytotherapy* that had been distributed before the annual meeting (Volume 1, Issues #1-6, and Volume 2, Issue #1) contained 36 original peer-reviewed papers, three letters to the editor on scientific issues, summaries and/or abstracts of five ISHAGE organized or associated meetings, reports of the activity of the ISHAGE Legal and Regulatory and the Stem Cell Evaluation Committees, a report of the FDA-NCI Workshop on Tumor Vaccines and the USP draft chapter on Cell and Gene Therapy Products. In its first year of publication the journal was accepted for indexing in INDEX MEDICUS/MEDLINE, the Institute for Scientific Information (Science Citations, ISI Alerting Services, Current Contents/Life Sciences and Current Contents/Clinical Medicine) and Chemical Abstracts.

## Late Journal Distribution Resolved

Co-editor-in-chief Adrian Gee summarized the current status of the publishing firm, Isis Medical Media. Isis Medical Media continues to be the traditional publishing arm of the company that has become IsisMednet, to reflect its growing strength in Internet publishing. Dr. Gee presented a report from the Director of Isis, John Harrison and the Journals Editor, Harriet Milles that explained the problems in typesetting and production that resulted in late distribution of the journal in the latter part of 1999 and early 2000. These problems have been resolved, and with the publication of Volume 2, Issue #3 immediately prior to the meeting, Isis has brought the production schedule up to date. The report outlined future developments in advertising, promotion and marketing that should increase circulation of the journal. Included in the materials was a letter from the publisher to *Cytotherapy* subscribers that was distributed with Volume 2, Issue #1. At Dr. Gee's suggestion, a direct e-mail connection has been added to the ISHAGE website for members to report problems in journal delivery.

## Upcoming Journal Content

Co-Editor-in-Chief Nancy Collins thanked the Editorial Board for their aid in the peer review of manuscripts. She noted that besides original research, *Cytotherapy* has published important transplant-related documents or reports from the new European Joint Accreditation Committee of ISHAGE-Europe and EBMT, and the US Pharmacopeia. In the coming months, articles are scheduled on the US Food and Drug Administration's proposed Good Tissue Practices and the US Centers for Disease Control Blood and Marrow Safety Guidelines. Other upcoming issues of *Cytotherapy* will contain a summary of the NETCORD/FAHCT Cord Blood Standards, abstracts of the July 2000 meeting of the Bone Marrow Transplant Scientists of Australasia, abstracts of the 3<sup>rd</sup> International Symposium on Minimal Residual Cancer, and increased coverage of regional transplant activities. The Board discussed several suggestions to encourage submission of papers, streamline the review process by using e-mail, and solicit areas for targeted issues from ISHAGE committees.

## Guidelines for Manuscript Submissions

Editorial Assistant Jean Winter asked the board members for submission of books to be reviewed in the journal and experts to serve as reviewers. Other suggestions concerning manuscript submissions were: (1) Authors telephone/fax number and e-mail address should always be supplied with the manuscript, (2) Microsoft PowerPoint may be used for graphs and diagrams only, (3) Photographic images should be submitted as JPEG, GIFF, or TIFF images (on disk, by e-mail, or CD-ROM), or as PDF files, or as original hard copy only. Photographic images should not be imbedded into Microsoft Power Point or Word documents, as the resolution of the image is too low for quality reproduction.

Nancy Collins

## JACIE Visit

Dr. Alvaro Urbano-Ispizua, Executive Officer of the Joint Accreditation Committee of ISHAGE-Europe (JACIE) along with other members representing the Spanish government authority and inspectors of blood banks and cell processing laboratories in Spain, recently visited the FAHCT Office. The purpose of the visit was to observe a FAHCT inspection as well as meet with the staff of the FAHCT Office to discuss the accreditation process. JACIE has adopted the FAHCT standards and is in the initial stages of implementing the inspection and accreditation process in Europe.

## Standards Revision

A committee to revise the FAHCT Standards has been organized. The subcommittee will be requesting comments from members of ISHAGE and ASBMT. Interested individuals may also send comments directly to the FAHCT Office.

## Inspector Quality Improvement

An evaluation of the inspection process and continued education of inspectors are the goals of the FAHCT Inspector Quality Improvement Subcommittee chaired by Adrian Gee, Ph.D. The committee will review the current inspectorate and assess quality, thoroughness, and timeliness of inspections. Questions regarding interpretation of standards will be referred to the Standards Revision subcommittee.

## Accredited Facilities

Thirty-six BMT centers have earned voluntary FAHCT accreditation in the following categories:

### *Autologous peripheral blood progenitor cell transplantation, including collection and laboratory processing:*

- Baptist Cancer Center/Response Oncology, Memphis, TN
- Cancer & Hematology Centers of Western Michigan, Grand Rapids, MI
- Fox Chase Cancer Center, Philadelphia, PA
- IMPACT Center of Middle Tennessee, Nashville, TN
- Our Lady of the Lake Regional Medical Center, Baton Rouge, LA
- Providence Portland Medical Center, Portland, OR
- University Medical Center, Lubbock, TX
- Via Christi Regional Medical Center, Wichita, KS

### *Autologous marrow & peripheral blood progenitor cell transplantation, including collection and laboratory processing:*

- Memorial Medical Center, New Orleans, LA

### *Autologous peripheral blood progenitor cell collection, marrow and peripheral blood progenitor cell transportation, processing and storage:*

- Pacific Northwest Regional Blood Services, Portland, OR

# Just the FAHCTs



### *Allogeneic & autologous peripheral blood progenitor cell transplantation, including collection and laboratory processing.*

- University of Chicago, Chicago, IL

### *Allogeneic & autologous peripheral blood progenitor cell collection, marrow and peripheral blood progenitor cell transportation, processing and storage.*

- The Canadian Blood Services, Ottawa, Ontario, CAN

### *Allogeneic & autologous peripheral blood progenitor cell collection, progenitor cell processing, cryopreservation, transport and storage.*

- New York Blood Center, Valhalla, NY

### *Allogeneic & autologous marrow and autologous peripheral blood progenitor cell transplantation, including collection and laboratory processing:*

- Children's Hospital of Philadelphia, Philadelphia, PA

### *Allogeneic & autologous marrow, peripheral blood progenitor cell transplantation, including collection and laboratory processing:*

- Baylor University Medical Center, Dallas, TX
- Cardinal Glennon Children's Hospital, St. Louis, MO
- Children's Memorial Hospital, Chicago, IL
- Christiana Care Health Services, Newark, DE
- Fox Chase-Temple Bone Marrow Transplant Program, Philadelphia, PA
- H. Lee Moffitt Cancer Center, Tampa, FL
- Hackensack University Medical Center, Hackensack, NJ
- Indiana Blood and Marrow Transplantation, Indianapolis, IN
- Palmetto Richland Memorial Hospital/University of South Carolina, Columbia, SC
- Rush Presbyterian - St. Luke's Medical Center, Chicago, IL
- Stanford University Medical Center, Stanford, CA
- Texas Transplant Institute, San Antonio, TX
- University of Alabama at Birmingham, AL
- University of California-San Diego, CA
- University Medical Center, Tucson, AZ
- University of Minnesota Hospital, Minneapolis, MN
- University of Texas, MD Anderson Cancer Center, Houston, TX
- University of Utah Health Sciences, Salt Lake City, UT
- Wayne State Univ./Karmanos Cancer Institute, Detroit, MI

*Continued on page 15*

*Continued from page 14*

*Allogeneic & autologous marrow, peripheral blood progenitor cell and cord blood cell collection, processing and transplantation:*

- University of Louisville Blood and Marrow Transplant Program, Louisville, KY

Facilities Registered	182
Facilities Inspected	109
Accredited	36
Inspected/Pending Accreditation	73
Inspections in Process	23
Facilities Completing Checklists	50
Inspectors Trained	306

*Allogeneic & autologous marrow and peripheral blood progenitor cell transplantation, including cell collection and processing, and allogeneic human cord blood collection, transportation and storage in association with the Civitan Regional Blood Center.*

- Shands Hospital - University of Florida, Gainesville, FL

*Allogeneic & autologous marrow and peripheral blood progenitor cell transplantation, including bone marrow collection, and also the PBPC collection and laboratory processing services provided by contract with the Canadian Blood Services.*

- Ottawa General Hospital, Ottawa, Ontario, CAN

Linda Miller



FAHCT Accreditation Office: (402) 595-1111  
[www.fahct.org](http://www.fahct.org)

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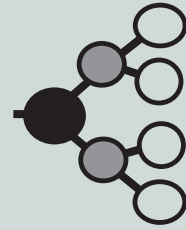
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**ISHAGE Telegraft** is published by the International Society for Hematotherapy and Graft Engineering.

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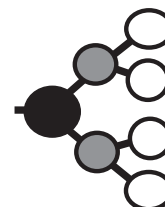
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# International Society for Hematotherapy and Graft Engineering

## GMP 2000 WORKSHOP

Thursday, November 30, 2000  
Marriott, San Francisco, California  
7:30am - 7:00pm



### PROGRAM

**Introduction and Overview**

*Scott Rowley - Fred Hutchinson Cancer Research Center*

**Facility Design, Validation and Monitoring**

*Doug Padley - Mayo Foundation*

**Equipment & Software Validation and Monitoring**

*Scott Burger - University of Minnesota*

**Process Validation and Control**

*Carolyn Keever-Taylor - Medical College of Wisconsin*

**Personnel Training, Competency & Proficiency Testing**

*Carlos Lee - Baylor College of Medicine*

**Quality Control and Release Testing**

*Adrian Gee - Baylor College of Medicine*

**Implementation of cGMP in a:**

- **Hospital Based Laboratory**  
*Elizabeth Read - N.I.H.*
- **Centralized Processing Facility**  
*Robert Preti - Progenitor Cell Therapy*
- **Implementation of cGMP in a Gene Vector Facility**  
*Donna Rill - Baylor College of Medicine*

**FAHCT Standards & Inspections**

*Phyllis Warkentin - University of Nebraska Medical Center*

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*See also the ISHAGE website at [www.ishage.org](http://www.ishage.org)*

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The Coordinator will manage all of the outpatient clinical activities of the New Jersey Cord Blood Bank (located in the University Medical Complex) under the supervision of the Medical Director; will work with and supervise Collection Specialists for NJCBB, design and implement parent/donor education programs, visit collection sites and practitioners offices, and promote outreach PR programs. Excellent oral and written communication skills; BS in Nursing; five years experience in clinical nursing; Experience in developing and implementing training and educational programs. Competitive salary, Excellent benefits package.

Please send resume and three references to: C. Tule, **Coriell Institute for Medical Research**, 401 Haddon Ave., Camden, NJ, 08103; Fax: 856-964-0254; E-mail: tuleci@umdnj.edu. **Coriell Institute is an Affirmative Action/Equal Opportunity Employer.**



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Please send resume and three references to: **Coriell Institute for Medical Research**, 401 Haddon Ave., Camden, NJ, 08103; Fax: 856-964-0254; E-mail: tuleci@umdnj.edu. **Coriell Institute is an Affirmative Action/Equal Opportunity Employer.**

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Hoxworth Blood Center is an NMDP recruitment and collection center and also supports the processing of approximately 150 human umbilical cord bloods monthly for a for-profit cord blood bank.

The Director will be responsible for all laboratory operations and will be expected to develop an active clinical and basic sciences research program. Candidates should possess MD, PhD, or MD/PhD degrees and meet the requirements for assistant or associate professor.

Send CV (including control #) and names of three references to:

Susan L. Wilkison, EdD  
Hoxworth Blood Center  
University of Cincinnati Medical Center  
PO Box 0055  
Cincinnati, OH, 45267-0055

Applications review will continue until position is filled.

# 13th Annual Bioprocess Technology Seminars

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FEATURING

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**TOPICS COVERED** (see website for complete list)

- Introduction, Applications, and Needs - *William Miller, Northwestern University*
- Leukocyte Antigen Expression and Cell Identification by Flow Cytometry - *James G. Bender, Nexell Therapeutics*
- Positive and Negative Selection for Cell Separations - *Adrian Gee, University of Texas, M.D. Anderson Cancer Center*
- Panel Discussion: Comparison of Cell Separation Technologies - lead by *Adrian Gee, University of Texas M.D. Anderson Cancer Center; James Bender, Nexell Therapeutics; Stefan Miltenyi, Miltenyi Biotec; Rod Monroy, Eligix; Jeffrey Chalmers, Ohio State University*
- Selection and Design of Gene Therapy Vectors - *Bernard Massie, National Research Council of Canada*
- Hematopoietic Cell Expansion I: Cells and Metabolism - *E. Terry Papoutsakis, Northwestern University*
- Applications of Mesenchymal Stem Cells - *Robert Deans, Osiris Therapeutics, Inc.*
- Immunotherapy and Dendritic-Cell Therapies - *Madhusudan Peshwa, Dendreon, Inc.*
- Hematopoietic Cell Expansion II: Physicochemical Environment and Modeling - *William Miller, Northwestern Univ*

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**UltraGen, Inc.**, a biotech company that provides HLA matched, genetically screened umbilical cord blood products for various immunotherapeutic purposes is seeking personnel for several positions in our state of the art laboratory facility located in Central New Jersey. Our Cord Blood Laboratory collects and processes umbilical cord blood and placental by-products for allogeneic purposes.

### Technical Supervisor:

Manages the daily operations of the Cord Blood Collection and Processing facility. At least five years of experience working in a Blood Bank, Blood Donor Center, HLA, immunology or hematopoietic progenitor cell processing laboratory required. Experience performing flow cytometry procedures and cell sorting, highly desirable. Supervisory experience required. Relocation expenses available.

### Technical Specialist:

Responsible for overseeing the daily operations of the Flow Cytometry section at our Cord Blood Collection and Processing facility in addition to performing other laboratory procedures. Knowledge of the specialized principles and techniques of flow cytometry and cell sorting required. At least two to four years of experience working in a flow cytometry laboratory required. Experience performing CD34 testing using the ISHAGE protocol highly desirable. Relocation expenses negotiable.

### Technical Specialist:

Responsible for overseeing the daily operations of the Cord Blood Processing section at our Cord Blood Collection and Processing facility in addition to performing other laboratory procedures. Knowledge of the specialized principles and techniques of hematopoietic progenitor cell processing required. At least two years of experience working in a hematopoietic progenitor cell processing laboratory required.

Send resume and cover letter to Beverly Robinson via e-mail at [par9005@netscape.net](mailto:par9005@netscape.net) or fax at 973-252-6208.



*When you work at Dana-Farber Cancer Institute, you're working to save lives. Vital to the search for a cure, each position offers a unique challenge. A challenge to share your passion for life.*

## Quality Assurance Manager

Dana-Farber Cancer Institute's Cell Manipulation Core Facility has an immediate opening for a qualified and motivated individual to oversee quality improvement activities in all areas of operations as well as review policies and procedures for compliance with applicable federal and state regulations, and accreditation agency standards. The core facility supports clinical trials in stem cell transplantation and anti-cancer immunotherapy at area hospitals. Applicants must have extensive working knowledge of FAHCT, AABB, CLIA, and FDA requirements for hematopoietic progenitor and other cell processing to include gene therapy. Ability to work in a team environment as well as effective interpersonal, oral, and written communication skills required. Must be skilled in observation and review of documentation and detail-oriented. Computer experience a must. Bachelor's degree with a major in a field of science required. At least 5 years of experience in a clinical cell processing laboratory, blood bank service, biotechnology or pharmaceutical manufacturing company also required. Three years of progressively responsible experience in QA and FDA regulated environment backgrounds, with direct responsibility for compliance inspection required. Interested applicants please send resume and letter of interest to: Darlys Schott, Dana-Farber Cancer Institute, Dana 530, 44 Binney Street, Boston, MA, 02115. Phone: (617) 632-2251; Fax: (617) 632-5759; Email: darlys\_schott@dfci.harvard.edu. We are an Affirmative Action/Equal Opportunity Employer.



## HEMATOLOGY AND ONCOLOGY CENTER

### MANAGEMENT OPPORTUNITY

Cook Children's Hematology and Oncology Center has an opportunity for a qualified Medical Technologist (ASCP certification is required) as the Hematology/Oncology Laboratory Supervisor. The successful candidate will join a team of two other full time Senior Medical Technologists while providing support to the growing Hematology and Oncology Center. He/she must possess strong progenitor cell processing experience as well as supervisory/management experience.

Currently, our program consists of nine full time physicians, seven of which are located in the Hematology and Oncology Center in Fort Worth, one in Midland and one in El Paso. Annual activity includes over 100 new oncology diagnoses, 40+ progenitor cell transplants and 10,000+ clinic visits. Our center is consistently among the top five in patient accrual to Pediatric Oncology Group cooperative trials. We participate in Phase I and pharmaceutical studies. We are an accredited National Marrow Donor Program facility providing apheresis, collection and transplant services. The lab specializes in autologous, allogeneic and unrelated progenitor cell transplants using cryopreservation, T-Cell depletion, positive selection and a variety of other techniques for the preparation of products for infusion. Other responsibilities will include routine hematologic services as well as administrative functions.

Cook Children's Medical Center offers a atmosphere of compassion for the children we serve. We offer competitive benefits package and salary structure. Fort Worth is an outstanding community, an excellent place to live and work. If this opportunity interests you, please contact: Teresa Clark at 817-885-4411; e-mail address: teresac@cookchildrens.org or fax your resume to 817-885-4396, attention Teresa Clark.