Program

Scale-Up and Manufacturing of Cell-Based Therapies IV

January 18 - 22, 2015
Hyatt Regency Mission Bay Hotel
San Diego, CA USA

Conference Co-Chairs
Thomas Brieva
Celgene Cellular Therapeutics, USA
(ISCT Process and Product Development Subcommittee)

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University College London, United Kingdom

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Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.

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*Project Management Support provided by Maria Fernanda Masri, University College London*
Previous conferences in this series:

**Scale-Up and Manufacturing of Cell-Based Therapies**
January 11-13, 2012
San Diego, California

*Conference Chairs:*
Chris Mason, University College London, UK
Lars Nielsen, University of Queensland, Australia
Greg Russotti, Celgene, USA

**Scale-Up and Manufacturing of Cell-Based Therapies II**
January 21-23, 2013
San Diego, California

*Conference Chairs:*
Chris Mason, University College London, UK
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Greg Russotti, Celgene, USA

**Scale-Up and Manufacturing of Cell-Based Therapies III**
January 5-9, 2014
San Diego, California

*Conference Chairs:*
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Conference Sponsors

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Lonza Bioscience
Pall Corporation
PBS Biotech
Pluristem Therapeutics Inc.
Sartorius Stedim Biotech
University of Washington Heart Regeneration Program
Sunday, January 18, 2015

18:00 – 19:30   Conference check-in (Mission Foyer)
19:30 – 20:30   Welcome Reception with appetizers (Mission Terrace)

Notes

- Technical sessions will be in the Mission Ballroom.
- Poster Sessions will be in the Regatta Pavilion.
- Breakfasts and dinners will be in the Regatta Pavilion. Lunches will be on the Mission Terrace.
- Audiotaping, videotaping and photography of presentations are prohibited.
- Speakers – Please have your presentation loaded onto the conference computer prior to the session start (preferably the day before).
- Speakers – Please leave at least 3-5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your mobile telephones to vibrate or off during technical sessions.
- Please write your name on your program so that it can be returned to you if lost or misplaced.
- After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.
Monday, January 19, 2015

08:00 – 09:30  Breakfast
09:00 – 09:45  Conference check-in (Mission Foyer)
09:45 – 09:55  Welcome
  Conference Chairs
  ECI Liaison (Barry Buckland)
09:55 – 10:00  Introduction to Plenary 1
10:00 – 11:00  **Plenary 1**
  **Manufacturing & supply chain: No longer a bridesmaid science**
  Stephen Ward, Cell Therapy Catapult, United Kingdom

  **Session 1: Scale-out, scale-up**
  Chairs: Yan Li (Florida State University)
  Ben Fryer (University of Washington)

11:00 – 11:25  **Making the choice to scale up**
  Donald Powers (invited), Janssen, USA
11:25 – 11:50  **Advancing pluripotent stem cells: Scaling-up when scaling-out won't do**
  Larry Couture (invited), Beckman Research Institute of City of Hope, USA
11:50 – 12:10  **Scalable production of human mesenchymal stem/stromal cells in microcarrier-based stirred culture systems**
  Ana Fernandes-Platzgummer, University of Lisbon, Portugal
12:10 – 12:30  **Production of autologous T cells for multi-center trials**
  Marc Better, Kite Pharma, USA
12:30 – 14:00  Lunch

  **Session 2: Product characterization, process monitoring, and potency**
  Chairs: Steven Bauer (FDA)
  Stephen Minger (GE)

14:00 – 14:25  **Genomic and epigenetic assays for quality control of stem cells**
  Jeanne Loring (invited), The Scripps Research Institute, USA
14:25 – 14:45  **Clinical-scale expansion of human periosteum-derived mesenchymal stem cells in a hollow fiber bioreactor and assessment of their in vivo bone forming activity**
  Toon Lambrechts, KU Leuven, Belgium
14:45 – 15:05  **Measuring the dielectric properties of human adipose derived stem cells**
  Binil Starly, North Carolina State University, USA
15:05 – 15:25  **Strategies to measure and enhance cell retention and vascular support characteristics of MSCs for ischemic injury**
  Ivan Wall, University College London, United Kingdom
15:25 – 16:00  Coffee break
  *Sponsored by Lonza Bioscience*
Monday, January 19, 2015 (continued)

16:00 – 16:05  Introduction to Plenary 2

16:05 – 17:05  **Plenary 2**
Mesenchymal stem cell therapy for protection and repair of injured vital organs and tissues
Martin Yarmush, Rutgers University, USA

17:05 – 18:45  **Poster Snapshots**
Chairs: Suzanne Farid (University College London)
        Peter Fuhrken (Cellular Dynamics International)

19:00 – 20:30  Dinner

20:30 – 22:00  **Poster Session with dessert and Social Hour**
Chairs: Suzanne Farid (University College London)
        Peter Fuhrken (Cellular Dynamics International)
Tuesday, January 20, 2015

07:30 – 09:00  Breakfast
Organizing Committee Breakfast (Crown Point Room)

Session 3: Process development, process characterization, and process integration
Chairs: Bob Deans (Athersys) (ISCT Commercialization Committee Member)
Jeff Chalmers (Ohio State University)

09:00 – 09:25  Process characterization, control, and cGMP operational challenges for autologous cell therapies
Matt Croughan (invited), Keck Graduate Institute, USA

09:25 – 09:45  Human cardiac stem cells characterization for rational therapy design: Exploring analytical proteomics platforms
Patrícia Gomes-Alves, ITQB-UNL/IBET, Portugal

09:45 – 10:05  Process development to drive the consistency of mesenchymal stem cell production from multiple donors
Thomas RJ Heathman, Loughborough University, United Kingdom

10:05 – 10:25  Cell therapy bioprocess economics and optimization: Lifecycle perspective
Suzanne Farid, University College London, United Kingdom (ISCT Business Models and COGs Subcommittee Member)

10:25 – 10:45  Evaluation of microcarrier-based processes as a scalable cell culture platform for MultiStem® cells
William Milligan, Newcastle University, United Kingdom

10:45 – 11:15 Coffee break
Sponsored by GE Healthcare

11:15 – 11:20 Introduction to Plenary 3

11:20 – 12:20  Plenary 3
Material matters in cell therapy product development
Fred Miesowicz, Argos Therapeutics, USA

12:30 – 14:00 Lunch

Session 4: Downstream: From purification to the patient
Chairs: Karen Coopman (Loughborough University)
Kim Warren (Lonza)

14:00 – 14:10 Session introduction by sponsor: Aby J. Mathew, BioLife Solutions, Inc., USA ISCT Commercialization Committee Member

14:10 – 14:35  A design of experiments workflow for low DMSO and serum-free cryopreservation of human bone marrow-derived mesenchymal stem cells harvested from microcarriers
Andrew Picken (invited), Loughborough University, United Kingdom

14:35 – 15:00  Single use technologies requirements: What standards? and what are the current trends?
James Vogel (invited), The Bioprocess Institute, USA
Bringing cell therapy up to patient bed side – The development of an automated and controlled point of care cell thawing device
Lior Raviv, Pluristem Therapeutics, Ltd., Israel

A novel filtration device for point of care preparation of cellular therapies
Rui Tostoes, University College London, United Kingdom

Coffee Break

Introduction to the ISCT Process and Product Development Subcommittee and Plenary 4
Dominic M. Clarke, Charter Medical, USA
Eytan Abraham Lonza, ISCT Process and Product Development Subcommittee Members

ISCT-Sponsored Plenary 4
Challenges in measurements for cell therapy products
Anne Plant, NIST, USA

Session 5: Industrial Highlights: Cell therapy manufacturing and implementation solutions
Chair: Kim Bure (Sartorius)

Biopreservation and biologistics considerations for GMP manufacturing
Aby J. Mathew, BioLife Solutions, Inc., USA (ISCT Commercialization Committee Member)

Designing a manufacturing system and disposable set(s) for scalable cell therapy production
Dominic M. Clarke, Charter Medical, USA (ISCT Process and Product Development Subcommittee Member)

Challenges and solutions for scalable manufacturing of anchorage dependent stem cells for allogeneic cell therapies
Brian Lee, PBS Biotech, Inc., USA

Efficient propagation of stem cells in stirred-tank reactors on novel microcarrier substrates
Mark Szczypka, Pall Life Sciences, USA

Poster Session / Social Hour
Chairs: Suzanne Farid (University College London)
Peter Fuhrken (Cellular Dynamics International)

Free evening /Dinner on your own
Wednesday, January 21, 2015

07:30 – 09:00  Breakfast  
Student Networking Breakfast (Crown Point Room)

**Session 6: Physical and biochemical regulation of cells in bioprocesses**  
Chairs: Dave Schaffer (University of California, Berkeley)  
Wen Bo Wang (Cellular Dynamics International)

09:00 – 09:25  
Differentiation of induced pluripotent stem cells – Scale-up and migration to bioreactors  
Peter Fuhrken (invited), Cellular Dynamics International, USA

09:25 – 09:45  
Temporal and spatial control of the neural commitment of human pluripotent stem cells as suspension aggregates  
Maria Margarida Diogo, University of Lisbon, Portugal

09:45 – 10:05  
SIRT1 is a critical regulator of proliferation, survival, and E/MK lineage commitment and differentiation of bipotent K562 cells  
Mark Duncan, Northwestern University, USA

10:05 – 10:25  
Controlled generation of hematopoietic progenitor cells from human pluripotent stem cells using microenvironmental cues  
Nafees Rahman, University of Toronto, Canada

10:25 – 10:45  
Actin-mediated contractility and functional activation in three-dimensional aggregates of human mesenchymal stem cells  
Teng Ma, Florida State University, USA

10:45 – 11:15  
Coffee break  
*Sponsored by Fisher BioServices and Life Technologies*

**Session 7: Vector production and scale-up for cell therapy applications**  
Chairs: Otto Wilhelm Merten (Genethon)  
J. Fraser Wright (CHOP)

11:15 – 11:40  
Vectorization of targeted nucleases for clinical-scale genome engineering  
Thomas Gaj (Invited), University of California, Berkeley, USA

11:40 – 12:05  
Lentiviral vector production from stable cell lines - The next generation meets the last  
John Gray (Invited), Audentes Therapeutics, Inc., USA

12:05 – 12:30  
The use and advantages of adenoviral vectors for genome editing with engineered nucleases  
Manuel Gonçalves (invited), Leiden University, The Netherlands

12:30 – 12:50  
Production of HIV-1 Gag-VLPs in 293 cells for protein delivery  
Bruno Gailliet, Université Laval, Canada

12:50 – 14:00  
Lunch

14:00 – 16:00  
Free time / Networking
Session 8: Automation and next generation biomanufacturing methods
Chairs: Kim Bure (Sartorius)
        Chris Hewitt (Loughborough University)

16:00 – 16:25 Mass production of human mesenchymal stem cells: An approach based
on stirred single-use bioreactors
Regeine Eibl-Schindler (invited), University of Zurich, Switzerland

16:25 – 16:50 Innovating technologies and processes to enable next generation
manufacture of cell based therapies
Robert Thomas (invited), Loughborough University, United Kingdom

16:50 – 17:10 Enzyme and inhibitor free sub-culturing of hES cells in suspension
cultures using the nanobridge system
Peter P. Gray, The University of Queensland, Australia

17:10 – 17:30 Cryopreservation without DMSO: One size doesn’t fit all
Sandro Matosevic, Akron Biotechnology, USA

17:30 – 17:50 A new paradigm of commercial manufacturing for autologous cell therapy
Dolores Baksh, GE Healthcare, USA (Member, ISCT Commercialization
Committee)

17:50 – 18:05 Break

18:05 – 18:15 Introduction to the NIST/AmTech Cell Manufacturing Consortium,
Robert M. Nerem, Georgia Institute of Technology, USA

18:15 – 18:45 Award lecture
Perspectives on Cell Therapy: Past, Present and Future
Kim Warren, Lonza, USA

19:30 – 21:30 Conference Banquet

21:30 – 22:30 Social Hour
Thursday, January 22, 2015

08:00 – 09:30     Breakfast and departures
Scale-Up and Manufacturing of Cell-Based Therapies IV

Poster List

1. Comparability and standardisation of scalable automated hMSC and pluripotent cell culture
   Peter Archibald, Loughborough University, United Kingdom

2. Serum-free expansion, harvest and preservation of mesenchymal stem cells from a scalable microcarrier process
   Thomas RJ Heathman, Loughborough University, United Kingdom

3. From pilot scale to mass production: Bioreactors scale-up in cell therapy industry
   Nadav Eshkol, Pluristem, Israel

4. Going the extra mile: How do we move bioreactors into manufacturing?
   Siddharth Gupta, Lonza Walkersville, USA

5. Optimal agitation conditions for human MSC expansion on microcarriers in stirred-tank bioreactors
   Céline Martin, Université de Lorraine, France

6. CFD large eddy simulation of the hydrodynamics of stirred mini-bioreactors operating with stem cell culture mixing conditions
   Marie-Laure Collignon, Université de Liège, Belgium

7. Clinic to commercial: Developing Scalable single-use closed-system solutions for continuous cell therapy manufacturing success
   Dominic M. Clarke, Charter Medical, USA (Member, ISCT Commercialization Committee)

8. Upstream expansion solutions for stem cells
   Aletta C. Schnitzler, EMD Millipore, USA

9. Scalable xeno-free culture system for human induced pluripotent stem cell expansion
   Sara M. Badenes, Institute for Bioengineering and Biosciences, Portugal

10. Scalable production of tissue engineered microunits for bone regeneration using bioactive glass microspheres and dynamic culture conditions
    David De Silva-Thompson, University College London, United Kingdom

11. Integrated 3D bioprocessing for the expansion and recovery of a functional human MSC cell population with uncompromised regenerative potential
    Toon Lambrechts, KU Leuven, Belgium

12. Optimized manufacturing process to generate CAR-T cells for clinical trials
    Pradip Bajgain, Baylor College of Medicine, USA

13. Scale up and manufacture of human mesenchymal stromal cells in a single use bioreactor system
    Ian Gaudet, Progenitor Cell Therapy, USA
14. Acellular matrices derived from pluripotent stem cells modulated tissue development
Yan Li, Florida State University, USA

15. Characterizing the response of human cells to processing by membrane separation operations using an ultra scale-down methodology
Maria Fernanda Masri, University College London, United Kingdom

16. Production of HIV-1 Gag-VLPs in 293 cells for protein delivery
Bruno Gaillet, Université Laval, Canada

17. Harvesting culture-derived platelets with functional activity from blood stem and progenitor cells
William M. Miller, Northwestern University, USA

18. Scale up of a hollow fiber bioreactor system for large scale cellular product manufacturing
Kristina Fuerst, Terumo BCT, USA

19. Efficient expansion of human mesenchymal stem cells (hMSCs) on Corning® Enhanced Attachment microcarriers using a continuous agitation protocol.
Jennifer Weber, Corning Incorporated, USA

20. Impact of allogeneic stem cell manufacturing decisions on cost of goods and process robustness
Tania D. P. Chilima, University College London, United Kingdom

21. An automated, functionally closed system for down-stream processing of large-scale cellular product manufacturing
Brian J. Nankervis, Terumo BCT, USA

22. A life cycle cost assessment of the cell production for clinicals in Japan
Takuro Kamiya, Waseda University Academic Solutions Corporation, Japan

23. Assembly of hES cell clusters in cell cultivation bags
Arvind Pradip, Novo Nordisk A/S, Denmark

24. Development of low-cost chromatographic alternatives to magnetic affinity cell sorting (MACS)
Christine Mueller, University of Loughborough, United Kingdom

25. Three dimensional culture of human mesenchymal stem cell improves stem cell property via energy metabolism regulation
Teng Ma, Florida State University, USA

26. Data management in cell therapy development and manufacturing
Hasan Saleheen, GE, USA

27. Engineered phosphate bioactive glass microcarriers for hBM-MSCs expansion and osteodifferentiation
Carlootta Peticone, University College London, United Kingdom

28. Expansion of mesenchymal stem cell derived from umbilical cord matrix in a fixed bed and stirred tank bioreactor: A comparative study
Amanda Mizukami, University of São Paulo, Brazil
29. **Towards standardized functional release assays for cell therapy candidates for ischemic injury**  
Fatumina Abukar, University College London, United Kingdom

30. **Impact of culture strategy on transcriptomic and metabolic profiles of human pluripotent stem cells**  
Patrícia Alves, iBET, Portugal

31. **Metabolic profiling of stem cell-derived human neural cells by 13C-NMR spectroscopy**  
Paula M. Alves, iBET/ITQB-UNL, Portugal

32. **Novel 3D co-culture strategy for the establishment of highly functional human hepatic cell models in bioreactors**  
Patrícia Alves, iBET, Portugal

33. **Scale up and recovery of a gammaretroviral vector**  
Timothy J. Langer, Kite Pharma, USA

34. **Filtration methodologies for the concentration and washing of human mesenchymal stem cells**  
Bárbara Cunha, ITQB-UNL/iBET, Portugal

35. **Manual vs. automated induced pluripotent stem cell bioprocessing: Process economics and optimisation**  
Michael Jenkins, University College London, United Kingdom

36. **An aqueous two-phase system strategy for the elimination of contaminating cell debris**  
Mirna González-González, Tecnológico de Monterrey, Mexico

37. **Human pluripotent stem cell expansion in the Xuri cell expansion system W25**  
Brian M. Davis, GE Global Research, USA

38. **Process modeling: A critical tool for process evaluation and development**  
Meagan O’Kane, Celgene Cellular Therapeutics, USA

39. **Production of recombinant AAV and scAAV vectors for alcoholism treatment: Inhibiting ALDH2 gene expression in human hepatoma cells**  
Anamaria C. Sanchez, University of Chile, Chile

40. **Process characterization of a Placental-Derived cell therapy utilizing quality by design strategies in preparation for process validation**  
Keith Wilson, Celgene Cellular Therapeutics, USA

41. **Screening study of key process conditions for anchorage dependent stem cell cultivation in scale-down model of vertical-wheel bioreactors**  
Daniel Giroux, PBS Biotech, Inc., USA

42. **Downstream solutions for scaling allogeneic stem cells**  
Aletta C. Schnitzler, EMD Millipore Corporation, USA

43. **Manufacturing set-up: Advancement and evolution of consumables for cell therapy production**  
Dolores Baksh, GE Healthcare, United Kingdom
Upcoming ECI Biotechnology Conferences

For complete details on the conferences below, please visit the ECI web site: www.engconfintl.org

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Advances in Optics for Biotechnology, Medicine, and Surgery XIV
An ECI Conference Series

June 14-17, 2015 Vail, Colorado, USA

The primary goal of this, the 14th conference in the series, is to bring together scientists, engineers and clinicians interested in the application of optics to biotechnology, medicine, and surgery.

Co-Chairs
- R. Leitgeb, Medical University of Vienna
- R. Levenson, University of California – Davis
- Laura Waller, University of California, Berkeley

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Biochemical and Molecular Engineering XIX
Engineering Next Generation Solutions
An ECI Conference Series

July 12-16, 2015 Los Cabos, Mexico

This 19th edition of the Biochemical and Molecular Engineering conference continues on a long tradition of bringing together the community around core topics associated with biochemical engineering such as advances in biomanufacturing, metabolic engineering and synthetic biology, protein aggregation and stability, cell culture engineering, molecular engineering and design, enzyme engineering and vaccine manufacturing, while highlighting emerging topics in the field.

Co-Chairs
- Theresa Good, National Science Foundation
- Gargi Seth, Intas Pharmaceuticals Ltd.

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Enzyme Engineering XXIII
An ECI Conference Series

September 6-10, 2015 St. Petersburg, Florida, USA

Co-Chairs
- Jon Stewart, University of Florida, USA
- Robert DiCosimo, DuPont, USA

The Enzyme Engineering Conferences were initiated in 1971 and have become the leading international forum for the discussion of new developments in enzyme technology and biocatalysis, putting an emphasis on emerging technologies and focusing on both the fundamental and practical aspects. The proposed scope and thrust of the conference will continue this tradition and will additionally focus on new developments in the field. This conference series typically draws international participation both from industry and academia.
Upcoming ECI Biotechnology Conferences

For complete details on the conferences below, please visit the ECI web site: www.engconfintl.org

Integrated Continuous Biomanufacturing II
An ECI Conference Series

November 1-5, 2015 Berkeley, California, USA

Co-Chairs
- Chetan T. Goudar, Amgen, Inc.
- Suzanne Farid, University College, London
- Christopher Hwang, Genzyme-Sanofi
- Karol Lacki, GE HealthCare

The second ICB conference in the series aims to build on the success of the inaugural 2013 event with an expanded scope which includes a review of the state-of-the-art technologies and emerging trends in upstream, downstream, and drug product unit operations. Topics such as facility design, financial modeling, control strategies, and quality and regulatory considerations will also be discussed. The ICB conference is intended to assemble a selected group of leading scientists and engineers from both academia and industry who are actively engaged in or are considering continuous bioprocessing.

Cell Culture Engineering XV
An ECI Conference Series

May 8-13, 2016 La Quinta (Palm Springs), California, USA

Co-Chairs
- Robert Kiss, Genentech, Inc.
- Sarah Harcum, Clemson University
- Jeff Chalmers, The Ohio State University

Since 1988, the Cell Culture Engineering conferences have been held bi-annually and have developed into the leading global venue for the academic, industrial and regulatory communities for intensive interactions and debates to create solutions for improving human health and life by enabling rapid development and high quality manufacturing of an ever increasing number of viral vaccines, recombinant proteins and monoclonal antibodies.

Vaccine Technology VI
An ECI Conference Series

June 12-17, 2016 Albufeira, Portugal

Co-Chairs
- Laura Palomares, UNAM, Mexico
- Manon Cox, Protein Sciences Corporation, USA
- Tarit Mukhopadhyay, University College London, UK
- Nathalie Garcon, GSK Vaccines, Belgium
Engineering Conferences International

Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program that has served the engineering/scientific community since 1962 as successor program to Engineering Foundation Conferences. ECI has received recognition as a 501(c)3 organization by the U.S. Internal Revenue Service and is incorporated in the State of New York as a not-for-profit corporation.

The program has been developed and is overseen by volunteers both on the international Board of Directors and international Conferences Committee. More than 1,400 conferences have taken place to date. The conferences program is administered by a professional staff and the conferences are designed to be self-supporting.

ECI Mission

To serve the engineering/scientific community with international, interdisciplinary, leading edge engineering research conferences

ECI Purposes

The advancement of engineering arts and sciences by providing a forum for the discussion of advances in the field of science and engineering for the good of mankind by identification and administration of international interdisciplinary conferences

To work with engineering, scientific and social science societies and the interested general public to jointly sponsor conferences and to take other actions that will foster complementary programming.

To initiate conferences that will have a significant impact on engineering education, research practice and/or development.

ECI Encouragement of New Conference Topics

The ECI Conferences Committee invites you to suggest topics and leaders for additional conferences and encourages you to submit a proposal for an ECI conference.

Ideally, proposals should be submitted from 18 to 24 months in advance of the conference although the staff can work on a shorter timeline.

The traditional format for an ECI conference is registration Sunday afternoon with technical sessions held each morning and evening through Thursday or Friday noon. Afternoons are used for informal gatherings, poster sessions, field trips, subgroup meetings and relaxation. This format has served well to build important professional networks in many areas.

ECI welcomes proposals for shorter conferences and for conferences which span weekends in order to reduce the number of working days participants are away from their offices.
ECI Works With You

ECI works with conference chairs in two complementary ways. First, an experienced member of the Conferences Committee acts as your technical liaison from the proposal stage through the conference itself. He or she is always available to consult with you on any conference issue.

Second, after your proposal has been approved by the Conferences Committee, the ECI staff will assume responsibility for the administration of the conference.

Your primary responsibilities will be recruiting the organizing committee, developing the technical program and securing third-party funding necessary to support the travel of key speakers.

The responsibilities of ECI's "full service" staff include -- but are not limited to -- the following:

- Recommend, negotiate, contract and make substantial deposits for housing, meals, meeting space, A/V equipment and tours.
- Maintain web sites for the conference and for submission of abstracts.
- Publicize via electronic and print media.
- Administer all finances including grants, contributions and purchase orders. (ECI makes grant funds available as soon as a grant is approved.) There is no need for chairs to set up a conference bank account or file tax returns for their conference.
- Process all applications and registrations.
- Produce bound program/abstracts book.
- Contract for the publication of print or electronic proceedings, if any.
- Provide on-site staff during the conference.

For more information, please contact the ECI Director at Barbara@engconfintl.org