



# NEWSLETTER

of the European Society for Animal Cell Technology

May 2008

## A Word from the Chairman

Florian Wurm

**E**SACT is fine - at least I did not hear any news that would make me nervous. Here are few issues that I wish to share with you in order to assure you.

### *Dublin 2009*

On May 12 I have had the chance to participate at an organizational meeting in Dublin – at the place where the conference will be held in about a year from now – and I ensure you, I have been enchanted! The setting is just marvelous; we will all be together in a very beautiful countryside hotel complex, within a most wonderful setting (3 golf courses, lakes, and the Irish landscape). The site is big enough so that all the delegates can stay there. The hotel itself feels very Irish with bars and restaurants that make you want to stay ... have a “pint” and have fun. Michael Comer’s team has done an outstanding job and now has the outlines of a superb scientific structure for the meeting combined with concepts for social events that will make the Dublin meeting, I am sure, an unforgettable event in 2009.

### *ESACT Award*

As was decided during our last XC meetings and discussed before during the last members assembly in Dresden - we wish to give to the ESACT Award (and lecture) a higher visibility and even connect it with a true monetary reward (modest). I quote here the first few words of the purpose of the award: The ESACT Cell Culture Technology Award is intended to recognize an outstanding contributor to the field of Animal Cell Culture Biotechnology. An important issue in this context was to define rules and regulations on the process for choosing the deserving person for this award. While all members of the XC have contributed to this process, I wish to give a lot of credit to Professor Terry Papoutsakis for his invaluable input and our Secretary Steph Grammatikos who did not give up and pushed the team to a final suggestion for two documents (one on definitions and criteria, the **Guidelines for the Award** and the other on **Guidelines for the Appointment of the Chair and the Award Committee**) that are now subject for

approval by the board. I will leave it up to Steph to explain in a few words what the basic philosophy of the process will be. The next step is the selection of the Chairman of the Award Committee who should be an eminent scientist and highly respected and an impartial member of our wider community. Here the board will, as we hope, come to a decision during our next XC meeting. In fact names have already been proposed that are most likely very familiar to most of you (I will not disclose them here for reasons of confidentiality).

### *Martin Fussenegger Recipient of the 2008 Merck & Co. Award in Cell Culture Engineering*

It is with great pleasure to inform you about the recent attribution of the prestigious Merck&Co Award in Cell Culture Engineering to our friend and colleague Martin Fussenegger. I quote from the laudatio: *Professor Fussenegger's research has had a large impact on both fundamental and applied aspects of cell culture engineering. He has advanced numerous new and creative technologies that have profoundly impacted the practice of cell culture operations. In a short period of time, Professor Fussenegger conceived and reduced to practice pioneering applications of molecular biology to the solution of several important cell culture problems. His work has been published in*

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Contributions should be sent to [elletter@esact.org](mailto:elletter@esact.org)  
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Animal Cell Technology

high visibility journals and applied broadly to the practice of cell culture technology for biopharmaceuticals production.

Nothing further to add – congratulations to you Martin – we are so proud of you!

Please also look at the laudatio given later on these pages ....

## ***JIN - our service offer to the industry and interested cell culture professionals for finding matching interests.***

The JIN is apparently becoming more and more successful and the website is heavily utilized. We are still looking, however, for sponsor companies who would help us to pay for the costly program that ESACT has supported since its establishment several years ago. In return for a sponsor contribution the logo of the sponsor company will be displayed on the web site.

→ <http://www.jin-esact.org>

### **ESACT is LinkedIn !**

Quite a large number of ESACT members, including some of the members of the executive committee seem to have put their profiles on the professional network LinkedIn, so we have recently created an ESACT group, which all the members are welcome to join.

Please go to my profile and click on the ESACT logo at the bottom of the page to join the group.

<http://www.linkedin.com/in/losberger>

or copy the link address below in your browser

<http://www.linkedin.com/groupInvitation?groupID=88108&sharedKey=42A79229EEBF>

*Christophe Losberger*

## ***Biogenerics / similars - workshop, training, etc.***

Europe has seen now the first approvals for biosimilars and we will soon see how this will affect the industry and the markets for the newcomers and those who have to defend the "originators". I have been invited to talk about processes at some recent biosimilar conferences (mostly attended by pharmacists and hospital doctors) and was amazed how little is known in general about the way protein pharmaceuticals are made. I am sure that this rapidly evolving field will also strengthen our role as an institution for reference science and technology.

With respect to training and workshop activity in addition to our regular ESACT meetings, I am still wondering what and if we are ready to embark into more work, especially designed for newcomers to our field. My understanding is that Quico (Professor Francesc Godia) and Paula Alves Marquez will put together a questionnaire for attacking this question.

## ***Proceedings on-line***

We soon hope to have our conference proceedings on-line which will be a great benefit for our members who look for key words and key papers. I believe that a lot of "new" papers at our conferences are actually not that new, but remakes of work that has been executed by a previous generation of scientists and that are somehow lost in the older proceedings. Here, a careful use of the old literature will probably bring some interesting insights.

In the hope that all you are all healthy, happy and productive, I remain, faithfully

*your chairman*

*Florian*

## **New members**

**C Losberger**

ESACT welcomes the following new members:

Bakker Wilfried

Netherlands Vaccine Institute

Eyer Kurt

University of Applied Science of Western Switzerland

Goergen Jean-Louis

INPL-CNRS

Velthof Pim

Solvay Biologicals B.V.

Reminder: In order to activate your membership, please do not forget to pay your subscription as described in the the email you have received.

# ESACT Cell Culture Technology Award

Stefanos Grammatikos

In order to recognize better accomplishments impacting our community, the ESACT Executive Committee (XC) has decided to consolidate various acts of recognition associated in the past with ESACT and ESACT Meetings to two significant types of awards: The ESACT Medal (combined with a lifetime honorary membership), which will be awarded periodically to individuals recognized for their long-term membership, commitment and service to ESACT, and a new “ESACT Cell Culture Technology Award” for outstanding contribution and scientific excellence in the field of animal cell culture technology.

The ESACT Cell Culture Technology Award, intended to be a prestigious honor in the field, will be presented every two years during the General Scientific Meeting of ESACT. The Award will consist of € 5000 together with a commemorative plaque. The Award recipient will be invited to present the ESACT Award Lecture at the ESACT Meeting immediately following his/her selection. The invitation to attend the ESACT Meeting will include all travel expenses, accommodation during the Meeting and the waiver of registration fees.

Nomination for the Award is open to all researchers and practitioners in the cell culture biotechnology field. It is expected that the Award recipient will fully attend the ESACT Meeting following his/her selection and will deliver personally the Award Lecture. Inability to participate in the specific ESACT Meeting for any reason other than medical reasons will automatically disqualify the selected individual. The Award will then be given to the runner-up who becomes subject to the same eligibility criteria as outlined above. Not eligible for the Award are ESACT Executive Committee members as well as Award Committee members during the term of their respective Committee membership and for a two-year period thereafter.

Nominees will be judged based on two criteria:

1. Originality, impact, quantity and quality of work in Animal Cell Culture Biotechnology and its applications, as judged by publications, citations, patents, presentations, books and related educational and/or research documents; involvement in student education and/or training will also be taken into consideration;
2. Significant contributions to the advancement of Animal Cell Culture Biotechnology by

leadership in the development of novel and high impact educational and/or technological/business activities;

Candidates for the Award will be nominated by the scientific community and selection of the Award recipient will be carried out by an Award Committee under the direction and guidance of a Chairperson.

The Chair of the Award Committee will be appointed by the ESACT XC. The Chairperson selected will be an individual who is widely respected in the field of animal cell culture technology, who is known for his/her impartiality and broad knowledge of the Cell Culture Technology and ESACT communities. He/she will have strong leadership and managerial skills that enable him/her to fulfill the role of the Chair in an impartial, confidential and timely fashion.

The committee members will be selected by the Chair of the Award Committee in strict confidence. The committee will consist of 5 or 7 members including the Chair. The committee operates in strict confidence and with total independence from the ESACT XC and/or the Meeting Chair(s). It is the responsibility of the Chair to assure compliance to this confidentiality.

Members of the Award Committee will be respected in the field, known for their impartiality and will possess a broad perspective of Cell Culture Technology. They should be equally distributed between the academic and industrial communities. It is desirable but not obligatory that the Award Committee includes up to two members of the ESACT XC. The Chair monitors the impartiality and function of the Award Committee and he/she may replace a committee member if necessary or if and when justified.

The ESACT XC has given a lot of thought to the issue of independence, confidentiality and impartiality of the selection process and believes to have taken all necessary measures in order to guarantee from the very beginning the reputation and value of the ESACT Cell Culture Technology Award. ESACT Members and the Cell Culture community can look forward to the first Call for Nominations by sometime this summer and to the first Award Lecture in Dublin!

On behalf of the Executive Committee

*Stefanos Grammatikos*

*ESACT Secretary*

## Martin Fussenegger Recipient of the 2008 Merck & Co. Award in Cell Culture Engineering

The original version of this article is on the CCE website at <http://www.engconfintl.org/8acmerckaward.html>

Engineering Conferences International (ECI), the Cell Culture Engineering (CCE) XI Conference, and Merck & Co. are proud to announce Prof. Dr. Martin Fussenegger of ETH (Federal Institute of Technology) Zürich, Switzerland, as the winner of the 2008 Merck Cell Culture Engineering Award.

Dr. Fussenegger (<http://www.fussenegger.ethz.ch/>) is Professor of Biotechnology and Bioengineering, Director of the Institute for Chemical and Bioengineering, & Director of Studies in Biotechnology at ETH Zürich.

Professor Fussenegger's research has had a large impact on both fundamental and applied aspects of cell culture engineering. He has advanced numerous new and creative technologies that have profoundly impacted the practice of cell culture operations. In a short period of time, Professor Fussenegger conceived and reduced to practice pioneering applications of molecular biology to the solution of several important cell culture problems. His work has been published in high visibility journals and applied broadly to the practice of cell culture technology for biopharmaceuticals production.

He has also dedicated himself to the advancement of the field as a whole such as through this CCE conference series and also leadership within ESACT (the European Society for Animal Cell Technology). Collectively, his research and professional activities have established Professor Fussenegger as an international leader in the cell culture engineering field. His awards and recognitions include a 2002 Professorship Award by the Swiss National Science Foundation; the 2002 business award "Venture 2002" by McKinsey and ETH; the 2002 Swiss Commission of Technology and Innovation Award; the 2003 De Vigier Award, the most prestigious Swiss innovation award; and the 2004 Gaden Award by the journal Biotechnology & Bioengineering. In 2007, he was elected Fellow of the American Institute for Medical and Biological Engineering (AIMBE).

Over the years, he was appointed to Editorial Boards of many prestigious journals in the biotechnology field. He is the author of more than 165 publications and of several patents, and has developed extensive industrial interactions through consulting and company start-up activity. He has supervised 14 post-doctoral and 28 doctoral students in addition to a large number of diploma thesis students.



Professor Fussenegger will receive the Merck Cell Culture Engineering Award at the Cell Culture Engineering XI conference, April 13-18, 2008, at Sunshine Coast, Queensland, Australia, and will deliver the Award lecture during the next (2010) CCE conference.

### About the Merck Cell Culture Engineering Award

This prestigious Award is supported by Merck & Co., Inc. (<http://www.merck.com/>), a global research-driven pharmaceutical company. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Award is to recognize outstanding contributions to the field of Cell Culture Technology & Engineering, and significant service and dedication to the profession. The award was established in 2001, and is given bi-annually at the Cell Culture Engineering conference (ECI Conferences). Former recipients were: Wei-Shou Hu (2002), Eleftherios T. Papoutsakis (2004), and W. Robert Arathoon (2006).

## Book Review

# Animal Cell Technology: from Biopharmaceuticals to Gene Therapy

Thierry Battle & Christophe Losberger

Dear ESACT members,

We would like to share with you some comments that came up after our review of the book entitled “Animal Cell Technology: from Biopharmaceuticals to Gene Therapy”.

The book starts with a continuous progression and linear structure from chapter 1 to 15, from cells and cloning to some aspects of intellectual property and regulatory issues, covering the entire industrial process for the release of biopharmaceutical products, with some highlights on important features such as post-translational modifications. Other chapters include the development of virus-like particles (VLP) for vaccination purposes, Gene Therapy or the usage of Stem Cells.

**Chapter 1** opens the book with a very elegantly written history of cell culture, ranging from the very early pioneering work, covering all the steps and all the applications of the process leading to the commercial release of therapeutics from recombinant sources. The description is very exhaustive and also oriented towards the future (pharmacogenomics).

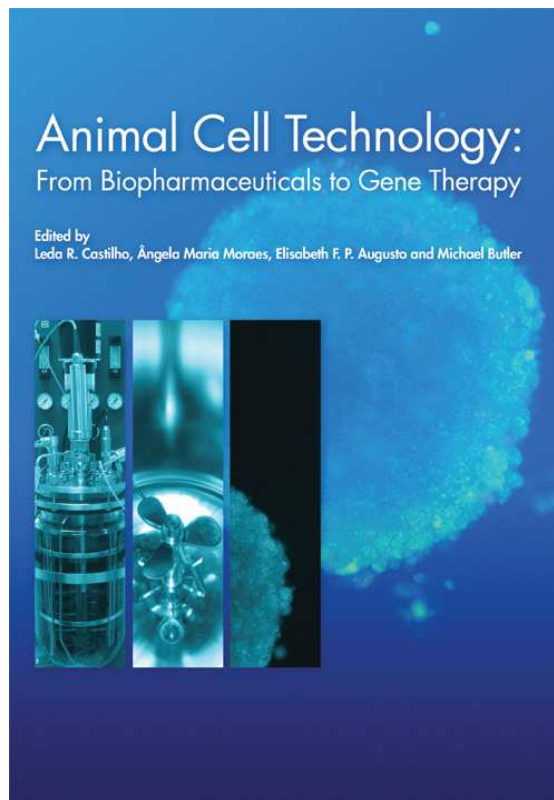
The concept of using animal cell culture (**chapter 2**) for cytotoxic assays now encompasses a wide breath of techniques nicely described in this chapter but we could not detect any mention on how many *in vivo* procedures have actually been completely replaced in the drug progression decision making process. Indeed, we got the feeling that these are still running in parallel with conventional techniques and some data about this integration of cultured cells to fully alleviate some degree of animal experimentation would have been useful.

**Chapter 3** can be somewhat considered – together with cell culture – as the central core of the process leading to the expression of biopharmaceuticals. This chapter explains all the genetic elements and the vectors necessary for protein expression and the methods for the introduction of the DNA into the cells (e.g. various transfection agents). It contains interesting insights into transcriptional regulatory elements to be used within heterologous expression systems.

The way the section dedicated to cell metabolism (**chapter 4**) is written succeeds in providing a very dynamic link between the biochemical pathways and models, and their direct implication in the maintenance of complex cell culture systems. By reading this chapter the scientist will get a very complete idea of how to set-up and implement strategies to monitor the impact of by products and metabolites both on the cells and the protein end product, prior to purification. Introducing this information at that stage of the book helps to better understand all the comments made later on the way to correctly equip cell culture systems with data recording, metabolic sensors and other controlling devices.

Back to the basics of culture media (**chapter 5**) often necessitates making sure that we, as biotechnologists, remember about the fundamental mechanisms and needs of cells inoculated in culture. In parallel with the precedent chapter, the reader will find here a complete description of the nutrients and essential background of medium composition needed for the development of culture media, including the most recent trends to replace some elements (such as FBS) for commercial, risk avoidance or ethical reasons.

We confirm that **chapter 6**, describing the post-translational modification, has to be placed centrally in



the organization of such a book. Indeed, cells are behaving like individual and tiny biosensors that are placed as numerous quantities (millions per milliliter) that may generate metabolic differences.

Some analytical techniques have been developed according to these specificities and more has to be implemented not only to record changes on the post-translational modification level but also to approach a better controlling of these features.

Although it is important to detect and know at the early stage of the R&D process (impact on pharmacokinetics, pharmacodynamics and tissue bio-distribution and metabolism), since we may change expression systems of cell clones during the progression of the molecule, it is of utmost importance to master these aspects at the time when the process is the product. This will limit the number of production batches rejected as per out of specifications.

Even though there has not been that much more recent research on cell death applied to animal cell technology (**chapter 7**), this field is still an important area of research which could lead to the improvement of cell expression by better understanding the complex mechanisms of apoptosis and necrosis

The next chapter (**chapter 8**) is where it was the most difficult for two biotechnologists with neither expertise nor experience in mathematical models to comment about the adaptability of these to our jobs tasks and duties. What we confirm is that the positioning of statistical experimental design is of primary importance when conducting experiments with a high variety of subtle fluctuating parameters which is very often the case for cell culture and cell biology.

**Chapter 9** provides a good overview of all equipment utilized for biotechnological applications and recombinant protein production. Notions of industrialization are being provided. As far as cell retention devices are concerned, readers will be interested to shift towards the chapter 11 which is fully dedicated to such systems. Comments on aeration and agitation are still at the heart of the cell culture processes since lots of devices present various agitation regiment of critical impact on cell behaviour and viability which need to be modeled and analyzed in combination with the mathematical models described in the precedent chapter.

At this stage of the book (**chapter 10**) the reader will be invited to link all elements gathered before to make sure he can relate the various ways to monitor critical factors and to manipulate them wisely for the sake of high productivity within as homogeneous as possible protein post-translational modification. It is interesting

at this point to also refer to protein pre-translational modifications which can occur at the gene transcriptional level and which may drastically affect long lasting cultures.

It is always very interesting to read data about off line versus on line recording systems and the complementary knowledge they provide.

Since end product contaminants and metabolites are often very complex to remove (**chapter 11**) we have to start the first capture process by removing as best as we can cells and debris. It then seemed logical to have a full chapter dedicated to cell retention devices and their application from physical separation down to electronic or even acoustic separation which shows the breadth of the technological approaches actually followed.

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1. Introduction to Animal Cell Technology
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7. Mechanisms of Cell Proliferation and Cell Death in Animal Cell Culture *In Vitro*
8. Mathematical Models for Growth and Product Synthesis in Animal Cell Culture
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20. Cell Therapies and Stem Cells
21. Gene Therapy

**Editor(s)** - Leda Castilho, Angela Moraes, Elisabeth Augusto, Mike Butler.

ESACT members are entitled a 10% discount on this book

Although this book being mainly dedicated to upstream events, it was natural to insert at **chapter 12** some general notions of downstream purification. The reader will notice that these DSP techniques are mainly connected to untagged proteins which is logical owing to the industrial application nature of the wording. As far as early R&D is concerned, lots of data are being generated via tagged proteins and other useful resins and useful techniques will be found in other sources.

**Chapter 13** summarizes all the essential steps to ease the expression of recombinant proteins including cell banking and end product control. To achieve this, it covers all the essential techniques and methods for the analysis of both the final product and related impurities. This chapter finishes by a very interesting description of the importance of the various types of bioassays and cognate statistical analysis. In the future we also expect to read about the phasing out of these very important elements in the development of a biopharmaceutical.

In the following section we note the wide scope of the impacts of regulatory aspects (**chapter 14**) on all the steps of the biotech process. Key regulatory agencies in the field are listed, which is very useful and this chapter reminds the reader about the importance of early and proactive communication with these authorities.

Intellectual property (**chapter 15**) can be breached at so many stages of our discovery process that numerous essential elements have to be put in place, ranging from the laboratory notebook down to intellectual property (IP) and technology transfer. IP technicity has to adapt to guidelines and laws originating from a high variety of countries and regions and this complexity is shown here. Impact on budgets can also explain why companies may decide not to exploit their IP fully.

**Chapter 16** and the other ending chapters of this book are dedicated to highly specific and focused topics. This one details the different groups of proteins available on the market or in final phases in a very useful table summarizing e.g. protein indications, cell lines and type of manufacturing process. Economic aspects are mentioned as well as future alternative production systems.

We find in **chapter 17** a detailed explanation on how to produce monoclonal antibodies, which are very specialized recombinant proteins and constitute one of the major tools of the actual therapeutic arsenal.

Very interesting display of tables and figures in **chapter 18** emphasizes the key steps necessary to the development of viral particles, which have a major role in vaccination regimen.

Similar to nanotechnology

which mimics natural occurring events, **chapter 19** describes a very elegant natural cycle involved in the generation of virus particles. The reader will familiarize himself with this relatively complex system and its broad range of applications from recombinant material down to bio-insecticides.

**Chapter 20** focuses on cell therapies and stem cells and this topic confirms that, after the initial hope for regenerative medicine to benefit from various lineage from stem cell, the intrinsic complexity of routing stem cells towards fully functional organs will take considerable time before reaching maturity.

The ultimate chapter of the book (**21**) is a very nice overview of the technologies available in gene therapy, from the various viral vectors to the introduction into the cells of plasmid DNA, accompanied by interesting figures summarizing the current status of this field.

## Conclusion

In conclusion, each theme is very well treated with appropriate references including early work in the field of ACT, and most recent publications. As mentioned on the back cover, this book is addressed to undergraduates, technologists and scientists interested in ACT, but more widely to anybody who wishes to have a state-of-the-art snapshot and a broader view of all the technologies that we are daily using in our labs.

*Thierry Battle and Christophe Losberger  
Merck Serono Geneva Research Center*



Picture of a 300 Liters bioreactor, by Ary from Brussels ([www.flickr.com](http://www.flickr.com))

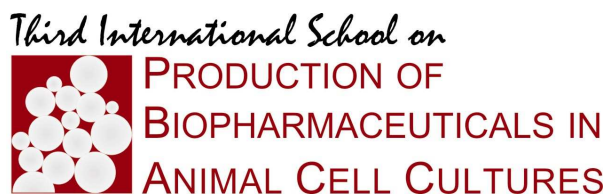
## Next Meetings

### Third International School on Production of Biopharmaceuticals in Animal Cell Cultures

Jul 14-18, 2008 - Rio de Janeiro, Brasil

[www.peq.coppe.ufrj.br/biopharma](http://www.peq.coppe.ufrj.br/biopharma)

Following the success of the two first editions held in 2004 and 2006, the **Third International School on Production of Biopharmaceuticals in Animal Cell Cultures** will address important technical aspects, as well as regulatory and market issues regarding this quickly growing area of Biotechnology. Considering the challenges of producing and purifying biopharmaceuticals, as well as the increasing demand for these products, this event will train participants in this important research area, allowing them to apply and further develop the knowledge obtained during the School when they return to their home countries.



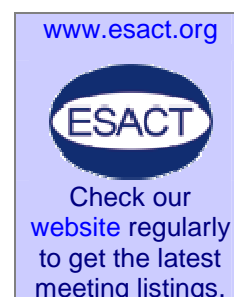
FEDERAL UNIVERSITY OF RIO DE JANEIRO

JULY 14-18, 2008



The event will consist of a one-week series of lectures and workshops discussing case studies, congregating renowned lecturers from 9 different countries. It will be held at the Federal University of Rio de Janeiro (UFRJ), Brazil, being organized by the Cell Culture Engineering Laboratory of COPPE/UFRJ. More details on the event programme, as well as on the registration procedure can be found at the website [www.peq.coppe.ufrj.br/biopharma](http://www.peq.coppe.ufrj.br/biopharma). For participants from academic institutions, no registration fee is charged and applications should be received electronically by May 25<sup>th</sup>, 2008. For participants from companies, different registration fees apply until May 31<sup>st</sup> and after this date.

1. Paula Alves, Instituto de Biologia Experimental e Tecnológica - IBET, Portugal
2. Elisabeth Augusto, Instituto de Pesquisas Tecnológicas - IPT, Brazil
3. Amaro Barreto Junior, Universidade Federal do Rio de Janeiro - UFRJ, Brazil
4. Mike Betenbaugh, Johns Hopkins University - JHU, USA
5. Mariela Bollati, Instituto Pasteur de Montevideo - IPMont, Uruguay
6. Marcelo Brígido, Universidade de Brasília - UnB, Brazil
7. Mike Butler, University of Manitoba, Canada
8. Manuel Carrondo, Instituto de Biologia Experimental e Tecnológica - IBET, Portugal
9. Leda Castilho, Universidade Federal do Rio de Janeiro - UFRJ, Brazil
10. Ernesto Chico, Centro de Inmunología Molecular - CIM, Cuba
11. José Cremata, Centro de Ingeniería Genética y Biotecnología - CIGB, Cuba
12. Marina Etcheverrigaray, Universidad Nacional del Litoral - UNL, Argentina
13. Helen Ferraz, Universidade Federal do Rio de Janeiro - UFRJ, Brazil
14. Hansjoerg Hauser, Helmholtz Centre for Infection Research - HZI, Germany
15. Konstantin Kostantinov, Genzyme, USA
16. Ricardo Medronho, Universidade Federal do Rio de Janeiro - UFRJ, Brazil
17. Angela Moraes, Universidade Estadual de Campinas - UNICAMP, Brazil
18. Ana Maria Moro, Instituto Butantan - IB, Brazil
19. Stevens Rehen, Universidade Federal do Rio de Janeiro - UFRJ, Brazil
20. Aldo Tonso, Universidade de São Paulo - USP, Brazil
21. Luuk van der Wielen, Technical University of Delft - TU Delft, The Netherlands



**ESBES7** - 7th European Symposium on Biochemical Engineering Science - Sep 7-10, 2008 - Faro, Portugal - [www.esbes2008.org](http://www.esbes2008.org)

**Metabolic Engineering** - Sep 14-19, 2008 - Puerto Vallarta, Mexico - [www.engconfintl.org/8ay.html](http://www.engconfintl.org/8ay.html)

**RESCUE Meeting 2008** - Sep 29 - Oct 1, 2008 - Stockholm, Sweden - [www.rescue-society.org](http://www.rescue-society.org)

**IBS2008** - The 13th International Biotechnology Symposium and Exhibition - Oct. 12-17, 2008 - Dalian, China - [www.ibs2008.org](http://www.ibs2008.org)

# Society

## Executive Committee

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