

IABs International Scientific Workshop



International Association for Biologicals

New Cells for New Vaccines: Focus on Plant and Insect Cell Technologies

28 - 29 September 2006 • Biltmore Hotel • Coral Gables (Miami), Florida • USA

Organized in Association with:



Workshop Topics:

- Insect and Plant Cell Biology & Expression Systems
- Product Development and Manufacturing
- Case Studies – Recent Clinical Trials
- International Regulatory Perspectives

With Major Support and Coordination From:

**InB: Biotechnologies
Inc.**

And Additional Support From:

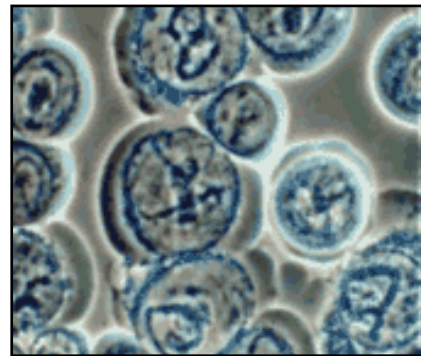


IABs International Scientific Workshop

New Cells for New Vaccines: Focus on Plant and Insect Cell Technologies

A key aspect of the success and viability of a vaccine development project is the choice of an appropriate cell substrate. The past fifty years have seen a dramatic increase in the substrates available for consideration. In 1954, an NIH committee considered that only two cell types were suitable for the production of a human vaccine, primary monkey kidney cells and a human tumour cell line (HeLa), neither of which would be considered ideal today. Nowadays, the situation is very different and a wide range of cells of mammalian and chicken origin is available. These do not meet all needs however and there remains substantial scope for innovative approaches.

Recent developments in cell and molecular biology and virology involving cells of highly different origins, namely plant and insect cells, employing recombinant plant viruses (e.g. TMV) or insect viruses (e.g. baculovirus) as the expression system, are now of considerable scientific and practical interest. Examples of recent successes include the development of a veterinary vaccine for Newcastle Disease virus prepared in plant cells, the first plant-produced vaccine to be officially licensed, and a human papilloma virus vaccine against cervical carcinoma prepared in insect cells using a baculovirus vector. Such new cell substrates are of intense interest and relevance to industry, and the focus of much R&D activities. Many vaccine development projects, including influenza virus vaccines, are in progress internationally as the potential advantages of these new cells and production systems are increasingly recognized.



About the New Cells for New Vaccines Workshop

The workshop is being held under the auspices of the International Association for Biologicals (IABs) in association with the US National Institute of Allergy and Infectious Diseases (NIAID), the Fraunhofer USA Center for Molecular Biotechnology, the World Health Organization (WHO), and the International Society for Influenza and other Respiratory Virus Diseases (isirv).



This two-day workshop will consist of presentations from international leaders in the field, oral presentations selected from submitted abstracts, poster displays and trade exhibits.

New Cells for New Vaccines will be of interest to the biotechnology and pharmaceutical industry involved in vaccine development and production, as well as academics, regulatory and public health authorities, and medical and veterinary experts.

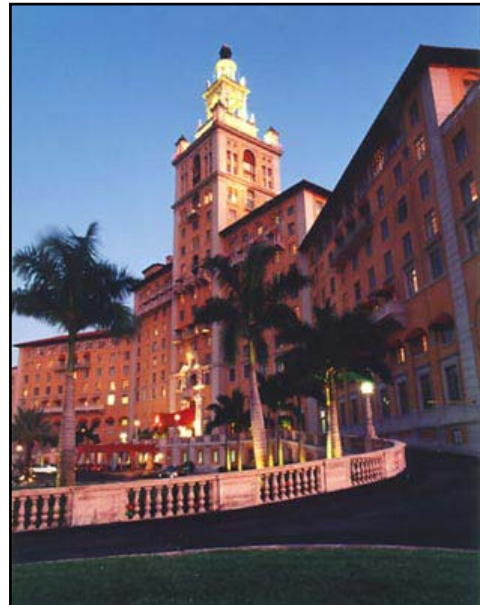
28 - 29 September 2006

**The Biltmore Hotel
Coral Gables, Florida, USA**

Registration:

- \$850 Industry
- \$395 Academic, Government, Public Health
- \$150 discount for post-docs and graduate students
- \$100 discount for IABs and isirv members
- \$ 50 presentation discount (see details below)

Deadline: 22 September 2006



Registration form and additional details can be found on page 8.

Abstract Submissions

The International Program Committee invites attendees to submit a one page abstract for each paper they wish to be considered for an oral and/or poster presentation. The abstract should contain sufficient information for the committee to determine its relevance to the aims of the workshop. Abstracts should be submitted by e-mail to Dr. Geoffrey Schild at gschild@inb-biotechnologies.com (please attach abstracts as Word documents). Closing date for submissions is 31 August 2006. Attendees with abstracts accepted for oral or poster presentations will receive a \$50 discount off the registration fee. Selected presentations for **New Cells for New Vaccines** will be published in *Biologicals*, the journal of the International Association for Biologicals (IABs).

Members of the **International Program Committee** include:

- Mr. Daniel Adams (Protein Sciences Corporation, USA)
- Dr. Lorne Babiuk (University of Saskatchewan, Canada)
- Dr. Elwyn Griffiths (Health Canada, Canada)
- Dr. Douglas Holtzman (Bill and Melinda Gates Foundation, USA)
- Dr. John Petricciani (IABs, USA)
- Dr. Stanley Plotkin (University of Pennsylvania and Consultant, sanofi pasteur, USA)
- Dr. James S. Robertson (NIBSC and IABs, UK)
- Dr. Philip Russell (Sabin Vaccine Institute, USA)
- Dr. Geoffrey Schild (InB:Biotechnologies, USA)
- Dr. David Wood (WHO, Switzerland)
- Dr. Vidadi Yusibov (Fraunhofer CMB, USA)
- Dr. Kathryn Zoon (NIAID, USA)

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Day One – Thursday, 28 September 2006

8:00 – 9:00 Registration and Continental Breakfast

9:00 – 9:05 Welcome

*Geoffrey Schild, Ph.D., Chief Scientific Officer, InB:Biotechnologies, Inc. (USA)
and Director, International Association for Biologicals (Switzerland)*

9:05 – 9:55 Keynote Presentation

Perspectives of Vaccine Manufacturers in Relation to Novel Substrates for Vaccine Production

*Jeffrey Almond, Ph.D., Senior Vice President of Research & Development,
sanofi pasteur (France)*

VACCINE DEVELOPMENT: NEW CELLS AND EXPRESSION SYSTEMS

9:55 – 10:00 Chairperson's Remarks

*Henry Daniell, Ph.D., Professor of Molecular Biology & Microbiology, Burnett
College of Biomedical Sciences, University of Central Florida (USA)*

10:00 – 10:45 Featured Presentation

Advantages & Challenges of Plant-Based Vaccine Development

*Vidadi Yusibov, Ph.D., Executive Director, Fraunhofer USA Center for Molecular
Biotechnology (USA)*

10:45 – 11:30 Featured Presentation

Advantages & Challenges of Vaccine Development in Insect Cells

*Spiros Agathos, Ph.D., Professor of Biochemical Engineering, University of
Louvain (Belgium)*

11:30 – 1:00 Lunch sponsored by InB:Biotechnologies, Inc.

PROGRESS ON NEW VACCINES EMPLOYING PLANTS AND INSECT CELLS

1:00 – 1:05 Chairperson's Remarks

*Kathryn Zoon, Ph.D., Director, Division of Intramural Research, National Institute
of Allergy and Infectious Diseases, National Institutes of Health (USA)*

1:05 – 1:25 **Immunogenicity of Plant-Produced Subunit Vaccines Against *Bacillus anthracis***

*Gene Palmer, Ph.D., Scientist, Fraunhofer USA Center for Molecular
Biotechnology (USA)*

1:25 – 1:45 **Production of a Novel Influenza Vaccine Using Insect Cells: Protection Against Drifted Strains**

Manon M.J. Cox, D.Sc., Chief Operating Officer, Protein Sciences Corporation (USA)

1:45 – 2:05 **A Novel Plant-Based Technology for Production of Flu Antigens (Case Study)**

*Louis-P. Vézina, Ph.D., Vice President, Research & Development, Medicago,
Inc. (Canada)*

Day One – Thursday, 28 September 2006

- 2:05 – 2:25 **Plant-Based Production of Vaccines and Antibodies**
Stefan Schillberg, Ph.D., Head of Department Plant Biotechnology, Fraunhofer Institute for Molecular Biotechnology and Applied Ecology (Germany)
- 2:25 – 3:00 Refreshment Break, Poster and Exhibit Viewing
- 3:00 – 3:20 **A New Therapeutic Vaccine Against HPV-Associated Cancers Based on Purified Plant-Derived HPV16 E7 Protein Fused to Bacterial Lichenase**
Aldo Venuti, Ph.D., Laboratory of Virology, Regina Elena Cancer Institute (Italy)
- 3:20 – 3:40 **Transient Systems for Manufacturing Recombinant Proteins in Plants**
Prof. Dr. Yuri Gleba, Managing Director, Icon Genetics GmbH (Germany)
- 3:40 – 4:00 **Chloroplast-Derived Vaccines and Biopharmaceuticals**
Henry Daniell, Ph.D., Professor of Molecular Biology & Microbiology, Burnett College of Biomedical Sciences, University of Central Florida (USA)
- 4:00 – 4:20 **Efficient Production of Recombinant Proteins in the Aquatic Plant *Lemna***
Kevin Cox, Senior Scientist, Biolex Therapeutics (USA)
- 4:20 – 5:30 Reception, Poster and Exhibit Viewing
- 7:30 Dinner sponsored by Retroscreen Virology Ltd.
Professor John Oxford, Scientific Director, Retroscreen Virology Ltd and Professor of Virology, St Bartholomew's and the Royal London Hospital, Queen Mary's School of Medicine and Dentistry (UK)

Day Two – Friday, 29 September 2006

- 8:00 – 8:30 Continental Breakfast
- CLINICAL EVALUATION OF NEW VACCINES DEVELOPED USING INSECT CELLS AND PLANTS**
- 8:30 – 8:35 Chairperson's Remarks
Ivana Knezevic, Ph.D., Scientist, Immunization Vaccines and Biologicals, Family and Community Health Cluster, World Health Organization (Switzerland)
- 8:35 – 8:55 *Charles Arntzen, Ph.D., Co-Director of the Center for Infectious Diseases and Vaccinology, The Biodesign Institute and Florence Ely Nelson Presidential Chair, Arizona State University (USA)*
- 8:55 – 9:15 **HPV Antigen Characterization**
Michel Deschuyteneer, Ph.D., GlaxoSmithKline Biologicals (Belgium)
- 9:15 – 9:35 **Plant-Cell-Produced Vaccines for Animal Health**
Steven Webb, Ph.D., Discovery Research Leader for Animal Health, Dow AgroSciences (USA)
- 9:35 – 9:55 Offered Presentation
- 9:55 – 10:25 Coffee Break, Poster and Exhibit Viewing

Day Two – Friday, 29 September 2006

SCALE-UP AND QUALITY CONTROL OF NEW SUBSTRATES

- 10:25 – 10:30 **Chairperson's Remarks**
R. Barry Holtz, Ph.D., Principal, Holtz Biopharma Consulting (USA)
- 10:30 – 10:50 **Moving from Lab to cGMP Manufacture in Plant-Based Systems**
Ursula Busse, Ph.D., MBA, Director, Quality Assurance and Regulatory Affairs, Medicago, Inc. (Canada)
- 10:50 – 11:10 **Quality Control of a Novel Expression System in Baculovirus**
Marguerite Deschamps, Ph.D., GlaxoSmithKline Biologicals (Belgium)
- 11:10 – 11:30 **New Approaches to Routine Testing of New Cell Substrates**
Isabelle Pierard, Ph.D., Director, Product Life Cycle Management, GlaxoSmithKline Biologicals (Belgium)
- 11:30 – 11:50 **Realities of Process Development**
Alex Day, Director of Business Development, Kentucky BioProcessing LLC (USA)
- 11:50 – 1:20 Lunch sponsored by Bayer Innovation GmbH

REGULATORY ISSUES SPECIFIC TO NEW SUBSTRATES

- 1:20 – 1:25 **Chairperson's Remarks**
William Egan, Ph.D., Executive Director, PharmaNet Consulting (USA)
- 1:25 – 1:45 **US Regulatory Perspective on New Substrates**
Philip Krause, M.D., Deputy Director, Division of Viral Products, Center for Biologics Evaluation & Research, Food & Drug Administration (USA)
- 1:45 – 2:05 **Canadian Regulatory Perspective on New Substrates**
Elwyn Griffiths, Ph.D., D.Sc., Associate Director General, Biologics and Genetic Therapies Directorate, Health Canada (Canada)
- 2:05 – 2:25 **Is Viral Safety Less of an Issue With Plant and Insect Cell-based Production?**
Dr. James S. Robertson, Principal Scientist, Division of Virology, National Institute for Biological Standards and Control (UK)
- 2:25 – 2:45 **Revision of WHO Requirements for Cell Substrates - Key Issues**
Ivana Knezevic, Ph.D., Scientist, Immunization Vaccines and Biologicals, Family and Community Health Cluster, World Health Organization (Switzerland)
- 2:45 – 3:15 Refreshment Break, Poster and Exhibit Viewing

WORKSHOP WRAP-UP: SUMMARY AND CONCLUSIONS

- 3:15 – 3:25 **Chairpersons' Remarks**
Reinhard Glück, Ph.D., Chief Scientific Officer, Berna Biotech, Ltd. (Switzerland)
Alan Shaw, Ph.D., Chief Executive Officer, VaxInnate (USA)
- 3:25 – 4:00 **Panel Discussion of Issues and Future Targets**
Charles Arntzen, Ph.D., Co-Director of the Center for Infectious Diseases and Vaccinology, The Biodesign Institute and Florence Ely Nelson Presidential Chair, Arizona State University (USA)

Day Two – Friday, 29 September 2006

Manon M.J. Cox, D.Sc., Chief Operating Officer, Protein Sciences Corporation (USA)

Dr. James S. Robertson, Principal Scientist, Division of Virology, National Institute for Biological Standards and Control (UK)

Geoffrey Schild, Ph.D., Chief Scientific Officer, InB:Biotechnologies, Inc. (USA)

Vidadi Yusibov, Ph.D., Executive Director, Fraunhofer USA Center for Molecular Biotechnology (USA)

Kathryn Zoon, Ph.D., Director, Division of Intramural Research, National Institute of Allergy and Infectious Diseases (USA)

4:00 Workshop Adjournment

Sponsorship and Exhibit Opportunities

Sponsorship and exhibit opportunities are available for the **New Cells for New Vaccines** workshop. Please contact Jennifer Kmiec at jkmiec@inb-biotechnologies.com or 302-355-0650 for more information.

Join our Current Workshop Sponsors:

**InB: Biotechnologies
Inc.**



New Cells for New Vaccines: Focus on Plant and Insect Cell Technologies

28 - 29 September 2006 • Biltmore Hotel • Coral Gables, Florida • USA

Workshop and Hotel Venue:

The Biltmore Hotel

1200 Anastasia Avenue
Coral Gables, Florida 33134 USA

Phone: 800-727-1926 or 305-445-1926
Fax: 305-913-3158 (use form on page 9)
E-mail: reservations@biltmorehotel.com
Web: www.biltmorehotel.com (enter group code 4276 and password 68690)

Room Rate: \$180.00
Cut-off Date: 08 September 2006

Please contact The Biltmore Hotel directly to make your room reservation. Identify yourself as a **New Cells for New Vaccines** workshop attendee and reference group code 4276 to receive the group room rate.



Rooms are limited, so please book early!
Reservations made after the cut-off date or after the group room block has been filled will be accepted on a space and rate available basis.

The Biltmore Hotel in Coral Gables, Florida is a National Historic Landmark resort featuring luxury accommodations and 76,000 sq. ft. of meeting & function space. Other highlights include an 18-hole, Donald Ross-designed championship golf course, 10 lighted tennis courts, newly renovated spa, full service fitness center, an array of fine restaurants and bars including the award-winning Palme d'Or, private wine cellar club, and the largest hotel swimming pool in the continental United States. More information about the hotel and its amenities can be found on the web at www.biltmorehotel.com.



Transportation:

The **Miami International Airport** is 5 miles (10-15 minute drive) from The Biltmore Hotel. The cost of transportation is approximately \$17.00 each way by taxicab from MIA. Driving directions to the hotel can be found at www.biltmorehotel.com/en/location.asp.

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Registration:

Please print and complete this form and send it together with your payment details by fax or mail to:

InB:Biotechnologies, Inc.
9 Innovation Way, Suite 100
Newark, DE 19711 USA
Fax: 302-356-1173

Name: _____

Title (Prof, Dr, Mr, Mrs, Ms): _____

Organization: _____

Job Title: _____

Address: _____

City/State: _____

Postal/Zip Code: _____ Country: _____

Telephone: _____ Fax: _____

E-mail: _____

Payment Information:

- \$850.00 (Industry) \$395.00 (Academic, Government, Public Health)
- I am a post-doc or graduate student (\$150.00 discount)
- I am an IABs or isirv member (\$100.00 discount)
- I am submitting an abstract for oral and/or poster presentation (\$50.00 discount)

Registration fees include workshop attendance, workshop materials, breakfasts, lunches, dinner and breaks listed in the program.

Enclosed is a check or money order drawn on a US bank, in US currency, made payable to:
"InB:Biotechnologies"

Please charge: AMEX Visa MasterCard Discover

Card #: _____ Exp. Date: _____

Cardholder Name: _____

Signature: _____

Cardholder's Billing Address: _____

City/State: _____

Postal/Zip Code: _____ Country: _____

Registration and payment must be received by 22 September 2006

Questions? Please contact Jennifer Kmiec at 302-355-0650 or jkmiec@inb-biotechnologies.com

FACSIMILE COVER SHEET

TO: **Reservations Department, The Biltmore Hotel**
1200 Anastasia Avenue, Coral Gables FL 33134

DATE: _____ FAX NUMBER: (305) 913-3158

FROM: _____

FAX NUMBER: _____ GROUP CODE: 4276

Name of Group: **New Cells for New Vaccines**
Group Dates: **9/27/06 - 09/30/06**
Special Group Rate: **ROH \$180.00**

1. Hotel Reservation must be received by **9/8/06**.
2. A credit card or payment for one night's room and tax is required to hold your reservation.
3. Hotel check-in time is 3:00 pm and checkout time is 12:00 pm.
4. Hotel reservations received after the cutoff date is subject to space availability only. For reservations by phone, call (305) 445-1926 or 1-800-727-1926 or fax (305) 913-3158.
5. Individual rooms may be canceled up to 48 hours prior arrival date. Cancellations within 48 hours or no shows will be charged one night's room and tax. Group blocks are subject to cancellation and attrition penalties as outlined in the group contract.
6. Incidental Fee of \$9.00 includes admission to Health & Fitness Center, local, long distance access and toll free calls, self-parking, and daily newspaper.
7. Porterage Fee and Maid gratuities of \$12.00 include roundtrip baggage handling.
8. Golf and Tennis are extra.

Name: _____

Arrival Date: _____ Estimated Arrival Time: _____ Departure Date: _____

Type of Room: _____

Home Address: _____

City: _____ State: _____ Zip: _____ Daytime Phone: _____

Fax: _____ E-mail: _____

NAME ON CARD MUST MATCH NAME ON RESERVATION

I will pay my account with:

American Express__ Master Card__ Visa__ Discover__ CB/Diners__ En-route__ Check__

Card holder _____ Account No. _____ Exp _____

Number of Rooms Required _____ No. of Adults in Room _____ Children _____ Crib _____

Special Instructions _____

Check Bed-type Preferences: Two Beds _____ King Bed _____ Non Smoking _____ Smoking _____

Special accommodations cannot be guaranteed. They are on request basis only.