



Fraunhofer IME

EPSO Workshop

Molecular farming: The path towards commercialization

Fraunhofer IME, Aachen, Germany

31 January – 1 February 2006



European Plant
Science Organisation

Molecular Farming: The Path Towards Commercialization

Dear Participants,

Molecular farming – the production of recombinant pharmaceutical and industrial proteins in plants – offers an unprecedented opportunity to produce valuable proteins safely, and on a massive scale, with minimal costs and labor. In the case of pharmaceutical proteins, however, this potential can only be realized if the current plethora of proof-of-principle studies can yield a clinically-approved, commercial product. Many of the former obstacles that blocked the path to commercialization have now fallen – technical limitations are being overcome, biosafety concerns are being addressed, and industry inertia is being replaced by a new positive outlook. One issue that needs to be tackled urgently is the uncertain regulatory landscape that governs the production of plant-derived pharmaceuticals, since without a framework to work within it will be difficult for any company to commit resources to molecular farming. This final issue is being addressed on several fronts through clinical performance and product safety trials as well as the active engagement of the regulatory agencies, in the hope of working with them to finalize the regulatory procedure.

The aim of this EPSO workshop is to bring together a small but influential group of scientists, regulators and industrialists from the EU, US and Canada to discuss and exchange ideas on the current challenges hindering the commercialization of plant-derived pharmaceutical and industrial proteins, and how best to overcome them.

After the meeting a white paper will be produced by the participants that will help EPSO suggest new directions for research within Europe at the European and national levels, such as the Strategic Research Agenda “Plants for the Future”. This document will also be forwarded to representatives of the Commission and the regulatory agencies to guide future policy decisions.

We hope you find the workshop both interesting and useful, and that together we can forge a positive future for molecular farming within the EU and the rest of the world.

Yours,

Rainer Fischer, Richard Twyman, workshop organizers

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Program of speakers

Speakers please limit your presentations to 20-25 minutes, leaving 5-10 minutes for discussion. Please also leave copies of your presentations with us, to help with the preparation of the white paper. Your presentations will be kept confidential.

Tuesday, 31 January 2006

- 9.00-9.15** **Welcome from the organizers. Introduction and purpose of the workshop: Rainer Fischer (Fraunhofer IME) and Karin Metzloff (EPSO)**
- 9.15-10.45** **Theme 1: Recent advances in the basic technology for molecular farming**
- Speakers**
- Richard Twyman, UK**
Gene expression and regulation
- Stefan Schillberg, IME**
Protein targeting and stabilization
- Loic Faye, France**
Post-translational modification – towards humanization of the plant N-glycan maturation pathway
- 10.45-11.00** **Coffee break**
- 11.00-12.45** **Theme 2: Platform technologies**
- Speakers**
- Eva Stoger, RWTH**
Stable nuclear transformation
- Phil Dix, Ireland**
Chloroplast transformation
- Vidadi Yusibov, Fraunhofer CMB, US**
Viral systems
- Stephan Hellwig, IME**
Plant cell fermentation
- 12.45-13.30** **Lunch**
- 13.30-14.30** **Theme 3: Molecules suitable for molecular farming**
- Speakers**
- Julian Ma, UK**
Antibodies and other therapeutic proteins

Reinhard Glück, Berna Biotech, Switzerland
Vaccines

14.30-15.30 **Theme 4: The ideal plant expression platform**

Speakers

Francois Arcand, ERA Plantech, Spain
Host systems for molecular farming

Johan Botterman, Bayer CropSciences
The economics of molecular farming

15.30-15.45 **Coffee Break**

15.45-17.00 **Theme 5: Safety, acceptability and the public interest – economics and commercialization of molecular farming**

Speakers

David Castle, Guleph, Canada
Plant-Derived Vaccines and the Public Interest: Modelling Regulatory Burden

Yuri Gleba, Icon Genetics, Germany
SME perspective

Gert Seidl, Bayer CropSciences
Large Corporation perspective

17.00-17.30 **Open discussion, with refreshments**

RETURN TO HOTEL

18.45 **Welcome and pre-dinner drink**

19.00 **Dinner**

Wednesday, 1 February 2006

8.30-9.45 **Theme 6: Integrated processes**

Speakers

Rainer Fischer, IME/RWTH
An integrated process for molecular farming

Uwe Gottschalk, Sartorius AG, Germany
Downstream processing of plant material

Klaus Kellings, NewLab, Duesseldorf, Germany
QA and QC in biopharmaceutical production

9.45-10.00 **Coffee break**

10.00-11.30	<u>Theme 7: Preclinical and clinical Trials with PMPs</u>
	Speakers
	Veronique Gomord , France Toxicity, immunogenicity and allergenicity of PMPs
	Juergen Drossard , IME cGMP processes
	Brigitta Vcelar , Polymun, Austria Clinical trials with PMPs
11.30-12.00	Lunch
12.00-14.00	<u>Theme 8: Regulation and approval</u>
	Speakers (order subject to revision)
	Reinhilde Schoonjans , EFSA EFSA risk assessment in the EU approval procedure
	Peter Philips , Saskatchewan Segregation, traceability and identity preservation
	Phil Dale , UK Risk assessment and regulation
14.00-14.15	Coffee break
14.15-16.00	Round table discussion, with refreshments: Initiation of a draft white paper on “Molecular farming – the path forward for commercialization”
16.00	Departure

Information

Where is the workshop being held?

The workshop will be held at the new Fraunhofer IME building in Aachen.



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Where is the workshop dinner being held?

The dinner will be held at the Hotel Kasteel Bloemendal. Speakers and other participants at this hotel will be picked up at 8.30 am on Tuesday 31st and at 8.00 am on Wednesday 1st.



Hotel Kasteel Bloemendal

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