



Editorial: From Tobacco Leaves to Global Pharmacies, How Molecular Pharming Is Reshaping the Biopharmaceutical Landscape

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Over the past four decades, plant biology has undergone a quiet yet profound paradigm shift. Plants are no longer merely vehicles for photosynthesis or the base of the food chain; they are becoming “green factories” for precise biological manufacturing. As the Editor-in-Chief of the *Journal of Applied Plant Biology*, I have chosen to dedicate my first editorial to this topic because I firmly believe that **molecular pharming stands at a critical inflection point between proof of concept and commercialization**, and this transition will have a structural impact on the accessibility and sustainability of global biopharmaceuticals.

Why Now?

In 2022, a COVID-19 virus-like particle vaccine expressed in the plant *Nicotiana benthamiana* received regulatory approval in Canada, becoming the world’s first formally approved plant-derived vaccine. This is not an isolated event but a signal: plant expression systems have crossed the gap between “proof of concept” and “commercial viability.”

Equally important is the shift in cost structure. Traditional mammalian cell culture platforms (such as CHO cells), although still dominant in producing complex proteins, have inherent limitations, high media costs, the maintenance burden of sterile bioreactors, viral contamination risks, and batch-to-batch glycan heterogeneity, that constitute nearly insurmountable barriers to scalability. In contrast, plant systems do not require expensive animal-derived media, can be cultivated at large scale in greenhouses or even open fields, and the plants themselves do not carry human-infecting pathogens.

But what truly makes molecular pharming impossible to ignore at this moment is the global maturation of the biosimilars market. Several blockbuster biopharmaceuticals have reached the end of their patent terms, and the demand from healthcare systems

to reduce biologic expenditures is growing. The structural cost advantage of plant platforms makes them a highly attractive alternative in the biosimilars space.

The Technological Frontier: Why Has Tobacco Become the Workhorse?

Among the many plant hosts, *N. benthamiana* has become the “workhorse” of molecular pharming due to a set of unique biological and engineering advantages:

The speed advantage of transient expression.

Through *Agrobacterium*-mediated or viral vector delivery, gene expression can reach high levels throughout the plant within weeks, cutting the timeline from sequence to candidate product from months to weeks. This capability has irreplaceable strategic value in pandemic response scenarios, the emergency use of the ZMapp antibody cocktail during the 2014 Ebola outbreak is a classic testament to this capacity.

The feasibility of glycoengineering. Plants and mammals differ in their N-glycosylation pathways, but these differences are not insurmountable. By co-expressing human glycosyltransferases, *N. benthamiana* can produce “mammalianized” glycoforms that reduce immunogenicity and improve the pharmacokinetics of therapeutic antibodies.

The inherent barrier of biosafety. Tobacco, as a non-food, non-feed crop, fundamentally severs the risk pathway of accidental drug entry into the food chain when used as a bioreactor. This characteristic has considerable value in the design of regulatory frameworks.

The Challenge Is Not in the Science, but in the Institutions



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If molecular pharming faces a real obstacle, it lies less in the science than in regulation and industrialization.

Regulatory pathways for plant-derived biopharmaceuticals have yet to be systematically defined in most jurisdictions. Existing regulatory frameworks are largely built around mammalian cell platforms, and their risk assessment logic is not entirely suitable for plant systems, for example, environmental release risk assessment, regulatory jurisdiction over transgenic plants, and the definition of batch-to-batch consistency for the final product. This institutional lag causes many promising candidate products to stall in late-stage clinical development.

At the industrial level, scaling from greenhouse to large-scale field cultivation is not a linear process. Biomass harvesting, the compatibility of protein extraction and purification processes with existing cGMP infrastructure, and the impact of seasonal cultivation on supply chain stability are all engineering problems requiring systematic solutions. The good news is that contract manufacturing organizations (CMOs) are gradually filling this capability gap.

The Mission of This Journal

The *Journal of Applied Plant Biology* was born at this very inflection point. Our mission is to facilitate the translation of plant biology from fundamental discovery to practical application, and molecular

pharming is precisely the most concentrated manifestation of this mission. We welcome submissions in the following areas: optimization and comparative studies of plant expression systems, glycoengineering and post-translational modification regulation, downstream processing and formulation of plant-derived biologics, and regulatory science and environmental risk assessment of molecular pharming.

I also take this opportunity to extend an invitation to the scholarly community: **please consider this journal a publication platform for the complete chain from laboratory innovation to industrial application in the field of molecular pharming.** We do not pursue short-term growth in impact factor; we pursue the publication of work that will still hold defining significance when viewed five years from now.

The future of plant biology extends beyond understanding plants. It lies in using our deepest understanding of plant mechanisms to solve humanity's most pressing problems. Molecular pharming is one of the most powerful answers to this proposition.

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