ABSTRACT

"Better, faster, more? -Opportunities and challenges for plant-made pharmaceuticals"

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Although the use of plant biotechnology has long been proposed for manufacture of clinical products, there are only few examples of regulatory approved products from transgenic plants entering clinical trials. In a recent project, HIV-neutralizing human monoclonal antibody 2G12 was produced in nuclear transformed corn and tobacco. In preparation for a clinical Phase I trial scientific, technical and regulatory demands were addressed by molecular characterization of the transgene insertion, analysis of genetic and phenotypic stability, generation of a master seed bank and by establishing procedures for plant cultivation and processing. The project highlighted unique properties of individual plant production platforms in terms of production time, scalability and storage properties. Plant tissues also differ in their abilities to sort, modify and accumulate proteins. Seeds are naturally adapted for protein accumulation and possess specialized storage organelles that may be exploited to accumulate recombinant proteins, offering stability both in planta and after harvest. The post-harvest stabilizing effect offered by native storage organelles such as starch granules, protein storage vacuoles and protein bodies thus offers interesting possibilities for the mucosal delivery of vaccines and antibodies, thereby providing novel strategies for medical intervention that remove some of the constraints of conventional manufacturing processes.