CRISPR-based drugs face tricky manufacturing problem

There are two key challenges in delivering a CRISPR-Cas9 therapy so it is effective in the body: It must be delivered to a specific tissue, and it must also be delivered to the cells within that tissue.

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As the gene-editing community focuses on the extraordinary promise of editing somatic cells to address profound unmet medical needs and its potential for alleviating human suffering, we also need to solve the more prosaic problems of delivery and manufacturing.

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Companies that advance to clinical trials will require a much larger quantity of experimental drugs. Two manufacturing questions face these companies: If we started our manufacturing program in house, should we continue down that road and build our own manufacturing facility? If we started with a contract manufacturing organization, should we continue working with it or bring manufacturing in-house and build our own facility?

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The right answer is tricky enough to qualify as a business school case study. Building manufacturing capacity is frighteningly expensive. And it won't be ready for three to five years after you've made the decision to green light the project. So making the right decision requires an extraordinary amount of capital, foresight, and luck.

Read full, original post: CRISPR-Cas9 commercialization may be slowed by delivery and manufacturing challenges