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PlasmidFactory expands offerings with customized cloning services for safer, compliant plasmid DNA

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New service enables precise replacement of antibiotic resistance gene cassettes, supporting regulatory compliance and reducing health risks in gene and cell therapy applications.



Cloning Services
Precise and customized modification of plasmid DNA

Replacement of antibiotic resistance genes cassettes
PlasmidFactory is expanding its service portfolio and now offers a customized cloning service.
A key focus is the replacement of antibiotic resistance (AB) gene cassettes to achieve regulatory compliance and to minimize potential risks for health.

Advantages

- Minimizing risks
- Ensuring compliance for clinical studies
- One source, one point of contacat, one trusted solution

Plasmid DNA plays a crucial role in modern medicine, from vaccine development over gene and cell therapies to the production of viral vectors. In many of these applications, integrated antibiotic resistance genes cassettes serve as selection markers. Unfortunately, the Ampicillin resistance (AmpR), which was frequently used in this context, can trigger allergic reactions possibly leading to anaphylactic shocks. Even the presence of parts of the AmpR sequences may result in detectable traces of the genes within in the final viral vectors.

However, deleting AB resistance cassettes completely will result in loss of plasmid carrying cells, being overgrown by “empty” cells. One approach, so far accepted in plasmid productions for clinical applications by the regulatory authorities, is

to exchange the AmpR by the Kanamycin resistance (KanR) genes cassettes. This replacement is now offered by PlasmidFactory.

Already in 2001, the European authority for the evaluation of medicinal products (EMA) proposed in its guidelines for medicinal gene transfer products to completely avoid selection markers like resistances against antibiotics (CPMP/BWP/3088/99).

This resulted in PlasmidFactory's even more elegant approach, the minicircle (https://www.plasmidfactory.com/custom-dna/minicircle-dna/) This miniaturized, monomeric, supercoiled, homogenous circular derivative of a plasmid consists only of the preventive / therapeutically active gene cassettes without any selection markers.