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Platform Technology FDA Guidance Overdue

MRNA, CRISPR, Cell & Gene, CDMOs Likely Benefit

Relevant Companies

Our Take & Next Up

The Food and Drug Administration (FDA) is due to release platform technology guidance that may be vague in nature at first but more specific/helpful upon finalization 2H24. FDA continues to suffer from a lack of highly qualified staff. The agency is also encountering innovative therapies that have unique regulatory barriers including CRISPR and mRNA therapies (non-COVID applications). To address their limitations, the agency is leaning on the private sector to assist in easing regulatory challenges and identifying applications. A potential beneficiary of the new designation is the rare & ultra rare disease space which may see more therapeutics being developed and succeed from the utility of novel techs that allow multiple different diseases to be addressed through the “plug and play” of different targets.

Key Points

CRISPR and mRNA platforms are expected to be early beneficiaries of the pathway. CRISPR-based and...

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