

# Global Gene Editing Safety Assessment Services Market Growth (Status and Outlook) 2026-2032

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## Abstracts

The global Gene Editing Safety Assessment Services market size is predicted to grow from US\$ 311 million in 2025 to US\$ 1044 million in 2032; it is expected to grow at a CAGR of 18.9% from 2026 to 2032.

Gene editing safety assessment services refer to third-party research, analytical testing, bioinformatics, and regulatory-support activities used to characterize the safety and genomic consequences of engineered edits in cells, tissues, animals, and clinical samples. The service scope centers on in silico risk screening, empirical off-target site nomination, targeted confirmation, on-target edit outcome characterization, detection of translocations and other structural variants, genome integrity analysis, biodistribution and tissue editing measurement, tumorigenicity or functional safety testing, and regulatory-ready interpretation. Typical workflows combine targeted amplicon sequencing, short- and long-read whole-genome sequencing, unbiased break-site mapping, cytogenetic assays, PCR, multi-omics, and validated bioinformatics, with study design adapted to nuclease, base-editing, prime-editing, and multiplex-editing systems. Customers primarily purchase stand-alone assays or integrated packages spanning discovery, lead optimization, preclinical development, IND-enabling studies, and clinical follow-up. The blended gross margin is approximately 55%.

## Market Trends

The industry is moving from limited validation of predicted loci toward orthogonal workflows that combine computational screening, unbiased cell-based or biochemical nomination, targeted deep confirmation, and structural-variant assessment. Short-read sequencing remains the main platform for scalable quantification and confirmation, while long-read sequencing is increasingly used to resolve complex rearrangements,

large deletions, and insertions. Dedicated workflows are also emerging for base editors, prime editors, multiplex editing, and different delivery systems. Customers increasingly evaluate providers on access to relevant cell models, sensitivity for low-frequency events, coverage of donor and population variation, method-validation status, data traceability, and regulatory-reporting experience, shifting demand from stand-alone sequencing toward integrated safety programs.

## Drivers

As gene editing pipelines advance into preclinical and clinical development, candidate-editor screening, off-target risk control, genome integrity assessment, and long-term safety monitoring are becoming mandatory budget items. More specific regulatory expectations for product design, manufacturing testing, nonclinical safety, and clinical follow-up are expanding the required evidence package. In vivo editing and allogeneic cell therapy add demand for tissue distribution, immune-response, and complex-rearrangement assessment, increasing both the breadth and technical depth of outsourced studies.

## Restraints

Safety studies often require therapeutically relevant cells, multiple donors, matched controls, and high sequencing depth, making sample preparation and method development difficult to standardize. Some low-frequency events approach platform noise limits, while complex genomic regions, clonal selection, and cell culture can introduce background variants. These factors raise project cost and duration and require sponsors to reserve adequate material, controls, and validation budgets early in development.

## Opportunities

Base editing, prime editing, multiplex editing, and individualized products create new analytical requirements for RNA off-target effects, non-double-strand-break editing outcomes, population variation, and complex structural events. Providers that integrate editing-system design, sample processing, unbiased nomination, confirmation testing, whole-genome integrity analysis, toxicology, and regulatory reporting within one project framework can reduce inter-laboratory variability and duplicate validation, capturing a larger share of program value.

## Challenges

The sector still lacks fully harmonized assay combinations, positivity thresholds, and standards for interpreting biological risk, and results may vary across platforms, experimental conditions, and bioinformatics pipelines. Providers must also respond to rapid editor innovation, updates to reference genomes and variant databases, data-security obligations, and cross-regional compliance requirements while avoiding the assumption that every detectable molecular event represents a confirmed clinical hazard.

### Value Chain Analysis

Upstream inputs include short- and long-read sequencing platforms, PCR and cytogenetic instruments, library-preparation reagents, reference materials, cell models, reference genomes, and analytical software. Midstream providers design studies, process samples, nominate and confirm sites, analyze data, manage quality, and prepare regulatory-ready reports. Downstream customers include gene and cell therapy developers, pharmaceutical and biotechnology companies, research institutions, and other industries using genome editing. The principal value is not raw sequencing output but an evidence chain connecting editing mechanism, sample background, detection limits, structural variation, and biological impact to candidate selection and regulatory communication. Major costs arise from deep sequencing, specialized reagents, scientific labor, bioinformatics, quality systems, and project management, while proprietary methods, validated workflows, and regulatory experience determine pricing power and margin.

### Segment Insights

By service scope, off-target nomination and confirmation remain the demand foundation and are commonly purchased together with on-target outcome and structural-variant assessment. Integrated safety packages carry higher project values and stronger growth as candidates approach regulatory submission. By technology, targeted amplicon sequencing retains a central role because of its depth, cost, and throughput; unbiased cell-based or biochemical break mapping supports site nomination; short-read whole-genome sequencing broadens variant screening; and long-read platforms are gaining use for complex rearrangements and difficult genomic regions. Preclinical and IND-enabling studies concentrate the highest-value work because they require stronger method performance, quality controls, and reporting completeness.

### Downstream Market Opportunities

Ex vivo edited cell therapies are the most established demand source because samples are accessible and editing sites and cellular backgrounds are comparatively well defined, enabling systematic nomination and confirmation. In vivo genome editing offers faster opportunity growth but requires more complex evaluation of tissue distribution, delivery systems, immune responses, low-frequency tissue editing, and long-term effects. Drug discovery, disease modeling, and basic research are more sensitive to price and turnaround time, while agricultural and industrial biotechnology emphasize trait stability, unintended variation, and compatibility with diverse reference genomes.

## Regional Insights

North America has the densest concentration of therapeutic genome editing companies, specialized analytical platforms, and regulatory-submission experience, making it the principal region for high-value outsourcing and commercialization of new assays. Europe has strong capabilities in cell therapy, genomics, and quality systems, with customers placing greater emphasis on multi-region filing compatibility and data governance. Asia Pacific is expanding through biopharmaceutical investment, growing clinical activity, and local laboratory capacity in China, Japan, South Korea, and Singapore. However, complex unbiased testing and integrated regulatory packages remain concentrated among a limited number of platforms, creating opportunities for cross-border partnerships and localized validation.

## Competitive Landscape Analysis

The market combines specialized technology platforms with integrated CROs. Specialist providers differentiate through proprietary nomination methods, variant-aware analysis, break-site mapping, or structural-rearrangement assays and often build strong technical retention in early editor selection and high-sensitivity genomic risk assessment. Large CROs and global testing groups compete through GLP or GxP systems, animal studies, clinical-sample networks, toxicology, and regulatory delivery across multiple development stages. Competition is shifting from isolated assay performance toward orthogonal method portfolios, relevant-cell handling, validation, integrated data interpretation, and submission-ready reporting. Partnerships, licensing, and acquisitions are increasingly used to connect editing tools, analytical assays, and broader safety-development capabilities.

## Report Scope

LPI (LP Information)' newest research report, the “Gene Editing Safety Assessment Services Industry Forecast” looks at past sales and reviews total world Gene Editing Safety Assessment Services sales in 2025, providing a comprehensive analysis by region and market sector of projected Gene Editing Safety Assessment Services sales for 2026 through 2032. With Gene Editing Safety Assessment Services sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Gene Editing Safety Assessment Services industry.

This Insight Report provides a comprehensive analysis of the global Gene Editing Safety Assessment Services landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Gene Editing Safety Assessment Services portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Gene Editing Safety Assessment Services market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Gene Editing Safety Assessment Services and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Gene Editing Safety Assessment Services.

This report presents a comprehensive overview, market shares, and growth opportunities of Gene Editing Safety Assessment Services market by product type, application, key players and key regions and countries.

Market Segmentation

## **Segmentation by Type:**

Discovery Screening

Lead Optimization

Preclinical Development

IND-Enabling Studies

Clinical Development

Commercial and Lifecycle Support

## **Segmentation by Primary Technology Platform:**

In Silico Risk Prediction

Targeted Amplicon Sequencing

Genome-Wide Sequencing

Cytogenetic and Functional Assays

Unbiased Break-Site Mapping

## **Segmentation by Sample Source:**

Established Cell Lines

Primary Somatic Cells

Stem and Progenitor Cells

Animal Tissues

Clinical Specimens

Other Biological Samples

## **Segmentation by Application:**

Biopharmaceutical and Cell & Gene Therapy Companies

Clinical and Independent Testing Laboratories

Academic and Government Research Institutes

Agricultural Biotechnology Companies

Industrial Biotechnology Companies

## **This report also splits the market by region:**

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Integrated DNA Technologies

MaxCyte

Avance Biosciences

Broken String Biosciences

Synthego

GenScript

CD Genomics

Creative Biogene

Labcorp

Charles River Laboratories

BioAgilytix

Precision for Medicine

Franklin Bio

Eurofins Scientific

SGS

## Contents

### 1 SCOPE OF THE REPORT

- 1.1 Market Introduction
- 1.2 Years Considered
- 1.3 Research Objectives
- 1.4 Market Research Methodology
- 1.5 Research Process and Data Source
- 1.6 Economic Indicators
- 1.7 Currency Considered
- 1.8 Market Estimation Caveats

### 2 EXECUTIVE SUMMARY

#### 2.1 World Market Overview

- 2.1.1 Global Gene Editing Safety Assessment Services Market Size (2021-2032)
- 2.1.2 Gene Editing Safety Assessment Services Market Size CAGR by Region (2021 VS 2025 VS 2032)
- 2.1.3 World Current & Future Analysis for Gene Editing Safety Assessment Services by Country/Region (2021, 2025 & 2032)

#### 2.2 Gene Editing Safety Assessment Services Segment by Type

- 2.2.1 Discovery Screening
- 2.2.2 Lead Optimization
- 2.2.3 Preclinical Development
- 2.2.4 IND-Enabling Studies
- 2.2.5 Clinical Development
- 2.2.6 Commercial and Lifecycle Support
- 2.2.7 Gene Editing Safety Assessment Services Market Size by Type
  - 2.2.7.1 Gene Editing Safety Assessment Services Market Size CAGR by Type (2021 VS 2025 VS 2032)
  - 2.2.7.2 Global Gene Editing Safety Assessment Services Market Size Market Share by Type (2021-2026)

#### 2.3 Gene Editing Safety Assessment Services Segment by Primary Technology Platform

- 2.3.1 In Silico Risk Prediction
- 2.3.2 Targeted Amplicon Sequencing
- 2.3.3 Genome-Wide Sequencing
- 2.3.4 Cytogenetic and Functional Assays

#### 2.3.5 Unbiased Break-Site Mapping

#### 2.3.6 Gene Editing Safety Assessment Services Market Size by Primary Technology Platform

##### 2.3.6.1 Gene Editing Safety Assessment Services Market Size CAGR by Primary Technology Platform (2021 VS 2025 VS 2032)

##### 2.3.6.2 Global Gene Editing Safety Assessment Services Market Size Market Share by Primary Technology Platform (2021-2026)

#### 2.4 Gene Editing Safety Assessment Services Segment by Sample Source

##### 2.4.1 Established Cell Lines

##### 2.4.2 Primary Somatic Cells

##### 2.4.3 Stem and Progenitor Cells

##### 2.4.4 Animal Tissues

##### 2.4.5 Clinical Specimens

##### 2.4.6 Other Biological Samples

##### 2.4.7 Gene Editing Safety Assessment Services Market Size by Sample Source

##### 2.4.7.1 Gene Editing Safety Assessment Services Market Size CAGR by Sample Source (2021 VS 2025 VS 2032)

##### 2.4.7.2 Global Gene Editing Safety Assessment Services Market Size Market Share by Sample Source (2021-2026)

#### 2.5 Gene Editing Safety Assessment Services Segment by Application

##### 2.5.1 Biopharmaceutical and Cell & Gene Therapy Companies

##### 2.5.2 Clinical and Independent Testing Laboratories

##### 2.5.3 Academic and Government Research Institutes

##### 2.5.4 Agricultural Biotechnology Companies

##### 2.5.5 Industrial Biotechnology Companies

##### 2.5.6 Gene Editing Safety Assessment Services Market Size by Application

##### 2.5.6.1 Gene Editing Safety Assessment Services Market Size CAGR by Application (2021 VS 2025 VS 2032)

##### 2.5.6.2 Global Gene Editing Safety Assessment Services Market Size Market Share by Application (2021-2026)

### **3 GENE EDITING SAFETY ASSESSMENT SERVICES MARKET SIZE BY PLAYER**

#### 3.1 Gene Editing Safety Assessment Services Market Size Market Share by Player

##### 3.1.1 Global Gene Editing Safety Assessment Services Revenue by Player (2021-2026)

##### 3.1.2 Global Gene Editing Safety Assessment Services Revenue Market Share by Player (2021-2026)

#### 3.2 Global Gene Editing Safety Assessment Services Key Players Head office and

## Products Offered

### 3.3 Market Concentration Rate Analysis

#### 3.3.1 Competition Landscape Analysis

#### 3.3.2 Concentration Ratio (CR3, CR5 and CR10) & (2024-2026)

### 3.4 New Products and Potential Entrants

### 3.5 Mergers & Acquisitions, Expansion

## 4 GENE EDITING SAFETY ASSESSMENT SERVICES BY REGION

### 4.1 Gene Editing Safety Assessment Services Market Size by Region (2021-2026)

### 4.2 Global Gene Editing Safety Assessment Services Annual Revenue by Country/Region (2021-2026)

### 4.3 Americas Gene Editing Safety Assessment Services Market Size Growth (2021-2026)

### 4.4 APAC Gene Editing Safety Assessment Services Market Size Growth (2021-2026)

### 4.5 Europe Gene Editing Safety Assessment Services Market Size Growth (2021-2026)

### 4.6 Middle East & Africa Gene Editing Safety Assessment Services Market Size Growth (2021-2026)

## 5 AMERICAS

### 5.1 Americas Gene Editing Safety Assessment Services Market Size by Country (2021-2026)

### 5.2 Americas Gene Editing Safety Assessment Services Market Size by Type (2021-2026)

### 5.3 Americas Gene Editing Safety Assessment Services Market Size by Application (2021-2026)

### 5.4 United States

### 5.5 Canada

### 5.6 Mexico

### 5.7 Brazil

## 6 APAC

### 6.1 APAC Gene Editing Safety Assessment Services Market Size by Region (2021-2026)

### 6.2 APAC Gene Editing Safety Assessment Services Market Size by Type (2021-2026)

### 6.3 APAC Gene Editing Safety Assessment Services Market Size by Application (2021-2026)

- 6.4 China
- 6.5 Japan
- 6.6 South Korea
- 6.7 Southeast Asia
- 6.8 India
- 6.9 Australia

## **7 EUROPE**

- 7.1 Europe Gene Editing Safety Assessment Services Market Size by Country (2021-2026)
- 7.2 Europe Gene Editing Safety Assessment Services Market Size by Type (2021-2026)
- 7.3 Europe Gene Editing Safety Assessment Services Market Size by Application (2021-2026)
- 7.4 Germany
- 7.5 France
- 7.6 UK
- 7.7 Italy
- 7.8 Russia

## **8 MIDDLE EAST & AFRICA**

- 8.1 Middle East & Africa Gene Editing Safety Assessment Services by Region (2021-2026)
- 8.2 Middle East & Africa Gene Editing Safety Assessment Services Market Size by Type (2021-2026)
- 8.3 Middle East & Africa Gene Editing Safety Assessment Services Market Size by Application (2021-2026)
- 8.4 Egypt
- 8.5 South Africa
- 8.6 Israel
- 8.7 Turkey
- 8.8 GCC Countries

## **9 MARKET DRIVERS, CHALLENGES AND TRENDS**

- 9.1 Market Drivers & Growth Opportunities
- 9.2 Market Challenges & Risks

## 9.3 Industry Trends

# 10 GLOBAL GENE EDITING SAFETY ASSESSMENT SERVICES MARKET FORECAST

## 10.1 Global Gene Editing Safety Assessment Services Forecast by Region (2027-2032)

### 10.1.1 Global Gene Editing Safety Assessment Services Forecast by Region (2027-2032)

#### 10.1.2 Americas Gene Editing Safety Assessment Services Forecast

#### 10.1.3 APAC Gene Editing Safety Assessment Services Forecast

#### 10.1.4 Europe Gene Editing Safety Assessment Services Forecast

#### 10.1.5 Middle East & Africa Gene Editing Safety Assessment Services Forecast

## 10.2 Americas Gene Editing Safety Assessment Services Forecast by Country (2027-2032)

### 10.2.1 United States Market Gene Editing Safety Assessment Services Forecast

### 10.2.2 Canada Market Gene Editing Safety Assessment Services Forecast

### 10.2.3 Mexico Market Gene Editing Safety Assessment Services Forecast

### 10.2.4 Brazil Market Gene Editing Safety Assessment Services Forecast

## 10.3 APAC Gene Editing Safety Assessment Services Forecast by Region (2027-2032)

### 10.3.1 China Gene Editing Safety Assessment Services Market Forecast

### 10.3.2 Japan Market Gene Editing Safety Assessment Services Forecast

### 10.3.3 Korea Market Gene Editing Safety Assessment Services Forecast

### 10.3.4 Southeast Asia Market Gene Editing Safety Assessment Services Forecast

### 10.3.5 India Market Gene Editing Safety Assessment Services Forecast

### 10.3.6 Australia Market Gene Editing Safety Assessment Services Forecast

## 10.4 Europe Gene Editing Safety Assessment Services Forecast by Country (2027-2032)

### 10.4.1 Germany Market Gene Editing Safety Assessment Services Forecast

### 10.4.2 France Market Gene Editing Safety Assessment Services Forecast

### 10.4.3 UK Market Gene Editing Safety Assessment Services Forecast

### 10.4.4 Italy Market Gene Editing Safety Assessment Services Forecast

### 10.4.5 Russia Market Gene Editing Safety Assessment Services Forecast

## 10.5 Middle East & Africa Gene Editing Safety Assessment Services Forecast by Region (2027-2032)

### 10.5.1 Egypt Market Gene Editing Safety Assessment Services Forecast

### 10.5.2 South Africa Market Gene Editing Safety Assessment Services Forecast

### 10.5.3 Israel Market Gene Editing Safety Assessment Services Forecast

### 10.5.4 Turkey Market Gene Editing Safety Assessment Services Forecast

## 10.6 Global Gene Editing Safety Assessment Services Forecast by Type (2027-2032)

## 10.7 Global Gene Editing Safety Assessment Services Forecast by Application (2027-2032)

### 10.7.1 GCC Countries Market Gene Editing Safety Assessment Services Forecast

## 11 KEY PLAYERS ANALYSIS

### 11.1 Integrated DNA Technologies

#### 11.1.1 Integrated DNA Technologies Company Information

#### 11.1.2 Integrated DNA Technologies Gene Editing Safety Assessment Services Product Offered

#### 11.1.3 Integrated DNA Technologies Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

#### 11.1.4 Integrated DNA Technologies Main Business Overview

#### 11.1.5 Integrated DNA Technologies Latest Developments

### 11.2 MaxCyte

#### 11.2.1 MaxCyte Company Information

#### 11.2.2 MaxCyte Gene Editing Safety Assessment Services Product Offered

#### 11.2.3 MaxCyte Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

#### 11.2.4 MaxCyte Main Business Overview

#### 11.2.5 MaxCyte Latest Developments

### 11.3 Avance Biosciences

#### 11.3.1 Avance Biosciences Company Information

#### 11.3.2 Avance Biosciences Gene Editing Safety Assessment Services Product Offered

#### 11.3.3 Avance Biosciences Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

#### 11.3.4 Avance Biosciences Main Business Overview

#### 11.3.5 Avance Biosciences Latest Developments

### 11.4 Broken String Biosciences

#### 11.4.1 Broken String Biosciences Company Information

#### 11.4.2 Broken String Biosciences Gene Editing Safety Assessment Services Product Offered

#### 11.4.3 Broken String Biosciences Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

#### 11.4.4 Broken String Biosciences Main Business Overview

#### 11.4.5 Broken String Biosciences Latest Developments

### 11.5 Synthego

#### 11.5.1 Synthego Company Information

#### 11.5.2 Synthego Gene Editing Safety Assessment Services Product Offered

11.5.3 Synthego Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

11.5.4 Synthego Main Business Overview

11.5.5 Synthego Latest Developments

11.6 GenScript

11.6.1 GenScript Company Information

11.6.2 GenScript Gene Editing Safety Assessment Services Product Offered

11.6.3 GenScript Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

11.6.4 GenScript Main Business Overview

11.6.5 GenScript Latest Developments

11.7 CD Genomics

11.7.1 CD Genomics Company Information

11.7.2 CD Genomics Gene Editing Safety Assessment Services Product Offered

11.7.3 CD Genomics Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

11.7.4 CD Genomics Main Business Overview

11.7.5 CD Genomics Latest Developments

11.8 Creative Biogene

11.8.1 Creative Biogene Company Information

11.8.2 Creative Biogene Gene Editing Safety Assessment Services Product Offered

11.8.3 Creative Biogene Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

11.8.4 Creative Biogene Main Business Overview

11.8.5 Creative Biogene Latest Developments

11.9 Labcorp

11.9.1 Labcorp Company Information

11.9.2 Labcorp Gene Editing Safety Assessment Services Product Offered

11.9.3 Labcorp Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

11.9.4 Labcorp Main Business Overview

11.9.5 Labcorp Latest Developments

11.10 Charles River Laboratories

11.10.1 Charles River Laboratories Company Information

11.10.2 Charles River Laboratories Gene Editing Safety Assessment Services Product Offered

11.10.3 Charles River Laboratories Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)

11.10.4 Charles River Laboratories Main Business Overview

- 11.10.5 Charles River Laboratories Latest Developments
- 11.11 BioAgilytix
  - 11.11.1 BioAgilytix Company Information
  - 11.11.2 BioAgilytix Gene Editing Safety Assessment Services Product Offered
  - 11.11.3 BioAgilytix Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)
  - 11.11.4 BioAgilytix Main Business Overview
  - 11.11.5 BioAgilytix Latest Developments
- 11.12 Precision for Medicine
  - 11.12.1 Precision for Medicine Company Information
  - 11.12.2 Precision for Medicine Gene Editing Safety Assessment Services Product Offered
  - 11.12.3 Precision for Medicine Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)
  - 11.12.4 Precision for Medicine Main Business Overview
  - 11.12.5 Precision for Medicine Latest Developments
- 11.13 Franklin Bio
  - 11.13.1 Franklin Bio Company Information
  - 11.13.2 Franklin Bio Gene Editing Safety Assessment Services Product Offered
  - 11.13.3 Franklin Bio Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)
  - 11.13.4 Franklin Bio Main Business Overview
  - 11.13.5 Franklin Bio Latest Developments
- 11.14 Eurofins Scientific
  - 11.14.1 Eurofins Scientific Company Information
  - 11.14.2 Eurofins Scientific Gene Editing Safety Assessment Services Product Offered
  - 11.14.3 Eurofins Scientific Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)
  - 11.14.4 Eurofins Scientific Main Business Overview
  - 11.14.5 Eurofins Scientific Latest Developments
- 11.15 SGS
  - 11.15.1 SGS Company Information
  - 11.15.2 SGS Gene Editing Safety Assessment Services Product Offered
  - 11.15.3 SGS Gene Editing Safety Assessment Services Revenue, Gross Margin and Market Share (2021-2026)
  - 11.15.4 SGS Main Business Overview
  - 11.15.5 SGS Latest Developments

## **12 RESEARCH FINDINGS AND CONCLUSION**

## List Of Tables

### LIST OF TABLES

Table 1. Gene Editing Safety Assessment Services Market Size CAGR by Region (2021 VS 2025 VS 2032) & (\$ millions)

Table 2. Gene Editing Safety Assessment Services Annual Sales CAGR by Country/Region (2021, 2025 & 2032) & (\$ millions)

Table 3. Major Players of Discovery Screening

Table 4. Major Players of Lead Optimization

Table 5. Major Players of Preclinical Development

Table 6. Major Players of IND-Enabling Studies

Table 7. Major Players of Clinical Development

Table 8. Major Players of Commercial and Lifecycle Support

Table 9. Gene Editing Safety Assessment Services Market Size CAGR by Type (2021 VS 2025 VS 2032) & (\$ millions)

Table 10. Global Gene Editing Safety Assessment Services Market Size by Type (2021-2026) & (\$ millions)

Table 11. Global Gene Editing Safety Assessment Services Market Size Market Share by Type (2021-2026)

Table 12. Major Players of In Silico Risk Prediction

Table 13. Major Players of Targeted Amplicon Sequencing

Table 14. Major Players of Genome-Wide Sequencing

Table 15. Major Players of Cytogenetic and Functional Assays

Table 16. Major Players of Unbiased Break-Site Mapping

Table 17. Gene Editing Safety Assessment Services Market Size CAGR by Primary Technology Platform (2021 VS 2025 VS 2032) & (\$ millions)

Table 18. Global Gene Editing Safety Assessment Services Market Size by Primary Technology Platform (2021-2026) & (\$ millions)

Table 19. Global Gene Editing Safety Assessment Services Market Size Market Share by Primary Technology Platform (2021-2026)

Table 20. Major Players of Established Cell Lines

Table 21. Major Players of Primary Somatic Cells

Table 22. Major Players of Stem and Progenitor Cells

Table 23. Major Players of Animal Tissues

Table 24. Major Players of Clinical Specimens

Table 25. Major Players of Other Biological Samples

Table 26. Gene Editing Safety Assessment Services Market Size CAGR by Sample Source (2021 VS 2025 VS 2032) & (\$ millions)

Table 27. Global Gene Editing Safety Assessment Services Market Size by Sample Source (2021-2026) & (\$ millions)

Table 28. Global Gene Editing Safety Assessment Services Market Size Market Share by Sample Source (2021-2026)

Table 29. Gene Editing Safety Assessment Services Market Size CAGR by Application (2021 VS 2025 VS 2032) & (\$ millions)

Table 30. Global Gene Editing Safety Assessment Services Market Size by Application (2021-2026) & (\$ millions)

Table 31. Global Gene Editing Safety Assessment Services Market Size Market Share by Application (2021-2026)

Table 32. Global Gene Editing Safety Assessment Services Revenue by Player (2021-2026) & (\$ millions)

Table 33. Global Gene Editing Safety Assessment Services Revenue Market Share by Player (2021-2026)

Table 34. Gene Editing Safety Assessment Services Key Players Head office and Products Offered

Table 35. Gene Editing Safety Assessment Services Concentration Ratio (CR3, CR5 and CR10) & (2024-2026)

Table 36. New Products and Potential Entrants

Table 37. Mergers & Acquisitions, Expansion

Table 38. Global Gene Editing Safety Assessment Services Market Size by Region (2021-2026) & (\$ millions)

Table 39. Global Gene Editing Safety Assessment Services Market Size Market Share by Region (2021-2026)

Table 40. Global Gene Editing Safety Assessment Services Revenue by Country/Region (2021-2026) & (\$ millions)

Table 41. Global Gene Editing Safety Assessment Services Revenue Market Share by Country/Region (2021-2026)

Table 42. Americas Gene Editing Safety Assessment Services Market Size by Country (2021-2026) & (\$ millions)

Table 43. Americas Gene Editing Safety Assessment Services Market Size Market Share by Country (2021-2026)

Table 44. Americas Gene Editing Safety Assessment Services Market Size by Type (2021-2026) & (\$ millions)

Table 45. Americas Gene Editing Safety Assessment Services Market Size Market Share by Type (2021-2026)

Table 46. Americas Gene Editing Safety Assessment Services Market Size by Application (2021-2026) & (\$ millions)

Table 47. Americas Gene Editing Safety Assessment Services Market Size Market

Share by Application (2021-2026)

Table 48. APAC Gene Editing Safety Assessment Services Market Size by Region (2021-2026) & (\$ millions)

Table 49. APAC Gene Editing Safety Assessment Services Market Size Market Share by Region (2021-2026)

Table 50. APAC Gene Editing Safety Assessment Services Market Size by Type (2021-2026) & (\$ millions)

Table 51. APAC Gene Editing Safety Assessment Services Market Size by Application (2021-2026) & (\$ millions)

Table 52. Europe Gene Editing Safety Assessment Services Market Size by Country (2021-2026) & (\$ millions)

Table 53. Europe Gene Editing Safety Assessment Services Market Size Market Share by Country (2021-2026)

Table 54. Europe Gene Editing Safety Assessment Services Market Size by Type (2021-2026) & (\$ millions)

Table 55. Europe Gene Editing Safety Assessment Services Market Size by Application (2021-2026) & (\$ millions)

Table 56. Middle East & Africa Gene Editing Safety Assessment Services Market Size by Region (2021-2026) & (\$ millions)

Table 57. Middle East & Africa Gene Editing Safety Assessment Services Market Size by Type (2021-2026) & (\$ millions)

Table 58. Middle East & Africa Gene Editing Safety Assessment Services Market Size by Application (2021-2026) & (\$ millions)

Table 59. Key Market Drivers & Growth Opportunities of Gene Editing Safety Assessment Services

Table 60. Key Market Challenges & Risks of Gene Editing Safety Assessment Services

Table 61. Key Industry Trends of Gene Editing Safety Assessment Services

Table 62. Global Gene Editing Safety Assessment Services Market Size Forecast by Region (2027-2032) & (\$ millions)

Table 63. Global Gene Editing Safety Assessment Services Market Size Market Share Forecast by Region (2027-2032)

Table 64. Global Gene Editing Safety Assessment Services Market Size Forecast by Type (2027-2032) & (\$ millions)

Table 65. Global Gene Editing Safety Assessment Services Market Size Forecast by Application (2027-2032) & (\$ millions)

Table 66. Integrated DNA Technologies Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 67. Integrated DNA Technologies Gene Editing Safety Assessment Services Product Offered

Table 68. Integrated DNA Technologies Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 69. Integrated DNA Technologies Main Business

Table 70. Integrated DNA Technologies Latest Developments

Table 71. MaxCyte Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 72. MaxCyte Gene Editing Safety Assessment Services Product Offered

Table 73. MaxCyte Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 74. MaxCyte Main Business

Table 75. MaxCyte Latest Developments

Table 76. Avance Biosciences Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 77. Avance Biosciences Gene Editing Safety Assessment Services Product Offered

Table 78. Avance Biosciences Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 79. Avance Biosciences Main Business

Table 80. Avance Biosciences Latest Developments

Table 81. Broken String Biosciences Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 82. Broken String Biosciences Gene Editing Safety Assessment Services Product Offered

Table 83. Broken String Biosciences Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 84. Broken String Biosciences Main Business

Table 85. Broken String Biosciences Latest Developments

Table 86. Synthego Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 87. Synthego Gene Editing Safety Assessment Services Product Offered

Table 88. Synthego Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 89. Synthego Main Business

Table 90. Synthego Latest Developments

Table 91. GenScript Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 92. GenScript Gene Editing Safety Assessment Services Product Offered

Table 93. GenScript Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 94. GenScript Main Business

Table 95. GenScript Latest Developments

Table 96. CD Genomics Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 97. CD Genomics Gene Editing Safety Assessment Services Product Offered

Table 98. CD Genomics Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 99. CD Genomics Main Business

Table 100. CD Genomics Latest Developments

Table 101. Creative Biogene Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 102. Creative Biogene Gene Editing Safety Assessment Services Product Offered

Table 103. Creative Biogene Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 104. Creative Biogene Main Business

Table 105. Creative Biogene Latest Developments

Table 106. Labcorp Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 107. Labcorp Gene Editing Safety Assessment Services Product Offered

Table 108. Labcorp Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 109. Labcorp Main Business

Table 110. Labcorp Latest Developments

Table 111. Charles River Laboratories Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 112. Charles River Laboratories Gene Editing Safety Assessment Services Product Offered

Table 113. Charles River Laboratories Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 114. Charles River Laboratories Main Business

Table 115. Charles River Laboratories Latest Developments

Table 116. BioAgilytix Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 117. BioAgilytix Gene Editing Safety Assessment Services Product Offered

Table 118. BioAgilytix Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 119. BioAgilytix Main Business

Table 120. BioAgilytix Latest Developments

Table 121. Precision for Medicine Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 122. Precision for Medicine Gene Editing Safety Assessment Services Product Offered

Table 123. Precision for Medicine Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 124. Precision for Medicine Main Business

Table 125. Precision for Medicine Latest Developments

Table 126. Franklin Bio Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 127. Franklin Bio Gene Editing Safety Assessment Services Product Offered

Table 128. Franklin Bio Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 129. Franklin Bio Main Business

Table 130. Franklin Bio Latest Developments

Table 131. Eurofins Scientific Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 132. Eurofins Scientific Gene Editing Safety Assessment Services Product Offered

Table 133. Eurofins Scientific Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 134. Eurofins Scientific Main Business

Table 135. Eurofins Scientific Latest Developments

Table 136. SGS Details, Company Type, Gene Editing Safety Assessment Services Area Served and Its Competitors

Table 137. SGS Gene Editing Safety Assessment Services Product Offered

Table 138. SGS Gene Editing Safety Assessment Services Revenue (\$ million), Gross Margin and Market Share (2021-2026)

Table 139. SGS Main Business

Table 140. SGS Latest Developments

## List Of Figures

### LIST OF FIGURES

- Figure 1. Gene Editing Safety Assessment Services Report Years Considered
- Figure 2. Research Objectives
- Figure 3. Research Methodology
- Figure 4. Research Process and Data Source
- Figure 5. Global Gene Editing Safety Assessment Services Market Size Growth Rate (2021-2032) (\$ millions)
- Figure 6. Gene Editing Safety Assessment Services Sales by Geographic Region (2021, 2025 & 2032) & (\$ millions)
- Figure 7. Gene Editing Safety Assessment Services Sales Market Share by Country/Region (2025)
- Figure 8. Gene Editing Safety Assessment Services Sales Market Share by Country/Region (2021, 2025 & 2032)
- Figure 9. Global Gene Editing Safety Assessment Services Market Size Market Share by Type in 2025
- Figure 10. Global Gene Editing Safety Assessment Services Market Size Market Share by Primary Technology Platform in 2025
- Figure 11. Global Gene Editing Safety Assessment Services Market Size Market Share by Sample Source in 2025
- Figure 12. Gene Editing Safety Assessment Services in Biopharmaceutical and Cell & Gene Therapy Companies
- Figure 13. Global Gene Editing Safety Assessment Services Market: Biopharmaceutical and Cell & Gene Therapy Companies (2021-2026) & (\$ millions)
- Figure 14. Gene Editing Safety Assessment Services in Clinical and Independent Testing Laboratories
- Figure 15. Global Gene Editing Safety Assessment Services Market: Clinical and Independent Testing Laboratories (2021-2026) & (\$ millions)
- Figure 16. Gene Editing Safety Assessment Services in Academic and Government Research Institutes
- Figure 17. Global Gene Editing Safety Assessment Services Market: Academic and Government Research Institutes (2021-2026) & (\$ millions)
- Figure 18. Gene Editing Safety Assessment Services in Agricultural Biotechnology Companies
- Figure 19. Global Gene Editing Safety Assessment Services Market: Agricultural Biotechnology Companies (2021-2026) & (\$ millions)
- Figure 20. Gene Editing Safety Assessment Services in Industrial Biotechnology

## Companies

Figure 21. Global Gene Editing Safety Assessment Services Market: Industrial Biotechnology Companies (2021-2026) & (\$ millions)

Figure 22. Global Gene Editing Safety Assessment Services Market Size Market Share by Application in 2025

Figure 23. Global Gene Editing Safety Assessment Services Revenue Market Share by Player in 2025

Figure 24. Global Gene Editing Safety Assessment Services Market Size Market Share by Region (2021-2026)

Figure 25. Americas Gene Editing Safety Assessment Services Market Size 2021-2026 (\$ millions)

Figure 26. APAC Gene Editing Safety Assessment Services Market Size 2021-2026 (\$ millions)

Figure 27. Europe Gene Editing Safety Assessment Services Market Size 2021-2026 (\$ millions)

Figure 28. Middle East & Africa Gene Editing Safety Assessment Services Market Size 2021-2026 (\$ millions)

Figure 29. Americas Gene Editing Safety Assessment Services Value Market Share by Country in 2025

Figure 30. United States Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 31. Canada Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 32. Mexico Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 33. Brazil Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 34. APAC Gene Editing Safety Assessment Services Market Size Market Share by Region in 2025

Figure 35. APAC Gene Editing Safety Assessment Services Market Size Market Share by Type (2021-2026)

Figure 36. APAC Gene Editing Safety Assessment Services Market Size Market Share by Application (2021-2026)

Figure 37. China Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 38. Japan Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 39. South Korea Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 40. Southeast Asia Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 41. India Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 42. Australia Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 43. Europe Gene Editing Safety Assessment Services Market Size Market Share by Country in 2025

Figure 44. Europe Gene Editing Safety Assessment Services Market Size Market Share by Type (2021-2026)

Figure 45. Europe Gene Editing Safety Assessment Services Market Size Market Share by Application (2021-2026)

Figure 46. Germany Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 47. France Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 48. UK Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 49. Italy Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 50. Russia Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 51. Middle East & Africa Gene Editing Safety Assessment Services Market Size Market Share by Region (2021-2026)

Figure 52. Middle East & Africa Gene Editing Safety Assessment Services Market Size Market Share by Type (2021-2026)

Figure 53. Middle East & Africa Gene Editing Safety Assessment Services Market Size Market Share by Application (2021-2026)

Figure 54. Egypt Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 55. South Africa Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 56. Israel Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 57. Turkey Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 58. GCC Countries Gene Editing Safety Assessment Services Market Size Growth 2021-2026 (\$ millions)

Figure 59. Americas Gene Editing Safety Assessment Services Market Size 2027-2032

(\$ millions)

Figure 60. APAC Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 61. Europe Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 62. Middle East & Africa Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 63. United States Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 64. Canada Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 65. Mexico Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 66. Brazil Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 67. China Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 68. Japan Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 69. Korea Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 70. Southeast Asia Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 71. India Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 72. Australia Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 73. Germany Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 74. France Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 75. UK Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 76. Italy Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 77. Russia Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 78. Egypt Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 79. South Africa Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 80. Israel Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 81. Turkey Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

Figure 82. Global Gene Editing Safety Assessment Services Market Size Market Share Forecast by Type (2027-2032)

Figure 83. Global Gene Editing Safety Assessment Services Market Size Market Share Forecast by Application (2027-2032)

Figure 84. GCC Countries Gene Editing Safety Assessment Services Market Size 2027-2032 (\$ millions)

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