

# **Bioprocess Validation Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Testing Type (Extractables & Leachables Testing, Bioprocess Residuals Testing, Viral Clearance Testing, Filtration & Fermentation Systems Testing, Others), By Stage (Process Design, Process Qualification, Continued Process Verification), By Mode (In house, Outsourced), By Region and Competition, 2019-2029F**

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## **Abstracts**

Global Bioprocess Validation Market was valued at USD 298.05 Million in 2023 and is anticipated to project impressive growth in the forecast period with a CAGR of 13.71% through 2029. Bioprocess validation is an approach used to obtain documentary evidence by demonstrating procedures, processes, and activities conducted during the production and testing of products. Its purpose is to ensure compliance at all phases. This comprehensive approach involves various testing services, such as extractable, microbiological, compatibility, integrity, and physiochemical testing, which are considered standard methods. These techniques are crucial in evaluating multiple active pharmaceutical ingredients (APIs) and potential contaminants, including endotoxin, mycoplasma, and bacteria, during the development of biological products and animal drugs. Bioprocess validation is not only cost-effective but also serves as a monitoring tool for practices and medication manufacturing procedures. As a result, it is widely adopted by pharmaceutical, biopharmaceutical, and contract development and manufacturing organizations (CMOs) to ensure drug quality, safety, efficacy, and predetermined attributes.

## Key Market Drivers

### Increasing Demand for Biopharmaceuticals

The increasing demand for biopharmaceuticals is undeniably propelling the need for robust bioprocess validation. Biopharmaceuticals, including monoclonal antibodies, vaccines, gene therapies, and recombinant proteins, have gained prominence in the pharmaceutical industry due to their efficacy and specificity in treating a wide range of diseases, including cancer, autoimmune disorders, and infectious diseases.

Biopharmaceuticals are highly complex molecules, often produced using living cells or biological systems. Ensuring their safety, efficacy, and consistent quality is paramount. Bioprocess validation guarantees that each batch of biopharmaceuticals meets predefined quality standards. The biopharmaceutical manufacturing process can be complex and involves various parameters, including cell culture conditions, purification methods, and formulation. Validation helps optimize these processes, ensuring efficient resource utilization and cost-effective production.

### Increasing Demand for Outsourcing Bioprocess Validation

The increasing demand for outsourcing bioprocess validation services is contributing to the overall demand for bioprocess validation. Bioprocess validation, a critical component of biopharmaceutical development and manufacturing, involves confirming that production processes consistently yield products meeting predefined quality and safety standards. Bioprocess validation requires specialized knowledge and expertise in regulatory compliance, analytical techniques, and quality control. Outsourcing to specialized service providers ensures access to a highly skilled workforce with extensive experience in validation protocols and regulatory requirements. Outsourcing can be a cost-effective alternative to building and maintaining in-house validation teams and infrastructure. Biopharmaceutical companies can allocate resources more efficiently by paying for validation services only when needed. The demand for biopharmaceuticals can be unpredictable, with peaks and troughs in production. Outsourcing allows companies to scale validation activities up or down as required, accommodating fluctuations in demand without incurring additional fixed costs.

Validation service providers stay current with evolving regulatory guidelines and industry best practices. Outsourcing to experts helps ensure compliance with complex and frequently updated regulations, reducing the risk of regulatory setbacks.

In the pharmaceutical sector, adherence to the standards set by regulatory bodies is

crucial, which is why bioprocess validation is an integral part of pharmaceutical operations. Validation ensures that all procedures comply with government regulations and requirements. Thorough documentation following standard operating procedures and ongoing activities is a key component of any validation process. To improve production yields, pharmaceutical manufacturing is increasingly outsourced to third-party service providers. The widespread use of disposable technologies in medication development helps in reducing production costs. The growing trend of outsourcing bioprocess validation to third-party service providers is expected to drive the growth of the bioprocess validation market.

### Rising Life Science RD Expenditure

Life science RD projects, particularly in biopharmaceuticals and biotechnology, are becoming increasingly complex. The development of novel therapies, vaccines, and biologics involves intricate processes and formulations. Bioprocess validation becomes indispensable to ensure these complexities are managed effectively. RD in the life sciences is heavily regulated, with strict adherence to regulatory guidelines essential. Bioprocess validation is a key component in demonstrating the safety, efficacy, and consistency of experimental products, supporting regulatory submissions and approvals. Quality control and assurance are paramount in life science RD to generate reliable and reproducible data. Bioprocess validation guarantees that research protocols and experimental methods consistently produce high-quality results, improving the credibility and impact of research findings.

In a highly competitive market, life science companies need to accelerate their RD pipelines to bring new products to market swiftly. Effective bioprocess validation expedites development timelines by ensuring efficient and reliable manufacturing processes. Increased RD investment often translates into greater innovation in the development of new drugs, biologics, and therapies. Bioprocess validation ensures that these innovative products can be produced at scale while maintaining safety and efficacy. RD investments are fueling the development of innovative therapies, including cell and gene therapies, monoclonal antibodies, and regenerative medicine. These emerging therapies require robust bioprocess validation to ensure their safety and efficacy.

### Rising Usage of Single Use Bioprocessing

The implementation of single-use bioprocessing systems improves manufacturing process productivity by reducing the cost and complexity of automation. It also

eliminates the need for changeover cleaning/validation between consecutive operations. Additionally, single-use bioprocessing systems eliminate the requirement for additional investments by eliminating the need for sterilization. The initial investment costs with single-use bioprocessing systems are lower compared to those of stainless-steel facilities at the same scale, making them suitable for new players with limited investments. This, in turn, enhances the demand for the bioprocess validation market. The rising usage of single-use bioprocessing technologies is indeed increasing the demand for bioprocess validation. Single-use bioprocessing, characterized by the use of disposable components and systems in the biopharmaceutical manufacturing process, offers numerous advantages, such as cost-effectiveness, flexibility, and reduced risk of contamination. However, it also introduces unique challenges and validation requirements that drive the demand for comprehensive validation services.

Single-use bioprocessing involves various disposable components, such as bags, filters, connectors, and sensors. Each of these components needs to be validated for its intended use, ensuring they meet quality and performance standards.

## Key Market Challenges

### Issues Related to Extractables Leachables

The food and pharmaceutical sectors encounter challenges related to trace amounts of contaminants resulting from the extraction or leaching process. Despite stringent governmental regulations, some corporations continue to overlook these concerns, posing risks to the lives of consumers and patients. Pharmaceutical manufacturers and regulatory agencies express concern regarding extractables and leachables. Various components of containers and pharmaceutical packaging systems, such as plastic bottles, labeling ink, packing materials, glass, and foil pouches, have the potential to release undesirable pollutants into food ingredients or drug products. Particularly, oral drugs, parental products, and ophthalmic products present a higher level of risk. Consequently, issues associated with extractables and leachables are expected to impede the growth of the bioprocess validation market.

Manufacturers often change suppliers or materials, introducing potential variability in extractable and leachable profiles. This variability can complicate validation efforts. Regulatory agencies, especially in the pharmaceutical and biopharmaceutical industries, closely scrutinize the presence of extractables and leachables in drug products and their potential impact on patient safety. The need to comply with regulatory requirements can increase the demand for validation.

The presence of harmful extractables and leachables can lead to product contamination, which can have serious consequences for patient safety and product integrity. Validation helps mitigate this risk and ensures that product quality is maintained. The absence of standardized methods for extractables and leachables testing can lead to variations in how these studies are conducted and interpreted. This lack of standardization can make validation more challenging and hinder its widespread adoption.

### Cost Constraints

Implementing a robust bioprocess validation program can be expensive. Costs include analytical equipment, materials, labor, and regulatory compliance efforts. Smaller companies or organizations with limited budgets may find it challenging to allocate resources for comprehensive validation. Validating bioprocesses often requires specialized analytical equipment to test product quality, safety, and consistency. This equipment can be costly to purchase, maintain, and operate. High-performance liquid chromatography (HPLC), mass spectrometers, spectrophotometers, and other analytical instruments are examples of necessary equipment.

Validating bioprocesses may involve the use of specific materials, such as reagents, chemicals, and disposable components. These materials must meet stringent quality and regulatory standards, which can increase their cost. Additionally, selecting materials that are compatible with the process and that minimize the risk of extractables and leachables may require more expensive alternatives. Comprehensive validation requires conducting numerous studies, including method validation, equipment qualification, process validation, and cleaning validation, among others. Each of these studies incurs costs related to materials, labor, and equipment usage.

### Key Market Trends

#### Growth of Personalized Medicine

Personalized medicine, which tailors medical treatments to individual patients, is gaining prominence. The development and production of personalized therapies often involve complex bioprocesses that require stringent validation to guarantee safety and efficacy for each patient. Personalized medicine enables the design of therapies that specifically target the underlying causes of diseases in individual patients. This requires the identification of precise therapeutic targets, often involving genetic or biomarker

analysis. Validation is essential to confirm that these targets are reliably identified and that the selected therapies are effective. Personalized therapies may involve complex bioprocesses, such as cell and gene therapies, where living cells are manipulated to produce therapeutic products. Validating these processes is critical to confirm that they consistently result in products meeting the required quality and safety standards. Maintaining stringent quality control is paramount in personalized medicine to ensure that therapies meet the highest safety and efficacy standards. Validation helps establish quality control measures to monitor and verify the characteristics of personalized treatments.

### Advancements in Bioprocessing Technologies

Emerging bioprocessing technologies, such as continuous manufacturing and single-use systems, are becoming more prevalent. These technologies require tailored validation approaches to ensure their efficiency, reliability, and compliance with regulatory standards. Continuous manufacturing is a departure from traditional batch processing, allowing for a continuous flow of materials through a production process. It offers advantages such as reduced cycle times, improved product quality, and enhanced process control. Validation is required to ensure that the continuous manufacturing process consistently produces products meeting predefined quality and safety standards. Single-use systems (SUS) involve the use of disposable components and equipment in bioprocessing, replacing traditional stainless-steel systems. SUS offer flexibility, reduced risk of cross-contamination, and cost savings. However, validation is necessary to confirm that these systems meet regulatory requirements, including extractables and leachables assessment, and that they are compatible with the specific bioprocess. Both continuous manufacturing and single-use systems are designed to improve process efficiency and reduce costs. Continuous manufacturing minimizes idle time and resource waste, while single-use systems eliminate the need for cleaning and sterilization. Validation ensures that these efficiency gains are achieved without compromising product quality or safety.

### Segmental Insights

#### Testing Type Insights

Based on the type of testing, the bioprocess validation market is categorized into Extractables Leachables Testing, Bioprocess Residuals Testing, Viral Clearance Testing, Filtration Fermentation Systems Testing, and Others. The segment of extractables leachables testing has significantly contributed to the revenue share in the



bioprocess validation market in 2023. This growth can be attributed to the adherence to good manufacturing practice guidelines and US FDA regulations, which have led to a high demand for certified quality bioproducts. Biotechnology and biopharmaceutical companies are actively involved in the production of cGMP-certified bioproducts. The need for government-certified products is expected to drive the growth of this segment in the forecasted period.

### Stage Insights

Based on the stage, the bioprocess validation market is categorized into Process Design, Process Qualification, and Continued Process Verification. In 2023, the continued process verification segment accounted for the largest revenue share in the bioprocess validation market. This is attributed to its comprehensive approach, encompassing data collection, analysis, and storage for each batch. The primary objectives of implementing a continued process verification plan are ensuring regulatory compliance, minimizing batch rejections, and identifying areas for continuous improvement. These characteristics, coupled with process automation, will drive the expansion of this segment.

### Regional Insights

The North America region exhibited dominant performance in the bioprocess validation market, capturing the largest revenue share in 2023. This can be attributed to the significant presence of outsourcing service providers, fostering the growth of life science research and biologics production. Additionally, the region boasts numerous FDA-approved biopharmaceutical and biotechnological industries. The increased government funding for bioprocess validation and clinical trials, coupled with the presence of key market players, is expected to drive further growth in the region.

### Key Market Players

Merck KGaA

SGS S.A.

Eurofins Scientific SE

Sartorius AG

Pall Corporation

Cobetter Filtration Equipments Co., Ltd

Laboratory Corporation of America Holdings

DOC S.r.l

Meissner Corporation

Thermo Fisher Scientific, Inc.

Report Scope:

In this report, the Global Bioprocess Validation Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Bioprocess Validation Market,By Testing Type:

- oExtractables Leachables Testing

- oBioprocess Residuals Testing

- oViral Clearance Testing

- oFiltration Fermentation Systems Testing

- oOthers

Bioprocess Validation Market,By Stage:

- oProcess Design

- oProcess Qualification

- oContinued Process Verification

Bioprocess Validation Market,By Mode:



oIn house

oOutsourced

Bioprocess Validation Market, By Region:

oNorth America

United States

Canada

Mexico

oEurope

France

United Kingdom

Italy

Germany

Spain

oAsia-Pacific

China

India

Japan

Australia

South Korea

oSouth America

Brazil

Argentina

Colombia

oMiddle East Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Bioprocess Validation Market.

Available Customizations:

Global Bioprocess Validation market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

## Contents

### **1.PRODUCT OVERVIEW**

- 1.1.Market Definition
- 1.2.Scope of the Market
  - 1.2.1.Markets Covered
  - 1.2.2.Years Considered for Study
  - 1.2.3.Key Market Segmentations

### **2.RESEARCH METHODOLOGY**

- 2.1.Objective of the Study
- 2.2.Baseline Methodology
- 2.3.Key Industry Partners
- 2.4.Major Association and Secondary Sources
- 2.5.Forecasting Methodology
- 2.6.Data Triangulation Validations
- 2.7.Assumptions and Limitations

### **3.EXECUTIVE SUMMARY**

- 3.1.Overview of the Market
- 3.2.Overview of Key Market Segmentations
- 3.3.Overview of Key Market Players
- 3.4.Overview of Key Regions/Countries
- 3.5.Overview of Market Drivers, Challenges, Trends

### **4.VOICE OF CUSTOMER**

### **5.GLOBAL BIOPROCESS VALIDATION MARKET OUTLOOK**

- 5.1.Market Size Forecast
  - 5.1.1.By Value
- 5.2.Market Share Forecast
  - 5.2.1.By Testing Type (Extractables Leachables Testing, Bioprocess Residuals Testing, Viral Clearance Testing, Filtration Fermentation Systems Testing, Others)
  - 5.2.2.By Stage (Process Design, Process Qualification, Continued Process Verification)

- 5.2.3.By Mode (In house, Outsourced)
- 5.2.4.By Region
- 5.2.5.By Company (2023)
- 5.3.Market Map

## **6.NORTH AMERICA BIOPROCESS VALIDATION MARKET OUTLOOK**

- 6.1.Market Size Forecast
  - 6.1.1.By Value
- 6.2.Market Share Forecast
  - 6.2.1.By Testing Type
  - 6.2.2.By Stage
  - 6.2.3.By Mode
  - 6.2.4.By Country
- 6.3.North America: Country Analysis
  - 6.3.1.United States Bioprocess Validation Market Outlook
    - 6.3.1.1.Market Size Forecast
      - 6.3.1.1.1.By Value
    - 6.3.1.2.Market Share Forecast
      - 6.3.1.2.1.By Testing Type
      - 6.3.1.2.2.By Stage
      - 6.3.1.2.3.By Mode
  - 6.3.2.Canada Bioprocess Validation Market Outlook
    - 6.3.2.1.Market Size Forecast
      - 6.3.2.1.1.By Value
    - 6.3.2.2.Market Share Forecast
      - 6.3.2.2.1.By Testing Type
      - 6.3.2.2.2.By Stage
      - 6.3.2.2.3.By Mode
  - 6.3.3.Mexico Bioprocess Validation Market Outlook
    - 6.3.3.1.Market Size Forecast
      - 6.3.3.1.1.By Value
    - 6.3.3.2.Market Share Forecast
      - 6.3.3.2.1.By Testing Type
      - 6.3.3.2.2.By Stage
      - 6.3.3.2.3.By Mode

## **7.EUROPE BIOPROCESS VALIDATION MARKET OUTLOOK**

## 7.1.Market Size Forecast

### 7.1.1.By Value

## 7.2.Market Share Forecast

### 7.2.1.By Testing Type

### 7.2.2.By Stage

### 7.2.3.By Mode

### 7.2.4.By Country

## 7.3.Europe: Country Analysis

### 7.3.1.Germany Bioprocess Validation Market Outlook

#### 7.3.1.1.Market Size Forecast

##### 7.3.1.1.1.By Value

#### 7.3.1.2.Market Share Forecast

##### 7.3.1.2.1.By Testing Type

##### 7.3.1.2.2.By Stage

##### 7.3.1.2.3.By Mode

### 7.3.2.United Kingdom Bioprocess Validation Market Outlook

#### 7.3.2.1.Market Size Forecast

##### 7.3.2.1.1.By Value

#### 7.3.2.2.Market Share Forecast

##### 7.3.2.2.1.By Testing Type

##### 7.3.2.2.2.By Stage

##### 7.3.2.2.3.By Mode

### 7.3.3.Italy Bioprocess Validation Market Outlook

#### 7.3.3.1.Market Size Forecast

##### 7.3.3.1.1.By Value

#### 7.3.3.2.Market Share Forecast

##### 7.3.3.2.1.By Testing Type

##### 7.3.3.2.2.By Stage

##### 7.3.3.2.3.By Mode

### 7.3.4.France Bioprocess Validation Market Outlook

#### 7.3.4.1.Market Size Forecast

##### 7.3.4.1.1.By Value

#### 7.3.4.2.Market Share Forecast

##### 7.3.4.2.1.By Testing Type

##### 7.3.4.2.2.By Stage

##### 7.3.4.2.3.By Mode

### 7.3.5.Spain Bioprocess Validation Market Outlook

#### 7.3.5.1.Market Size Forecast

##### 7.3.5.1.1.By Value

#### 7.3.5.2. Market Share Forecast

##### 7.3.5.2.1. By Testing Type

##### 7.3.5.2.2. By Stage

##### 7.3.5.2.3. By Mode

## **8. ASIA-PACIFIC BIOPROCESS VALIDATION MARKET OUTLOOK**

### 8.1. Market Size Forecast

#### 8.1.1. By Value

### 8.2. Market Share Forecast

#### 8.2.1. By Testing Type

#### 8.2.2. By Stage

#### 8.2.3. By Mode

#### 8.2.4. By Country

### 8.3. Asia-Pacific: Country Analysis

#### 8.3.1. China Bioprocess Validation Market Outlook

##### 8.3.1.1. Market Size Forecast

###### 8.3.1.1.1. By Value

##### 8.3.1.2. Market Share Forecast

###### 8.3.1.2.1. By Testing Type

###### 8.3.1.2.2. By Stage

###### 8.3.1.2.3. By Mode

#### 8.3.2. India Bioprocess Validation Market Outlook

##### 8.3.2.1. Market Size Forecast

###### 8.3.2.1.1. By Value

##### 8.3.2.2. Market Share Forecast

###### 8.3.2.2.1. By Testing Type

###### 8.3.2.2.2. By Stage

###### 8.3.2.2.3. By Mode

#### 8.3.3. Japan Bioprocess Validation Market Outlook

##### 8.3.3.1. Market Size Forecast

###### 8.3.3.1.1. By Value

##### 8.3.3.2. Market Share Forecast

###### 8.3.3.2.1. By Testing Type

###### 8.3.3.2.2. By Stage

###### 8.3.3.2.3. By Mode

#### 8.3.4. South Korea Bioprocess Validation Market Outlook

##### 8.3.4.1. Market Size Forecast

###### 8.3.4.1.1. By Value



#### 8.3.4.2.Market Share Forecast

##### 8.3.4.2.1.By Testing Type

##### 8.3.4.2.2.By Stage

##### 8.3.4.2.3.By Mode

#### 8.3.5.Australia Bioprocess Validation Market Outlook

##### 8.3.5.1.Market Size Forecast

##### 8.3.5.1.1.By Value

##### 8.3.5.2.Market Share Forecast

##### 8.3.5.2.1.By Testing Type

##### 8.3.5.2.2.By Stage

##### 8.3.5.2.3.By Mode

## **9.SOUTH AMERICA BIOPROCESS VALIDATION MARKET OUTLOOK**

### 9.1.Market Size Forecast

#### 9.1.1.By Value

### 9.2.Market Share Forecast

#### 9.2.1.By Testing Type

#### 9.2.2.By Stage

#### 9.2.3.By Mode

#### 9.2.4.By Country

### 9.3.South America: Country Analysis

#### 9.3.1.Brazil Bioprocess Validation Market Outlook

##### 9.3.1.1.Market Size Forecast

##### 9.3.1.1.1.By Value

##### 9.3.1.2.Market Share Forecast

##### 9.3.1.2.1.By Testing Type

##### 9.3.1.2.2.By Stage

##### 9.3.1.2.3.By Mode

#### 9.3.2.Argentina Bioprocess Validation Market Outlook

##### 9.3.2.1.Market Size Forecast

##### 9.3.2.1.1.By Value

##### 9.3.2.2.Market Share Forecast

##### 9.3.2.2.1.By Testing Type

##### 9.3.2.2.2.By Stage

##### 9.3.2.2.3.By Mode

#### 9.3.3.Colombia Bioprocess Validation Market Outlook

##### 9.3.3.1.Market Size Forecast

##### 9.3.3.1.1.By Value

#### 9.3.3.2.Market Share Forecast

##### 9.3.3.2.1.By Testing Type

##### 9.3.3.2.2.By Stage

##### 9.3.3.2.3.By Mode

### **10.MIDDLE EAST AND AFRICA BIOPROCESS VALIDATION MARKET OUTLOOK**

#### 10.1.Market Size Forecast

##### 10.1.1.By Value

#### 10.2.Market Share Forecast

##### 10.2.1.By Testing Type

##### 10.2.2.By Stage

##### 10.2.3.By Mode

##### 10.2.4.By Country

#### 10.3.MEA: Country Analysis

##### 10.3.1.South Africa Bioprocess Validation Market Outlook

###### 10.3.1.1.Market Size Forecast

###### 10.3.1.1.1.By Value

###### 10.3.1.2.Market Share Forecast

###### 10.3.1.2.1.By Testing Type

###### 10.3.1.2.2.By Stage

###### 10.3.1.2.3.By Mode

##### 10.3.2.Saudi Arabia Bioprocess Validation Market Outlook

###### 10.3.2.1.Market Size Forecast

###### 10.3.2.1.1.By Value

###### 10.3.2.2.Market Share Forecast

###### 10.3.2.2.1.By Testing Type

###### 10.3.2.2.2.By Stage

###### 10.3.2.2.3.By Mode

##### 10.3.3.UAE Bioprocess Validation Market Outlook

###### 10.3.3.1.Market Size Forecast

###### 10.3.3.1.1.By Value

###### 10.3.3.2.Market Share Forecast

###### 10.3.3.2.1.By Testing Type

###### 10.3.3.2.2.By Stage

###### 10.3.3.2.3.By Mode

### **11.MARKET DYNAMICS**

- 11.1.Drivers
- 11.2.Challenges

## **12.MARKET TRENDS DEVELOPMENTS**

- 12.1.Recent Development
- 12.2.Mergers Acquisitions
- 12.3.Product Launches

## **13.GLOBAL BIOPROCESS VALIDATION MARKET: SWOT ANALYSIS**

## **14.PORTER’S FIVE FORCES ANALYSIS**

- 14.1.Competition in the Industry
- 14.2.Potential of New Entrants
- 14.3.Power of Suppliers
- 14.4.Power of Customers
- 14.5.Threat of Substitute Products

## **15.COMPETITIVE LANDSCAPE**

- 15.1.Merck KGaA
  - 15.1.1.Business Overview
  - 15.1.2.Company Snapshot
  - 15.1.3.Products Services
  - 15.1.4.Financials (As Reported)
  - 15.1.5.Recent Developments
  - 15.1.6.Key Personnel Details
  - 15.1.7.SWOT Analysis
- 15.2.SGS S.A.
- 15.3.Eurofins Scientific SE
- 15.4.Sartorius AG
- 15.5.Pall Corporation
- 15.6.Cobetter Filtration Equipments Co., Ltd
- 15.7.Laboratory Corporation of America Holdings
- 15.8.DOC S.r.l
- 15.9.Meissner Corporation
- 15.10.Thermo Fisher Scientific, Inc.

## **16.STRATEGIC RECOMMENDATIONS**

## **17.ABOUT US DISCLAIMER**

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