

# GLO.POL.MIM.001 Integrated Management System Policy

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## 1. Introduction

The management team at bigfinite is committed to the Integrated Management System (IMS) that complies with ISO 9001 and ISO 27001.

The system's goal is to ensure that the products and services that bigfinite provides consistently meet or exceed the customer's expectations.

## 2. Purpose

This policy is designed to establish, implement and maintain bigfinite's Integrated Management System (IMS) to ensure compliance with the requirements of ISO 9001 and ISO 27001, as well customer agreements.

## 3. Scope

The Integrated Management System (IMS) affects bigfinite's employees who perform the following duties:

- Business development and sales
- People operations
- Develop internal procedures or processes
- Maintain and disposition records
- Procure goods and services
- Perform software design activities
- Write code
- Test and/or maintain artifacts
- Perform internal or external assessments
- Manage issues and associated corrective actions through resolution
- Develop services and projects to customers
- Provide customer support

## 4. Users

Bigfinite's employees who perform the above-mentioned duties are the users.

## 5. Responsibilities

Bigfinite's Chief Executive Officer (CEO):

- Acts as the company authority for the Integrated Management System (IMS) Policy
- Ensures that departments fully cooperate with the implementation of the IMS requirements

## 6. Reference documents

- ISO 9001:2015 Quality management systems - Requirements
- ISO/IEC 27001:2013 Information Technology – Security Techniques – Information management systems – Requirements

## 7. Policy statement

Bigfinite is a software provider that transforms manufacturing operations with the use of IoT, Cloud, advanced analytics, artificial intelligence, and pharma 4.0 technologies focused on optimizing pharmaceutical and biotech companies.

The bigfinite analytics platform seamlessly integrates unlimited sources of structured and unstructured data to deliver actionable insights across all manufacturing sites.

Bigfinite offers an intuitive way to gain meaningful operational intelligence with data by enabling real-time visibility and predictive insights in a GxP compliant manner with end-to-end data integrity.

Founded in 2014, the company is based in San Francisco, California and also has a European office in Barcelona, Spain.

Bigfinite is a modern, dynamically developing company, which creates a technologically advanced, specialized solution and information system.

Bigfinite establishes and maintains a system for performing activities in a reliable, safe, and quality manner based on the best practices and requirements set in ISO 9001, ISO 27001 and any other bigfinite-generated requirements and policies.

Bigfinite recognizes that successful quality and information security management is fundamental to its business and is committed to the continual improvement of all relevant processes and procedures to ensure all standards are met and exceeded.

Bigfinite strives to provide a healthy and safe-working environment to all employees and provide products and services which satisfy customers.



### bigfinite's drivers

Knowledge, Passion, Innovation, and a successful implementation of the Integrated Management System (IMS) will directly translate into a high-level of quality and security for projects, services, and information systems for customers.

Quality Management System (QMS)	Information Security Management System (ISMS)
Bigfinite is committed to quality in all aspects of its operation.	Bigfinite is committed to information security in all operational aspects.
A Quality Management System, based on the requirements of ISO 9001, formalizes this commitment and includes procedures that assist personnel with system application and continual improvement.	An Information Security Management System (ISMS), based on the requirements of ISO 27001, formalizes this commitment and includes procedures that assist personnel with system application and continual improvement.

<p><b>Quality objectives:</b></p> <ul style="list-style-type: none"> <li>• Provide a high standard for Software-as-a-Service (SaaS) platform and corresponding services relevant to a customer's expectations and needs</li> <li>• Continual service quality improvement</li> <li>• Obtain and maintain ISO 9001 certification</li> </ul>	<p><b>Information Security objectives:</b></p> <ul style="list-style-type: none"> <li>• Integrate Information Security in the business objectives of bigfinite as a distinguishable and competitive factor</li> <li>• Solve and reduce information security incidents in a timely manner</li> <li>• Ensure business continuity to maintain the highest levels of service quality</li> <li>• Promote internally a culture of responsibility and accountability for Information Security</li> <li>• Provide regular and transparent performance reports of the ISMS</li> <li>• Obtain and maintain the ISO 27001 certification</li> </ul>
<p><b>Specific objectives are established at various levels of the company and reviewed at regular intervals.</b></p> <p><b>The company is committed to:</b></p> <ul style="list-style-type: none"> <li>• Complying with the requirements of the Quality Management System</li> <li>• Improving business by continually improving the effectiveness of the Quality Management System</li> <li>• Achieving customer satisfaction by meeting or exceeding expectations</li> <li>• Promptly addressing customer feedback or complaints</li> <li>• Achieve statutory and regulatory requirements</li> <li>• Personnel training and development to ensure competency</li> </ul>	<p><b>Bigfinite's top management, based on the principles recommended in ISO 27001, is committed to:</b></p> <ul style="list-style-type: none"> <li>• Implementing internally and externally the principles outlined in this policy through publication and communication methods</li> <li>• Applying a strategy for Information Security management that aligns with bigfinite's strategy</li> <li>• Securing an organizational infrastructure and support system, which ensures sustainability and the necessary evidences, based on the Information Security Risk Management</li> <li>• Securing resources for the operation and management of Information Security processes and activities</li> <li>• Promoting internally and externally the Information Security policy, and corresponding responsibilities for the processes</li> <li>• Providing regular and transparent performance reports on Information Security</li> </ul>
<p><b>The system for implementing quality and information security requirements must include at least controls for:</b></p> <ul style="list-style-type: none"> <li>• Developing usable and sustainable procedures and other implementation documents for bigfinite's processes</li> <li>• Managing sales and customer support</li> <li>• Managing employee engagement and attrition</li> <li>• Training personnel who perform quality and information security-related functions, including inspections, testing, and audits</li> <li>• Managing training effectiveness</li> <li>• Qualifying suppliers</li> <li>• Inspecting and testing artifacts, systems, and platforms</li> <li>• Identifying and managing nonconformities</li> <li>• Monitoring for activities and behavior outside of accepted patterns</li> <li>• Engineering design for software, systems, and facilities</li> <li>• Managing services and projects to customers</li> <li>• Managing issues and corrective actions through resolution</li> <li>• Performing management assessments</li> <li>• Performing audits</li> </ul>	