

Quality and Compliance Management Policy

REVISION HISTORY

This Quality and Compliance Management Policy is reviewed to ensure continuous relevance to the systems and processes that it describes and a record of contextual additions or omissions is given below:

Ver. No.	Description of Change(s)	Effective Date
1.0	This is a new Policy	22-FEB-21
2.0	Compliance Management is added	30-JUN-22
2.1	Review of POL and adaptation of scope	19-MAY-24
2.2	Review of POL: administrative update	14-MAY-26

1. INTRODUCTION AND PURPOSE

Novellas Healthcare is an international strategic partner of the pharmaceutical, biotechnology and medical device industries, specializing in recruitment (selection and outsourcing) and patient solutions.

Novellas Healthcare recognizes it operates in a highly regulated industry. This Quality and Compliance Policy (POL) reflects the strong commitment of our Management to Quality and Compliance. This Policy sets the foundation of our Quality Management System (QMS) and organization. It demonstrates the commitment of Novellas Healthcare to maintain a high-level of quality and compliance of all the Novellas Healthcare services throughout their life-cycle, in full compliance with the applicable regulations and other health-related requirements, with a strong focus on customer expectations as a whole.

The Quality and Compliance Management System of Novellas Healthcare is set up in a flexible and adaptable way to include quality standards specific to each area of responsibility. It is constantly evolving to anticipate regulatory developments and to support the needs of this growing company.

2. SCOPE

Our Quality and Compliance Policy applies to all managers, employees, contractors and freelancers (“Staff”) of Novellas Healthcare and its affiliates and is communicated to all Staff throughout the organization via regular communication and/or training. It also applies to all service providers of Novellas Healthcare unless specifically mentioned otherwise.

3. GLOSSARY of TERMS

POL	Policy
SOP	Standard Operating Procedure
WI	Work Instruction
QMS	Quality Management System
GxP	Nominator of all Good Practice Guidelines
Staff	All people working for Novellas Healthcare being all managers and employees (including contractors and freelancers)

Quality and Compliance Manager	Quality and compliance Manager or designee (a person with suitable background and experience), who ensures that applicable quality and compliance standards are met and maintained.
Compliance Management	Compliance management is the process of ensuring employees and activities across the organization are in line with applicable laws, regulations, and requirements.

4. QUALITY CORE PRINCIPLES & VALUES

To ensure the quality of services, Novellas Healthcare has based its quality management on the requirements of ISO9001:2015.

By this approach, Novellas Healthcare wants to engage in meeting the expectations and requirements of its customers and ensure to align the internal management of the organization as such.

Novellas Healthcare is committed to an operating philosophy based on transparency in communication, integrity in serving our customers, as well as fairness and wellbeing of our staff. Additionally, we are dedicated to creating a profitable business culture that is based on the following principles:

a. Our people

Novellas Healthcare recognizes its responsibility with regards to ensuring the wellbeing of our staff. All necessary steps are taken to guarantee the health and safety of staff and contractors, wherever they may be working. Novellas Healthcare is committed to:


- Creating and nurturing an environment of success based on honesty and integrity
- Developing staff competencies, creativity, empowerment and accountability through appropriate development programs and show strong management involvement and commitment.
- Designing and providing a safe and secure working environment

b. Our Customers

Our vision is to meet and even exceed customer expectations in relation to speed, quality, sustainability, cost, delivery, value and sense of urgency. We continuously build on a mutually profitable relationship with our clients, ensuring their long-term success, through the understanding of their needs and the needs of their customers. We address our customers’ requests expeditiously without creating false expectations.

c. Our Quality

With a clear knowledge of our customers’ expectations, we strive to consistently meet and exceed them. Therefore, we adhere to all applicable standards and customer specific requirements and endeavor to provide and implement processes that ensure building a robust and world class business. Best practices in all levels and systematic research will result in a reliable risk management. Driving continuous improvement, enhancing innovation that is based upon efficient business processes, setting out good measurements, rolling out best practices and customer surveys, are key objectives for Novellas Healthcare.

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5. QUALITY ORGANISATION & RESPONSIBILITIES

5.1. Quality Management System

Novellas Healthcare will ensure an effective quality management system which is based on following principles:

- The processes and methods within the organization are consistent, documented and known to all staff. Processes are set-up to be as efficient as possible.
- The objectives are defined and communicated.
- The processes are monitored, analyzed and adapted if needed.
- All legal and other requirements of the stakeholders are met.
- New staff gets immediate insight in the way of working
- There is a philosophy of continuous improvement.

Staff must understand that their individual contribution is important to the company’s overall success and commitment to quality.

5.2. Compliance Management

A strong Ethics and Corporate Compliance Program has become a need for every regulated organisation. In addition to ensuring compliance to various regulations, such a program helps our organisation to proactively identify risks, improve ethical behavior and become audit ready.

The compliance management is based on the following principles:


- Identifying a clear compliance framework within which Novellas Healthcare operates;
- Design, develop, coordinate and conduct educational and training programs
- Develop action plans that lead to timely compliance
- Seeking to ensure standards of good corporate governance, ethics and community expectations; and
- Engendering a culture of compliance where every person within Novellas Healthcare accepts personal responsibility for compliance and acts ethically and with integrity.

5.3. Quality and Compliance Documents

The Quality documents include:

- Policies: documenting the Novellas Healthcare Management view on organizational activities
- Standard Operating Procedures (SOPs): required by relevant guidelines, laws and regulations and covering the Novellas Healthcare processes related to its activities
- Work Instructions (WI): providing details of a single, specific process, which can be indicated in the related Standard Operating Procedure

All Quality documents are reviewed and approved according to the Novellas Healthcare SOP “Development and Management of Quality Documents” (SOP-NH-001).

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5.4. Novellas Healthcare Management Responsibilities

The Novellas Healthcare Management has the responsibility to demonstrate strong and visible commitment to the Novellas Healthcare QMS by taking accountability and responsibilities for these activities. The participation and commitment of all personnel to the Novellas Healthcare QMS is effectively achieved through senior management leadership and action.

Executive management and their teams are responsible for implementing and maintaining the Novellas Healthcare QMS within their respective area of responsibility. Therefore, management commits to the following principles:

5.4.1. Planning

The Management fully integrates Quality into the organization’s strategic and operational planning and business processes. The Management establishes a companywide vision as a basis for the Quality strategy, goals and objectives and cascades them down throughout the organization with the purpose to involve personnel at all levels of the Company in quality improvement. Quality objectives are aligned with the Novellas Healthcare’s strategy and are consistent with this Quality and Compliance Policy.

5.4.2. Organizing

The Management provides the required capital and human resources to guarantee complete and timely delivery of the strategic and operational plans, and to implement, maintain and continuously improve the Quality and Compliance Management System. This includes: sufficient personnel with the necessary competencies to fulfil their roles and responsibilities; appropriate facilities and equipment; and, ways of working operating effectively across the entire Novellas Healthcare Company.

5.4.3. Communicating

The Management provides effective communication and related communication processes to promote the Quality and Compliance Policy and Quality objectives to increase awareness, engagement and involvement of everyone in Novellas Healthcare.

5.4.4. Measuring


The Management has a performance measurement and reporting system for quality and compliance results, quality and compliance issues and progress against quality/compliance objectives. Measures are used to identify areas for continuous improvements.

5.4.5. Reviewing

The Management has Quality /Key Performance Indicators reviewed at a regular basis in relevant management meetings.

Progress against the strategic and operational plans is evaluated regularly and the overall process performance, product quality and effectiveness of the Quality and Compliance Management System is reviewed actively. These reviews are intended to identify areas for continuous improvement.

Management commits ensuring issues get timely escalated and where appropriate, immediate involvement of Management is required.

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5.4.6.Improving

Management sets continuous quality improvement as an objective throughout Novellas Healthcare.

5.4.7.Monitoring Changes impacting the Quality and/or Compliance Management System

Management monitors internal and external factors with a potential to impact the Novellas Healthcare Quality and/or Compliance Management System. Monitored factors are:

- Emerging regulations and guidance
- Quality issues that can impact the Quality and Compliance Management System
- Innovations that may enhance the Quality and Compliance Management System
- Changes in the business environment and business objectives

5.5 Quality and Compliance Manager

The Quality and Compliance Manager is responsible for defining, in cooperation with the Novellas Healthcare Managing Partners and General Manager, the Quality and Compliance Policy, coordinating its implementation across the relevant entities and ensuring compliance with the related regulatory and Company requirements. The Quality and Compliance Manager will ensure follow-up of the compliance program/plan.

The Quality and Compliance Manager will oversee the Quality management system as well as the compliance management and will, in cooperation with the line managers and process owners, ensure training of staff on the Quality and Compliance Management, including POL, SOP, WI's and associated documents, as applicable.

The Quality and Compliance Manager will ensure that regular review of the suitability and effectiveness of the quality documents is performed in cooperation with relevant stakeholders. This review will take place at least once per two years. The objectives of this review are:

- To evaluate if the Quality Documents are still reflecting the current way of operating and meet the requirements of all relevant guidelines, laws and regulations.
- To expose defects and/or discrepancies in the Quality and Compliance Management system identify gaps and propose possible improvements.
- To assess if findings of internal/external audits and inspections require a revision of the related quality documents.
- To evaluate the impact of organizational changes on the quality documents.

The Quality and Compliance Manager will oversee both internal and external audits.

5.6. Other Responsibilities

Process Owners (responsible for different processes/departments such as Business Development, Recruitment, Human Resources, finance, patient support programs, etc) are responsible for:

- Working in compliance with all Quality Documents
- Appointing an author (process expert) for writing and updating relevant SOPs, WI's, Forms and Templates

All Staff is responsible for:

- Working in compliance with all applicable Quality Documents
- Working in compliance with all GxP and all relevant guidelines, laws and regulations
- Performing internal quality control of department processes and documents
- Generating the relevant/required “Documented Evidence” as output of the operational processes as described in the Quality Documents

General Manager is ultimately responsible for:

- The Quality Management System (QMS)
- Initiating independent internal audits
- Yearly management review of the suitability and effectiveness of the QMS.
- Compliance Management

5.7 . Responsibilities for Personnel Qualification and Training

All Novellas Healthcare employees who are directly or indirectly operating within the Novellas Healthcare QMS and are engaged performing the Novellas Healthcare services, must have the right education, skills, training and experience, to enable them to perform their assigned roles.

Training in the applicable regulations and Novellas Healthcare QMS is mandatory for all Novellas Healthcare employees and is regularly conducted within their functional areas and with sufficient frequency to assure that employees remain familiar with the applicable requirements.

The Novellas Healthcare employees have a responsibility to ensure that their activities on behalf of Novellas Healthcare comply with all applicable legal and external obligations and Novellas Healthcare procedures.

5.8. Quality Audit

The mission of a Quality Audit is to provide to the Management an accurate, independent assessment of the compliance to the Novellas Healthcare Quality Management System through regular surveillance audits of the different departments within Novellas Healthcare, and possibly key third parties including due diligence assessments. In addition to the review of the quality documents, internal audits thus may be performed to ensure the quality of the internal Novellas Healthcare processes.

5.8.1 Internal Compliance audit PSP

The objective of an internal Compliance audit is an examination of Novellas Healthcare activities to assess the effectiveness of its risk management, control, and governance processes. The goal is to be prepared in case the Client intends to conduct an external audit on a specific PSP.




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SIGNATURE PAGE

The signatures below certify that this quality policy has been authorized and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision

Date	Written, Reviewed and Signed by
2026-04-14	 Tue, Apr 14, 2026 5:41 PM CEST
	Inge Wyns, Quality and Compliance Manager

Date	Written, Reviewed and Signed by
2026-04-14	 di. 14 apr. 2026 17:52 CEST
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