

Quality Manual Summary

INTRODUCTION

PRINEOS is a strategic consulting company born and raised by passion, relying on a team with more than 25 years of expertise in the Life Sciences sector. Thanks to our team of physicians, biotechnologists, biostatisticians, regulatory & legal experts, we can identify customer needs and offer tailor-made solutions in the pharmaceutical, medical device and clinical research fields.

We believe that innovation is key to the progress of medical science, and our mission is to bridge the clinical development gap to ensure success for our clients. We make the client’s objectives our own by listening to their aspiration and understanding their goals. We support and guide the clients throughout the entire project lifecycle.

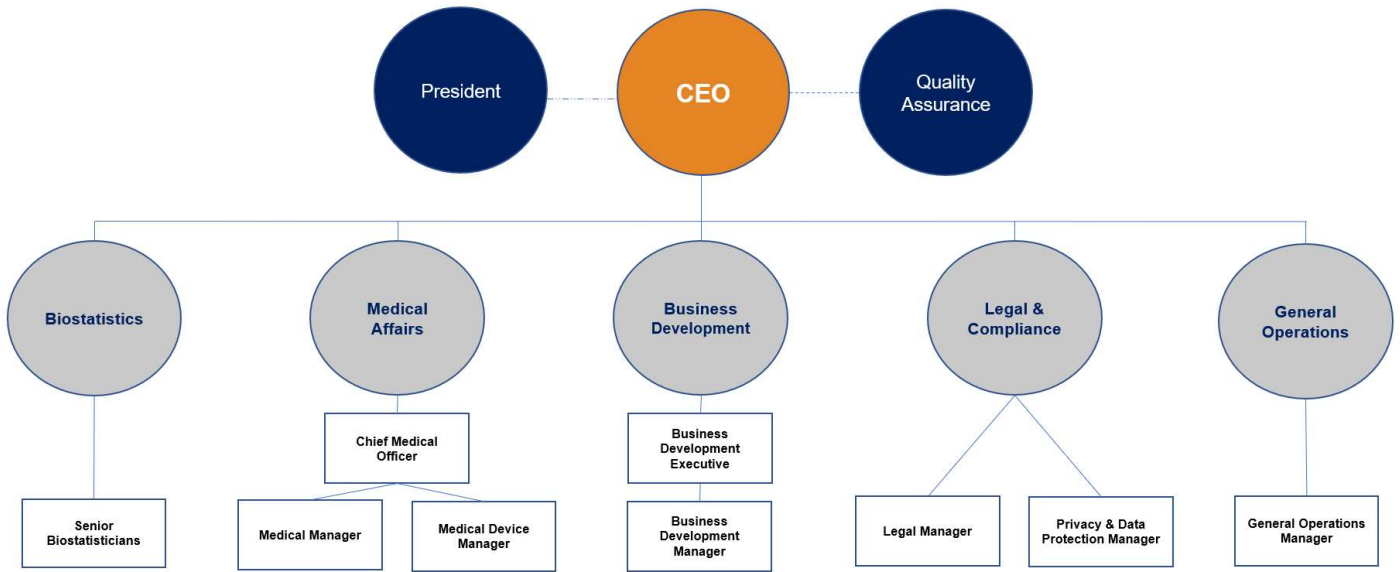
PRINEOS offers a comprehensive and competitive approach to the customer, by providing a wide range of services that meet any project needs (related to drugs, medical devices, diagnostics, food supplements & nutraceutical products): from project design to its completion.



The team of professionals at PRINEOS has excellent technical skills and long-standing experience in the Life Sciences field. PRINEOS believes in the importance of innovation, the added value of new technologies, the application of proper clinical research methodology and the attention to legal and regulatory aspects to enhance clinical research in the healthcare sector. Innovation, know-how, as well as open, proactive communication skills are hallmarks of PRINEOS’ dynamic, collaborative, and close-knit work environment.



The **company organizational chart** is structured as follows:



COMPANY QUALITY SYSTEM

PRINEOS has decided to implement a Quality Management System (QMS) based on the ISO 9001:2015 requirements. The company QMS has been structured by processes. In particular, to implement the Management System, PRINEOS proceeded by:

- identifying the processes necessary for the QMS
- establishing their sequence and their interactions
- establishing criteria and methods capable of ensuring their effective operation and control
- ensuring the availability of the resources and information necessary to support their implementation and monitoring
- defining criteria and methods for measuring, monitoring, and analysing processes, to implement the actions necessary for the continuous improvement of the QMS.

The Management recognizes the Quality Management System as a tool to identify and satisfy third parties' interests, through the conversion of their needs into system requirements by means of operating procedures and/or interventions and/or actions for continuous improvement.

The CEO establishes a Quality Politics to achieve defined objectives.

The **Quality Policy** is a fundamental instrument to achieve business improvement with a focus on customers, employees, suppliers, and company owner satisfaction. This Quality Policy represents the translation of the Management's commitment to operating in compliance with:

- the ISO 9001:2015 standard



- other applicable standard (e.g., UNI CEI EN ISO 13485:2016 on Medical Devices)
- local and international regulations (e.g., ICH-GCP E6 R2 “Good Clinical Practices”)
- requirements that the company itself has defined.

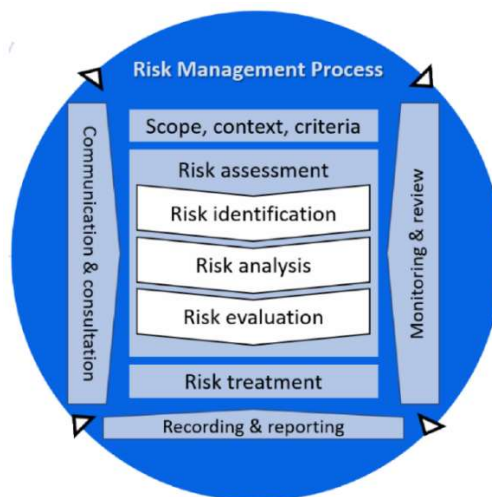
The macro-objectives of the Quality Policy can be summarized in the following points:

- always maintain a high level of satisfaction of the interested parties, in particular PRINEOS customers and partners
- facilitate the participation and the interaction between employees and collaborators
- carry out a QMS assessment based on objective evidence according to procedures in use.

When carrying out its activities, PRINEOS undertakes:

- to guarantee a corporate organizational model capable of ensuring high and adequate skills to be applied in the design and provision of its services
- establish every interaction with its customers and partners with the aim of creating value while identifying present and future needs for the success of the projects entrusted.

The PRINEOS Quality Management System is based on a corporate **risk management process**, which allows the organization to determine the factors that could generate process deviations from the ISO 9001:2015 standard and to implement preventive controls to minimize the negative effects, taking advantage of opportunities offered by the market, anticipating trends, and ensuring an approach targeted for continuous improvement.



General principles aimed by PRINEOS to pursue, measure and monitor are:

- be always focused on its staff needs and satisfaction
- continuously improve the QMS and the services offered with the consequent generation of positive results (both economical and in terms of customers and partners satisfaction)



- guarantee competencies and skills always adequate to the stakeholders' needs and the market
- guarantee a constant action of enhancement, motivation, and professional growth of employees
- respect QMS requirements and ensure its continuous and effective application
- continuously review the Quality Policy to implement them according to the context changes.

The Quality Policy, thanks to its principles, allows the **company continuous improvement**:



PRINEOS defines the activities necessary to maintain and ensure **effective communication with clients** at all project stages:

- before building the offer, through calls and meetings to identify and meet the specific expectations of our customers
- throughout the services' provision, thanks to a constant availability, in order to provide customers with any useful information and update
- after the service provision, through the management of all requests and needs that may arise.

The Management ensures that the Quality Policy is understood, shared, and implemented by all employees and collaborators and at the same time undertakes to share it with all the stakeholders by publishing it on the company website.

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