

POLYPLUS-TRANSFECTION



QUALITY MANUAL



Our Quality Policy

The aim of our Quality Policy is the satisfaction of our customers.

Since its creation, Polyplus-transfection has engaged in high quality standards as validated by the ISO 9001 version 2008 certification.

At Polyplus-transfection innovation dynamizes our Quality Management System: our goal is to always improve our customers' satisfaction by anticipating their needs when possible and by offering innovative technological solutions. For this purpose, we have developed methods to find out from our customers what their requirements are. This allows us to develop products meeting expectations of the most demanding scientists and to improve the existing reagents.

In accordance with the ISO 9001:2008 quality standards, the Quality Policy of Polyplus-transfection includes the commitment to permanently improve products, services, the involvement of its staff and the satisfaction of its customers. This therefore defines, the pillars of our Quality Policy:

- ▶ Understanding the requirements and the expectations of our customers
- ▶ Regular Development of our technical skill by a constant technology watch and by close maintenance of high-performance equipments
- ▶ Assuring the adequacy of the level of skills and the technical needs of the members of the company
- ▶ Setting up and conduct the quality training of the staff
- ▶ Managing and improving our Quality Management System

C.E.O.

Mark BLOOMFIELD



Quality Assurance Manager

Claire WEILL



The 9001:2008 Certification

The standard ISO 9001 defines the organizational requirements for a Quality Management System. The ISO 9001:2008 certification distinguishes the efficiency of our Quality Management System and allows us to guarantee the trust and the satisfaction of our customers. Its area of application covers all the activities of the company without any exclusion from requirements with regard to the standard. This certification was awarded by AFAQ with number 2002 / 19379a.

Polyplus-transfection, Dedicated to the intracellular delivery of biomolecules

Polyplus-transfection is focused on developing innovative solutions for delivery of biomolecules. The company has been marketing its transfection reagents worldwide since 2001 and is reinvesting most of its revenues in research and development. Its mission consists in supplying innovative products and a high quality technical support to scientists.



Transfection consists in introducing a gene or a small interfering RNA into cells. This technique makes it possible to cross the cellular barriers and deliver such biomolecules into the cells for research or therapeutic purposes.

The Strasbourg-based company is recognized as a leading innovator in the transfection market, with ISO 9001:2008 certification, exclusive licenses from the CNRS and numerous patent applications pending. Polyplus-transfection R&D has well-established partnerships with biotech companies and is also involved in several European research collaboration networks.

Polyplus-transfection has been selling its products and services through an international distribution network since 2001. Its customers include biotechnology companies, big pharma and research laboratories.



Polyplus-transfection offers high quality consultancy, personalized scientific support and expertise in regulatory affairs related to the use of its reagents in clinical trials.

Phases I/II cancer gene therapy and AIDS trials are underway in Israel, USA, Sweden and Germany using GMP-compliant reagents from Polyplus-transfection.



Our Quality Management System

Quality planning using the PDCA cycle

At Polyplus-transfection, we use the PDCA (plan, do, check, act) cycle to manage and improve our Quality Management System (QMS). This tool applies to all actions done by the company.

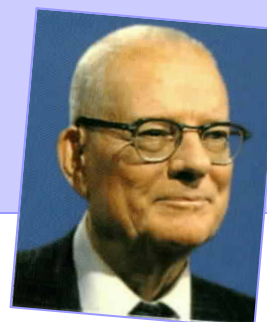
Customer care and the involvement of the Technical Support

Polyplus-transfection is very attentive to his customers thanks to the return of satisfaction surveys, to personal interviews during scientific congresses and particularly through the technical support activity. Each customer or prospect who contacts us benefits from an individual scientific and technical follow-up, unique in our field of activity.

PDCA for Plan, Do, Check, Act

The PDCA cycle is also called Deming Wheel or Cycle, by the name of W. Edwards Deming, statistician and American philosopher who is considered by many to be the father of modern quality control.

The PDCA cycle is an iterative four-step problem-solving process typically used in quality control.



Quality definitions

External Audit

An annual systematic and independent examination to determine whether operational activities or processes conform to planned arrangements, e.g., policy requirements, regulations, etc., and are being implemented effectively and suitably to achieve objectives.

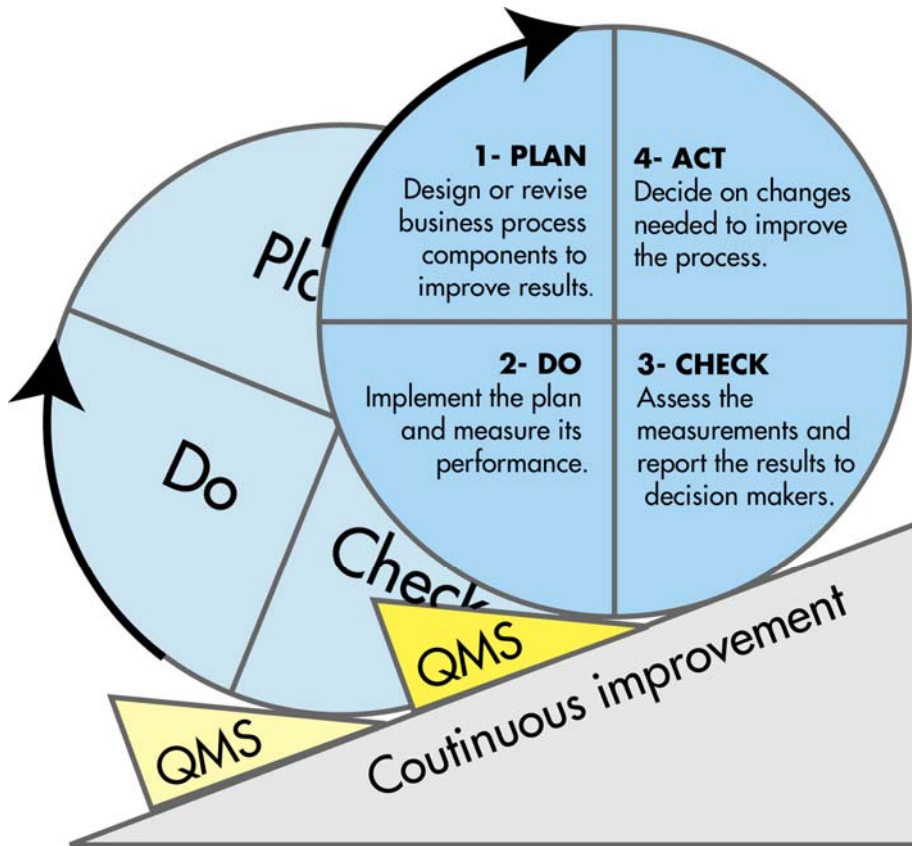
Internal Audit

Annual examination similar to an external audit but that is accomplished within our company by internal auditors.

A preventive action allows us to anticipate a problem and to set up new procedures / work instructions.

A corrective action is aimed at regulating a dysfunction and setting up new procedures / working instructions to eliminate it permanently.

THE PDCA CYCLE OR DEMING CYCLE



PLAN

Action plans
Quality plans
Preventive actions

DO

Improvement of the Quality Management System (QMS)

CHECK

Customer interview and feed-back
Staff feed-back
Indicator measures from processes

ACT

Process reviews
Management reviews
Correctives actions

A tool to control the manufacturing of our transfection reagents: **traceability**

We have set up several traceability methods to follow:

- ▶ raw materials entering in the synthesis of our transfection reagents,
- ▶ products used for the validation of lots,
- ▶ every lot, from synthesis to shipment to our customers.

Our Management Quality System

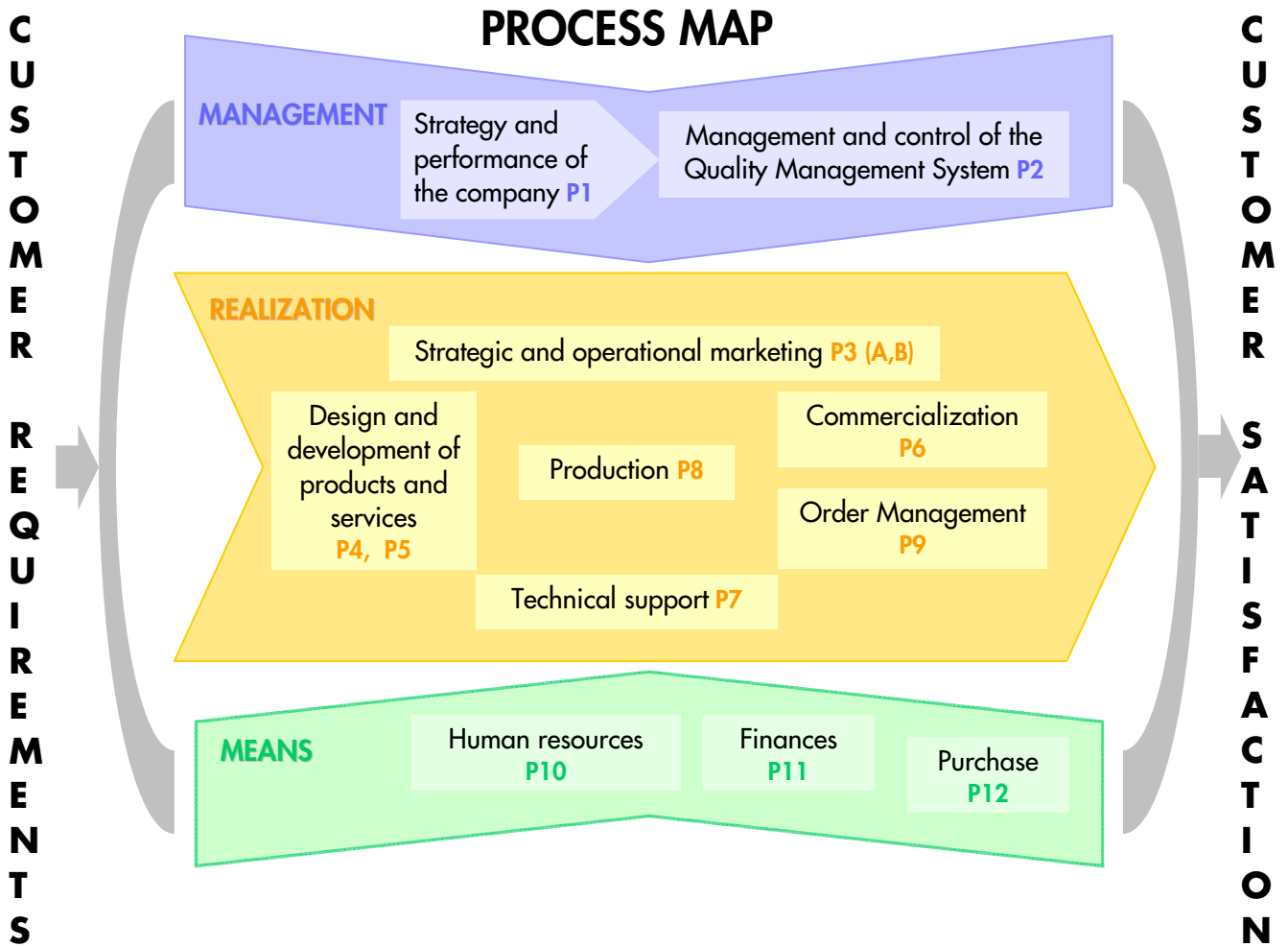
A Dynamic Process-based Approach

Nine processes allow to control the realization of Polyplus-transfection's activities; they are supported by management process and the resource process. Activities within a process, procedures, work instructions and links to related processes are detailed on each process map as well as objectives, indicators and targets. Each process pilot manages the process and evaluates its performance during the biannual process review.

A process is a set of interrelated or interacting activities which transforms inputs into outputs.

Approach adopted by ISO 9001:2008 is an approach by process in order to satisfy the customer in an efficient way.

- *Ameliorate efficiency and effectiveness of processes,*
- *Give priority to the perceptible added value from the customer point of view,*
- *Discern and correct dysfunctions,*
- *Prevent anomalies,*
- *Use means in an optimum way.*



Management processes

Their purpose is to plan out the quality policy of Polyplus-transfection, to fix quality objectives and areas of improvement as well as to control the Quality Management System.

Realization processes

They represent all processes that take part in the realization of the product.

Means processes

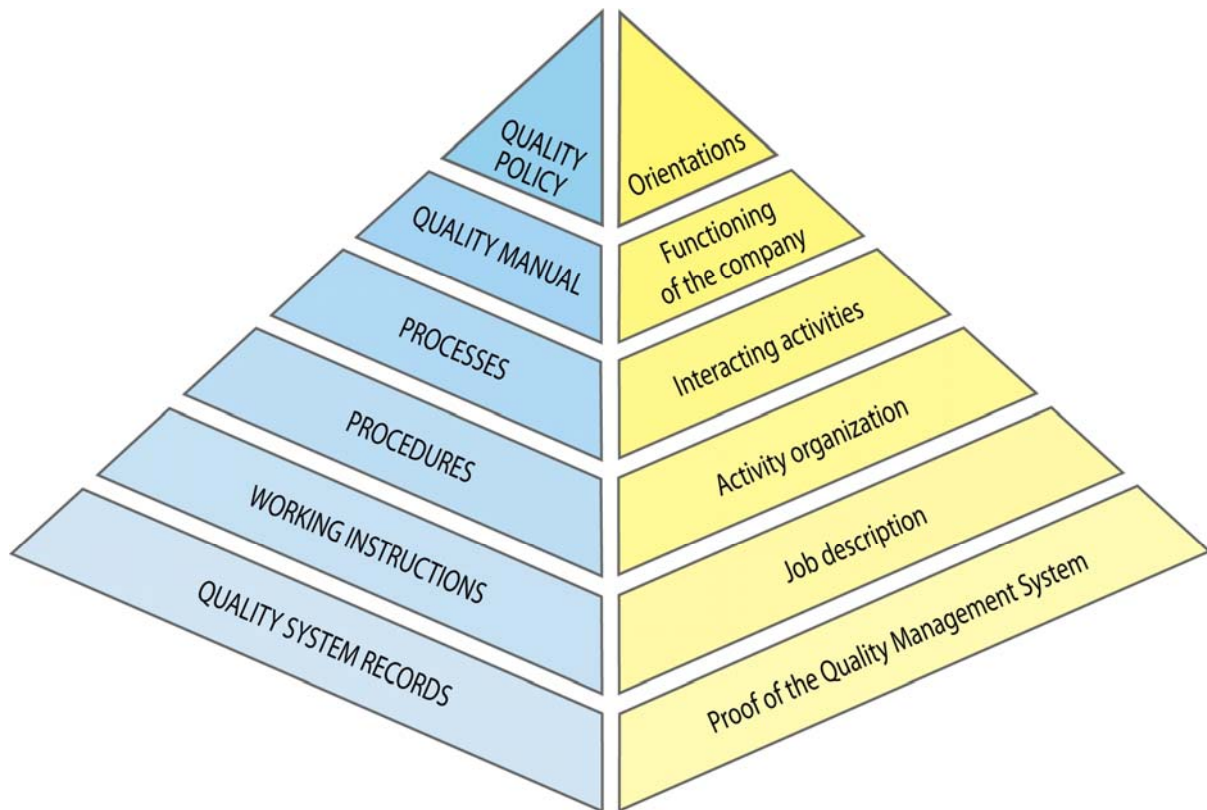
They provide necessary means for the running of the realization processes.

Our Management Quality System

Controlled Quality System Records

This Quality Manual describes the orientations of our quality approach and presents the general organization of our Quality Management System. It is written by the Head Management and the Quality Manager and updated regularly. Each new version is broadly distributed within and outside the company.

Documents describing our processes are reviewed as soon as required due to our continual improvement of the Quality System. The Head Management performs the normative watch of regulations applicable to the activity of the company.



Controlled Quality System Records

Procedures PR GE 01, PR GE 02 and PR GE 03 describe the creation of records, their control and distribution within the company.