

QUALITY MANAGEMENT HANDBOOK



TABLE OF CONTENTS

Quality Policy of EyeC	3
Our Products	3
Our Mission	4
Strategy and Goals	4
Our Sphere	4
• Customers	4
• Suppliers	4
• Worldwide Distribution and international Service	5
• Further Partners	5
• Employees	5
Responsibility and Authority	5
Our Resources	5
Organizational Structure	6
Product Development	7
Production and Services	7
Validation Support	7
Dealing with Non-Conformity	8
Quality Assurance	8
• Internal Audits	8
• Yearly Managment Review	8
• Customer Satisfaction Analysis	8



QUALITY POLICY OF EYEC

We at EyeC strive to realize quality in all areas - for our customers and for our businesses. We achieve this not by standing still, but rather from the continual improvement of our products, services, and processes.

We offer our growing number of employees the chance to move forward with us by giving everyone the opportunity to have a say and develop. All employees contribute to compliance with the quality principles.

Together we work to further optimize our quality standard and therefore remain true to our company philosophy:

YOUR VISION FOR QUALITY

We are ISO-9001 certified out of conviction. On the one hand, by supporting the standards of this globally recognized and widely used quality management standard we support our entrepreneurial success. On the other hand, we create the basis for our customers' trust in the consistently high quality of our work.

Our process-oriented Quality Management System (QMS) defines the processes within all departments. We think and act risk-based and customer-oriented and place value on complete documentation of all quality-relevant processes. The implementation of our QMS pertains to all areas of our business. The current version of DIN EN ISO 9001 is valid

(at the time of this handbook's publication, we refer to DIN EN ISO 9001:2015.)

The management is committed to quality management and works together closely with the quality management department.

To our customers in the pharmaceutical branch, we additionally offer the know-how of the legal requirements in Europe and the USA such as EU-GMP, Annex 11 and 21 CFR 11. etc.



Dipl.-Ing. Dirk Lütjens
- Managing Partner &
CTO Proofiler



Dr. Ansgar Kaupp -
Managing Partner &
CEO



Dipl.-Inform. Sören
Springmann - Managing
Partner & CTO
ProofRunner

OUR PRODUCTS

We at EyeC are experts in user-friendly and innovative software-based inspection systems for printed materials of all types.

Since 2002 our products have been supporting pharmaceutical companies, printers, and cosmetic and food producers to meet the highest quality standards when printing folding boxes, labels, package inserts, flexible packaging or tubes.

We are the only provider on the market whose systems monitor the print quality during the entire production process - from the first artwork to the finished printed product.

Our products for the artwork and pre-press stage inspection allow the artwork contents to be inspected quickly and easily against an approved template in every production step.

Our Proofiler series for offline-inspection allows for the inspection of finished printed products for errors in text, color, graphics, barcode, and Braille. These inspection sys-

tems are used in print shops or at the incoming goods inspection and helps the user to quickly and easily inspect random samples.

Our ProofRunner systems for the inline inspection inspect printed products during the production process. These print inspection systems check 100% of the printed order, comparing it against the approved customer proof and alerts the user of print problems during production.

Our high quality systems guarantee a high quality and flawlessness of delivered printed products. This helps to avoid time-consuming reprints, complaints from end customers or product recalls. This also saves not only costs and time, but also protects the image of our customers and supports them in the fulfillment of legal requirements.

OUR MISSION

- We are the worldwide technology leader for outstanding, usable image-processing products.
- We maintain long-term and trusting customer relationships.
- We treat each other with respect and economically successful in the long term.

STRATEGY AND GOALS

By formulating the mission, the executive management expresses a long-term goal to which all of our company's actions are geared.

The mission is reviewed by the executive management as part of the annual strategic planning and adjusted if necessary. Out of this, the four perspectives of our company's Balanced Scorecard are deduced: finances, customers, personnel, and processes.

Controlling creates monthly analyses that relate directly to the key figures of the Balanced Scorecard. Together with the mission and Balanced Scorecard, the results are made public to all employees over our "Controlling Dashboard". The executive management and management group also receive further data for their evaluation and if necessary can adapt and implement the measures of individual departments to achieve their goals.

OUR SPHERE

Customers

Worldwide there are over 1,700 EyeC inspection systems in use by pharmaceutical companies, printers, as well as cosmetic and food producers in more than 60 countries. 20 of the 25 largest pharmaceutical companies place their quality control in inspection systems from EyeC.

Our EyeC software is developed in accordance with the current GAMP-5 guidelines and includes all necessary functions for the production of conformity for qualified EyeC systems with the US-CFR Title 21, part 11 stated guidelines.

On request from our customers, we carry out sales demonstration-installations and test positions with real customer samples so that our customers can be sure that the scope of our products can work with their concrete and specific requirements.

Our Sales team creates customer-specific offers in close consultation with the interested parties and presents possible options that are useful and profitable for the respective application.

Through good internal communication between Sales, Production, and Service along with good consultation with our external partners, such as suppliers and distributors, we ensure the adherence to delivery dates and fulfillment of product and service criteria specified in the order.

Suppliers

Mutually beneficial supplier relationships increase the added value on both sides. Therefore we maintain trusting relationships based on good communication with our suppliers. For us, this means providing our suppliers with the data necessary for planning ahead of time and placing orders in a timely manner to support reliable and punctual delivery.

In return we expect discretion in trustworthy matters, delivery reliability, information about changes, and consistent quality from our suppliers. These expectations are set out in framework contracts with selected suppliers.

We also order on the basis of written general terms and conditions of purchase, which are intended to ensure that our minimum requirements for cooperation are always met. For selected partners we regularly perform supplier evaluations in order to be able to encounter problems in a timely manner if necessary.

Worldwide Distribution and international Service

We work together with a worldwide net of more than 25 distributors and sales partners. These partners are extensively trained to be able to make customers an offer tailor-made to their specific needs. We also equip our international service partners with the necessary know-how to ensure installation and support at the highest level for all customers transnationally.

Further Partners

We maintain long-term and trusting relationships to various, partly market-leading OEM partners and integrators. These partnerships exist for mutual benefit and offer our customers complete solutions through just one contact. In order to enable the optimal quality of our products and services, we rely on regular communication and the mutual exchange of skills.

Employees

Our leadership concept is based on a participatory-cooperative approach along with an open communication style with our employees. As company management, we are aware of our function as role models in this regard.

Regular performance reviews offer our staff the opportunity to express praise and criticism of us as an employer. Together we want to create a work environment that is satisfactory for everyone.



RESPONSIBILITY AND AUTHORITY

All responsibilities and authorities within EyeC are clearly regulated. These are communicated through a regularly updated organigramm and informative and detailed job descriptions. The scope of application for the processes within our QMS refers respectively to functions in accordance with the organigramm and allows for a direct assignment of responsibilities to people.

Our department heads are at the same time the process owners of the process descriptions in our QMS. These responsibilities can be read directly from the individual documents.

OUR RESOURCES

Our team aspires to do business with the highest competence and commitment for the good of our customers.

This is why we employ personnel with in-depth training in the relevant areas. All employees receive a general training in quality management and Good Manufacturing Practice. We want to ensure that the internal structure of our QMS can be understood and filled with life. A further important aspect of the training is to create an understanding of our customer's quality requirements and the regulatory requirements that our customers, in particular those in the pharmaceutical field, have to face.

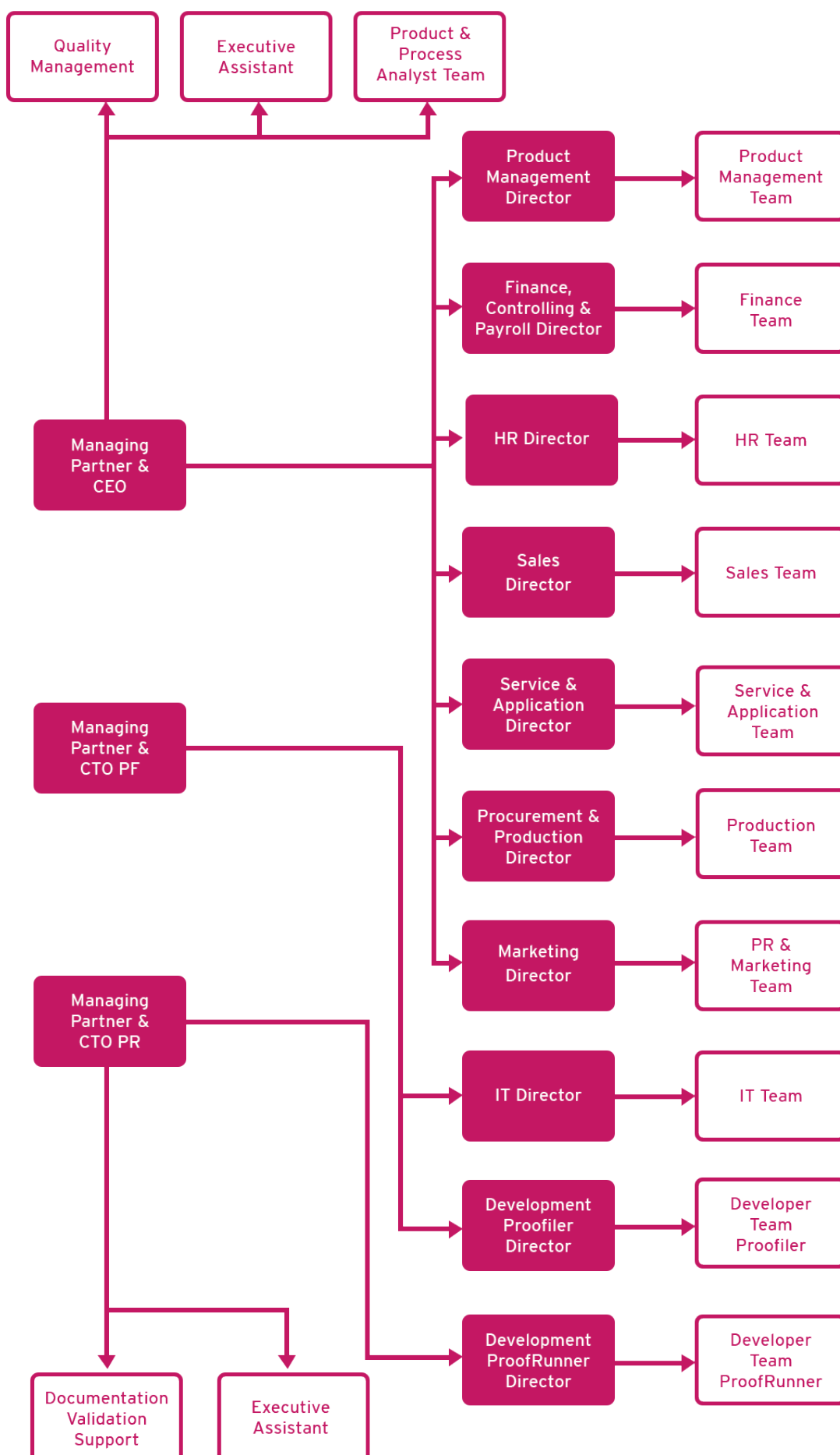
All employees are also regularly trained in our QMS's processes that are relevant for them. This is monitored through an elaborate training matrix.

In addition, as part of personnel development, further training can also take place through external providers in order to increase the skills of our employees, geared towards the needs of the company and our customers.

Modern work equipment and modern information and communication technology are a matter of course for us.

Our IT guarantees the security and restoration of our data at all times with comprehensive backup and restore measures.

ORGANIZATIONAL STRUCTURE



PRODUCT DEVELOPMENT

Through the development of our products and services, we always orient ourselves on the market. We want to offer solutions that surpass the present and future expectations of our customers and are attractive to further customer groups. That is why our product management occupies itself extensively with market analysis and holds close contact with our customers and potential customers to always be able to innovatively expand our product palette.

Our software products undergo extensive testing before each release so that it can enter the market as error-free as possible. We strive to further optimize our test procedures in order to guarantee maximum security to our customers.

Our technical editors ensure that the necessary documentation such as manuals, installation instructions and acceptance documents are made available in a timely manner for our customers, distributors, and internal departments.

After significant software changes, we perform internal release retrospectives with all involved departments. Our goal is to incorporate the knowledge gained in the next development cycles, to maintain or reinforce positive aspects, and to mitigate or eliminate negative influences.

PRODUCTION AND SERVICES

Through defined processes in Production and unequivocal acceptance criteria for our systems, we ensure that our products leave our company perfect, functional and always in the same condition.

Our well-trained service technicians perform the installation of systems on location at the customer and guarantee the quality of our products with detailed documentation of the final acceptance.

Through a systematic training, we ensure that our employees in Production and Service are always up to date with the latest technological knowledge about our systems.

Also after delivery and provision of services, we remain in contact for our customers. EyeC Service offers an extensive offer such as regular maintenance and professional, quick support in the case of a problem.

VALIDATION SUPPORT

Our customers in the pharmaceutical fields, such as medicinal product producers or their packers, constitute a strategically important market for us. Therefore, we have established the necessary know-how about the relevant regulatory requirements and the Good Manufacturing Practice (GMP) for these branches.

Our validation support offers our customers the best possible support for the validation of their processes used in connection with our systems.



DEALING WITH NON-CONFORMITY

We maintain responsible and systematic handling of non-conformities - whether they occur internally or are communicated to us through our customers or partners.

Through the extensive training of our employees, we make sure that each reported non-conformity is sent through the appropriate process. Here we differentiate between software bugs, complaints after delivery and installation of the system, or further QM-relevant processes. Depending on the risk review and associated escalation level,

the defined measures are taken to rectify the problem and to learn from their causes for the future. In each case, it is reviewed if customers need to be informed and which solutions we can offer to potentially affected customers.

All non-conformities are documented and measures for continuous improvement are derived beyond the immediate activities. When necessary, decisions are made in cross-departmental teams.

QUALITY ASSURANCE

As starting points to find the optimization of our work, we regularly monitor our own work.

Internal Audits

Every QM-relevant department must undergo an internal audit at least once every three years (but most take place yearly). We examine the contents of our internal standards as well as the fulfillment of the ISO-9001 requirements.

Yearly Management Review

Here the management reviews the ongoing suitability, appropriateness and effectiveness of the QMS and its alignment with the strategic direction of the company.

Customer Satisfaction Analysis

We perform frequent and systematic surveys with customers, wanting the results to lead to improvement in our processes. We strive to continually improve and expand our service and to strengthen our loyalty to our existing customers.

All measures adopted from the above-mentioned aspects are followed up and evaluated by the management, quality management and process owner with regard to their implementation and success. This is how we live out the continuous improvement of our products, services, and processes for our company and our customers.

EyeC GmbH
Burchardstraße 21
20095 Hamburg
Germany

Phone number: +49 40 226 3555-0

We, the executive management of EyeC GmbH, hereby declare that we assume responsibility for our quality management system.

Hamburg, June 18th 2020

Four handwritten signatures in blue ink, likely representing the executive management of EyeC GmbH, are displayed horizontally. The signatures are stylized and difficult to read, but they appear to be written in a professional context.