



PCS Intelligence

PERSONALIZED E-QMS SOLUTIONS MADE SIMPLE

If you are looking for an electronic Quality Management System you will end up with a myriad of choices, some software focuses solely on documentation, others on production management and if you are very lucky you may find a package that combines some elements. But there is one factor they all have in common; customization is difficult and costly.

PCS Intelligence offers you an unparalleled level of customization that requires zero coding. If your SOP changes, so will your e-QMS. If procedures are added to your QMS, you can easily create the workflows in PCS Intelligence; add operators, reports, define input limits and extract PQR/Management Review information in tables, graphs or any other format you desire.

FEATURES

Some of the features of PCS Intelligence include;

- Fully Customizable Workflow Management
- Linking Procedures (e.g. CAPA and Change Control)
- Custom Reporting and Document Creation
- Management Information in Virtually Any Format
- Centralized User Access Control (UAC)
- Customizable Equipment Input and Processing (scales, HPLC, thermocouples)

This intelligent software system is validated according to Annex 11 (EudraLex) and 21CFR11

ASSETS

PCS intelligence is a computerized system which is not only GMP/GDP compliant but efficient as well, and suitable for small, medium, large and corporate organizations.

One of the great assets of PCS Intelligence is that you can start using it within hours without having to spend a significant amount of money on implementation trajectories which last weeks. Minimal online training is required to be able to use the system. But, in case you do need help we offer designated services to help you implement and validate your configured or customized system.

SUPPORT FOR ALL BUSINESS PROCESSES

The software delivered by PCS Intelligence supports all business processes. A relationship management system (relationships) supplemented by a workflow management system (activities) and all forms of assignments and services (dossiers) that (pharmaceutical) organizations process. The system stores and monitors all information that plays a role within your organization. This allows the organizations respond fully to the wishes of all stakeholders, including the regulatory authorities worldwide, and realize their own business objectives even better.

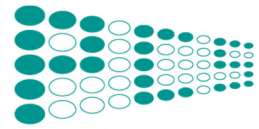
INCREASE PROCESS CONTROL

With the software of PCS Intelligence, you are always in control! You can lift your production, distribution or service levels to a higher level effectively and. With the integrated workflow management system, you clearly organize your quality processes. You are always in control. You can see what the status is, who is involved in which process, and more.

With the support of PCS Intelligence, you will not receive only the software, but a process- and people-oriented approach as well, including all documentation according to GDocP.

RELATIONSHIPS: RELATIONAL DATABASE

Your complex networks will be transposed into a relational database containing a set of formally described tables, forming the basis for a **relationship file** built by us. The software is designed with the capability of managing the most complex situations, however small business enterprises can use this software as easy as you may imagine.



ACTIVITIES: WORKFLOW MANAGEMENT

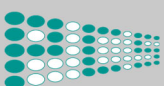
In addition to our **relationship file**, we also introduced the communication tool activities. The tool activities are the core of the software involving actions that are carried out daily by people. Also called workflow management. Stakeholders in the (Pharmaceutical) Quality Management System are communicating daily. Either by e-mail, document or social media channel. Many companies use a separate workflow management application to gain insight into all this communication. Within the software of PCS Intelligence this is implemented as a standard feature.

DOSSIERS

What all companies, anywhere in the world, do: processing assignments. The results we call in our software: dossiers. These dossiers are a collection of events and all associated activities that goes with it.

THE SPECIFICS FOR YOUR ORGANIZATION

Each company is of course unique and has its own specifics. That is why we ensure that we are able to deal with each and every specific demand related to the functioning of your quality system elements.



ONE-STOP SOLUTIONS FROM A TO Z

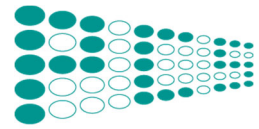
The software will support your quality system processes from A to Z. From the very first touch to the very last closure of the event and everything in between. This way you can accurately monitor where you can improve your processes. Where do you plan lead times? You get this information and more from the workflow management system. Your one-stop shop for all your quality system information. 'Report building makes growth opportunities clear' The management information tool 'report building' gives structure to this information. All your activities are translated back to a code: a unique number that remains the same throughout time. On the basis of these codes you see in your system who, when which activity performed. In this way, you get a grip on the workflows, insight opportunities become clear and you see exactly how your quality system really works.

USER-FRIENDLY FROM THE INSIDE AND OUTSIDE

The software is full of user-friendliness. We believe that consists of two factors. First of all, we focus on the content that offers you maximum support for the work process. This so that you only have to deal with the content of the work and not with the administration around it. In addition, we naturally also focus on the look & feel: overview and comprehensibility.

Two factors: content (functionalities) and look & feel (screen design) stand apart in the software. This means that you can relatively easily switch to a new design while retaining the powerful foundation. That way you can easily grow with the latest technological developments. Both in design and in functional management.



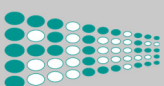
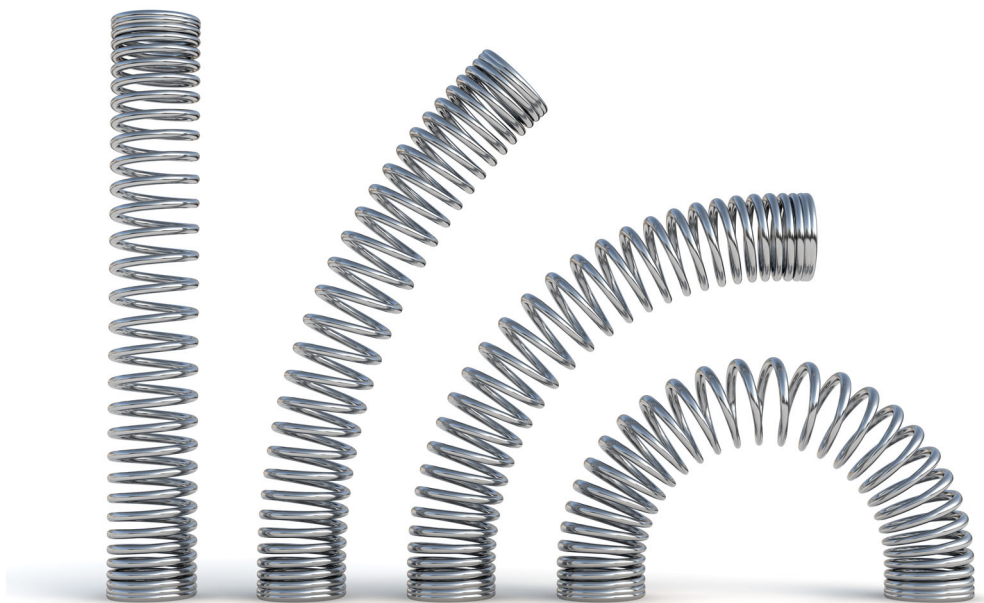


FLEXIBILITY

You never want to be caught by the choices you make now. That is why the software offers you maximum flexibility. If you still miss a certain component, it's easy to build it up and place it on the strong foundation of the software. In addition, thanks to the code-controlled design of our system, you also change things very easily yourself, though in compliance with the GMP requirements alike change control. In this way, you may save time and money. Our back office may help you out in this type of situation, if you doubt

SAFE ACCORDING TO THE REQUIREMENTS OF THE EUROPEAN GDPR

In addition to simplicity and flexibility, promise also offers you safety. For example, user management occupies a very dominant place within our application. Within this you can easily assign user profiles, preferably function-oriented. Each (new) employee will then have his own profile, based on function and authority, containing all the information he or she is allowed to see, create, edit and delete. In this way, you define what someone can and cannot do on different levels. And keep it safe, also according to the requirements of the GDPR.



Our management information programs, in turn, show exactly which users have which profiles and which profiles apply to which application rights. This information is organized to support regulatory (and customer) audits.

THE IMPLEMENTATION

We train all our customers, to start using the system yourself. In this we distinguish two situations.

'We take you step by step in your implementation'

We do this on the basis of a furnishing document, consisting of several chapters. For each chapter, we determine with you how the installation takes place. You make the system easy on the basis of examples. We start with your relationships and files, then we deal with your activities and the individual components. Gradually, we jointly put together your electronic pharmaceutical quality management system including documentation of the entire implementation process.

This implementation has a relatively short lead time: often only six months, from the first calls to go live. That has to do with flexibility. You can start basic and expand over time, without compromising what you stand for and go for. You can grow in this software without needing us for it. Because we are your functionally training application managers, you can ensure that you carry out your own management at your own pace.

SMARTER, FASTER AND CHEAPER!

Because with our implementation you learn to tackle many things independently, you work with the software quickly and flexibly. Because you can eliminate a lot of external applications overboard, you also save money. In short, with PCS Intelligence you are smarter, faster and cheaper, while in compliance. And you have the control, not others!

That's what we call: connecting people to quality

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