Ebook

15 requirements

you need to find
in a solid eQMS
for **GDP Logistics**

bizzmine QHSE

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Good Distribution Practices (GDP) describe the minimum standards that a wholesaler must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.

Compliance with GDP ensures that medicines in the supply chain are authorised under European Union (EU) legislation, that medicines are stored under the correct conditions at all times, including during transportation, that contamination by or with other products is avoided, that there is adequate turnover of stored medicines, and that the correct products reach the correct recipient within a satisfactory period of time. The distributor should also establish a traceability system to detect defective products and establish an effective recall procedure.

Logistics companies supplying the life sciences industry must comply with GDP requirements. To do so, they must implement an adequate quality management system.

The FDA and the European Union are urging companies to do this digitally, as it is the only sustainable way to maintain control. Hybrid and paper-based systems are proving inefficient and even dangerous as they do not provide full traceability. The digital way is the only way!

A proper eQMS is an essential part of GDP certification. This checklist of 15 requirements will help you choose the right solution for your business.

- *Peter De Brabandere – Founder Bizzmine*

Compliance, industry standards, and validation

The GDP industry is more regulated than many others.

You should go for validated software that has a proven track record in GDP Logistics with all its specific requirements.

> *As we also work with medical goods, it is crucial for us to work with the correct versions of documents. We are strictly bound to the GDP regulations and have to follow strict rules regarding documentation. With Bizzmine we can be sure that we meet these requirements.*
>
> **- H.Essers**

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Regulatory compliance is critical to your QMS system and key to its implementation. Validation and compliance with **21 CFR Part 11 / Annex 11** in terms of electronic signatures and full audit trails are must-haves.

If you are in an industry that requires **GAMP5** validation, be sure to choose a software vendor that has a proven track record with validated software. It's not just about the one-time validation when you go live with the software, but also about how updates are managed in a validated environment. For example, do you have a multi-staged environment where you have a test/validation environment and a production environment? These are all things you need to look at when you need a validated environment.

The scalability of the platform

Scalable software for QMS allows you to **easily transition from a small business to an enterprise environment** using the same platform. Moving from one QMS software to another includes a high risk, especially for companies that operate in a GDP regulated industry. It involves a lot of work, you have to run the software twice, there are hidden costs, and so on. In other words, this should be avoided.

The platform should also be **scalable in size - from small to large user configurations - and in distribution** across multiple geographic locations. A multilingual platform is an absolute plus for the end user.

You should also consider **process scalability** because as a company grows, business processes become more complex. The software should enable you to progress from simple to more complex processes that meet the needs of a larger organization.

Bizzmine brings quality and business excellence into the scope of all our departments.

- Geodis UK

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Flexible, customisable and easy to use

> *Low code/no code (LC/NC) applications can provide a close fit to business requirements, can be implemented quickly, and typically cost much less than systems developed in-house.*
>
> **- Harvard Business Review**

User-friendly software adapts to the way you work, not the other way around.

You should be able to configure the software so that the end-users only see what they need to see in their environment, and nothing more.

Today, people use software through different interfaces and in different places. People are not only working from their desktop or laptop, but also from their own devices, such as phones or tablets. So, look for a platform that allows you to use these devices.

In a flexible zero-code platform, there is no coding or scripting required. The fact that you can make the necessary changes to processes yourself, without any help from the software vendor, is a big advantage.

QMS software should have a user-friendly interface that adapts to the needs of each user. Forms, for example, should display only the information you need to see, and nothing more.

The benefits of automation

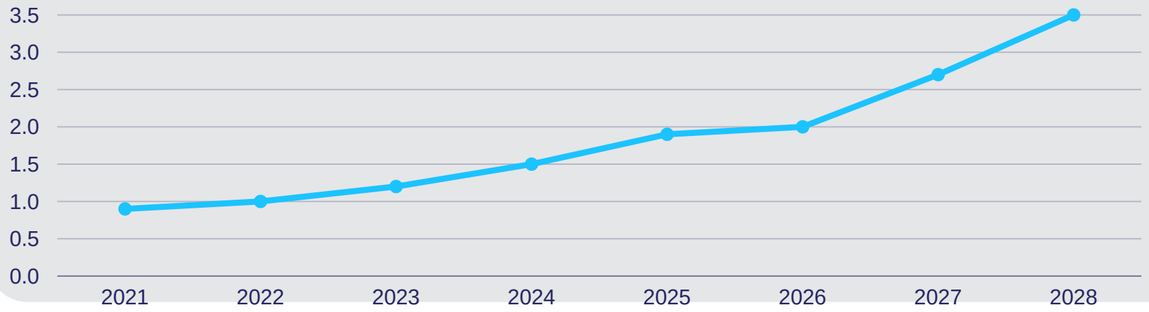
Automatic mechanisms in a software platform make your life easier.

These types of automation can save your users a lot of time.

The global workflow management system market size was valued at USD 6.85 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 30.6% from 2021 to 2028. Workflow management systems are gaining acceptance in the market as they help in improving efficiency and reducing operational cost. Furthermore, the systems optimize automation, workflow, and processes, thus, reducing the need for unnecessary rework and manual effort."

- Grand View Research

Annual growth rate (CAGR) of 30.6%



In digitisation, it's the **workflow** behind the process that provides value. For example, management approval and effectiveness checks will be easier through an automated workflow.

If you collaborate on projects that have a recurring pattern, you should be **notified automatically**. Processes can be started based on a specific recurring pattern. Calibration management is a good example of this type of process.

QMS software also gives you a **better overview** of what is pending and who is still working on what. Automatic reminders nudge those who are behind and have passed due dates.

What processes should your eQMS be able to cover?

With a good digital quality system, you can map all QMS processes and optimize the activities of your organisation.

- Document Control
- CAPA Management and Action Plans
- Non-conformance Management
- Risk Management
- Complaint Management
- Audit Management
- Change Control (MoC)
- Out of Specification (OOS) Out of Trend (OOT)
- Training & Skills Management

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Connecting all areas of quality management

A quality management system is a complete set of different processes that correlate and interact with each other. This is a prerequisite for easy retrieval of information and for full traceability.

In a good software platform, you can make the necessary connections between all the different processes without having to open another module or application.
A modern eQMS can perfectly link, for example, a CAPA to an audit or a non-conformance or a complaint from an audit.
You can start performances, and you can make links to the documents in your document control system, so you know exactly what procedures need to be reviewed during an audit.

The ability to link all processes should be an absolute requirement when you select software for QMS.

Turnkey workflows

If you do not have your own specific process from the start, it's a good idea to look at the vendor's workflow processes. **Get some ideas** before you develop an entire process for paperless auditing from scratch yourself.

Since all the data is in the QMS system and can be accessed with the click of a mouse, you can perform external and internal paperless audits. You will feel more secure knowing that all the data is right under your fingers, and you can retrieve it in a few seconds, instead of searching for it in many archives and files in different applications.

Having everything in one digital environment assures you that you can prove your compliance. The digital way is the only way!

A good GDP-database template should allow you to set up your QMS much faster. By leveraging the vendor's industry, product, and software expertise you can probably meet **80%** of your user requirements without having to implement anything.

Easy and fast to implement

Complexity, flexibility, and scalability often go hand in hand with extensive implementation. With ERP systems or larger CRM systems, it's not uncommon for implementation to take months or more than a year before you go live.

Experienced QMS software vendors typically allow a variety of industries to use templates. You should look for a platform that allows you to get your QMS up and running in a matter of weeks.

> *The struggles that we had were based on the fact that we were using a paper-based system with a mix of SharePoint and it was pretty much impossible to keep on top of quality management, especially with the size of our organization.*
>
> **- Geodis UK**

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Sometimes companies think they can do it themselves by setting up a SharePoint environment, and up to a point, that’s true. One problem is implementation time because if you want to build a complete QMS on SharePoint, you’ll need months, if not years, of internal development. And do not forget the associated costs and the risk of brain drain if developers leave the company.

Robust analytics are important

Gone are the days when a manager had to spend two or three days per month gathering all the information and creating analytics on data that was already historical.

Life analytics on rich visual dashboards that project all the data collected through your quality management system is very important and should be a firm requirement in eQMS today.

Improve processes and gain more insight into the root causes of distribution inbound issues.

> *Real-time performance monitoring is crucial to executive decision making at pharmaceutical and medtech companies. During a 2019 McKinsey roundtable discussion, 62 percent of quality assurance executives rated it as a high priority for the company, exceeding all other options.*
>
> **- McKinsey**

The total cost of ownership and ROI

> *Thanks to Bizzmine, we get more work done with the same number of staff.*
>
> **- DSV Solutions**

A typical eQMS should allow you to **avoid costs** in the first place and avoid the hidden costs of non-quality in wasted time. Like any other software, it's all about improvement of execution.

Without a complete **workflow process**, you lose track of the pending tasks. Building a QMS based on Excel files and emails via Outlook may work for a while in a small environment but is unthinkable in a mature company.

In the GDP industry, it is common to have various types of complaints. If you can **avoid a few complaints**, you have already recovered the entire investment in your QMS. If you can avoid a 1 or 2 million claim, or in life sciences, prevent a patient's death, that's priceless.

A typical ROI of a good QMS platform should pay for itself **within a year**. And if you move to an online platform, you can simply use it as a service, which also reduces the investment.

What about data security?

Should you choose data storage on your server or hosting in the cloud?

Experienced software providers run the data in a very secure environment, not only the software itself but also the data center location. Always look for geo-redundant backups that have a very good disaster recovery plan so that operations can resume if something happens. Take a close look at SLA. What is the uptime? Is it 99.99% or better? Bulletproof data centers should have **ISO 27001** certification these days.

The software company should have a data processing agreement and experience with GDPR compliance. Where is the data center located? Where is the data stored? These are very important elements if you are storing personal data that should remain within the European Union.

When it comes to the software itself, you should check what **security mechanisms** are in place. Has the software been tested enough to be secure enough? Does it have features like two-factor authentication or single sign-on?

1 platform that involves all stakeholders

Everyone in your organisation will benefit from a good QMS.

First of all, in **financial terms**: if you have a return on investment of about one year, that means you will make a profit by implementing a QMS.

It is very clear to **each user** what is required of them. They know exactly what tasks are waiting for them. All of this should be very clear in the application.

The **advantage for IT** is that they don't have to be much involved if they don't want to. A good vendor will offer the software as a service and all the services that go with it, such as implementation, training, follow-up changes, and updates. That takes away a lot of work off IT's plate. Of course, they need to be involved in the selection, implementation, and installation, and they should also be able to integrate the software with the other applications.

The **quality assurance team** can do what they need to do. With a complete overview of everything that is happening with the QMS, they know they are in control. They can also learn a lot from the data collected through the various analyses and statistics.

In the end, even the **customer** benefits, because you get a customer-focused organization that is better organized and can perform better processes.

> *With the Bizzmine's workflow module, we can establish communication between different departments in a very structured way.*
>
> **- DSV Solutions**

Read more

How is the application built?

When choosing a new application, pay attention to the technology stack it is built on. It should be 2024 proof. Do not go for a software application that is still based on old architecture.

Also, when it comes to data storage, it is important to have a fallback option. Make sure that the data is not stored in some exotic data formats, but in a relational database that is very common, such as Microsoft, SQL Server, or Oracle.

At the very least, you should choose a very modern application architecture.

The other aspect is maintenance.
Take a close look at the vendor's roadmap. What kind of techniques will be used? What about pre-release testing? How many versions are there per year? What does the update mechanism look like? ...

Rely on the expertise of the software provider

Quality should always be a top priority for management. In our fast-paced global economy, it is simply impossible to have a decent quality management system without organizing all processes digitally.

In many industries, there will be more regulations, and that’s just normal. To comply with the regulations, and more importantly, to stay compliant in this very competitive environment, a decent QMS system is essential. So, if you are going to set it up in an analog or do-it-yourself way, it's going to cost you a lot of money. You will need an army of IT specialists to develop an application.

Stick to your core business and do not build your QMS system yourself. Work with a specialised software provider and focus on your strengths, on your reputation.

Digital Quality Management is about money, avoiding claims, and compliance.

Did you know that **eQMS** is the easiest way to **Green Logistic**?

Reduce your carbon footprint through digital transformation.

Good preparation, fast execution

Why postpone your transition to eQMS?

The regulatory bodies are pushing for a structured digital environment instead of paper or a hybrid mix of paper and various tools.
Regulated companies that perform best are those that work in a very decentralized way, but with centralized IT tools. The better prepared you are for your next audit, the easier and faster the process will be.

So, it's no longer a question of IF you are going to implement a digital QMS, but WHEN you are going to do it.

Even small companies should start their digital phase very early. You do not want to wait until you are drowning in the Excel files. The lives of startups that are on board early in the process are much easier afterward.

75.000
USERS

40+
COUNTRIES

Check the boxes and see how the Bizzmine digital QMS can work for your GDP.

Bizzmine has been developing software for Quality Management & Workflow since 1995.
Today, we serve more than 75.000 users in 40+ countries in almost every industry: pharma, biotech, food, medical device, laboratories, logistics, services...

Our software is the smart preconfigured solution that adapts to your business.

Streamline all your QMS processes in one user-friendly validated platform.
Get up and running very fast and trust in our great support.

Find out for yourself: **Book a Demo**

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