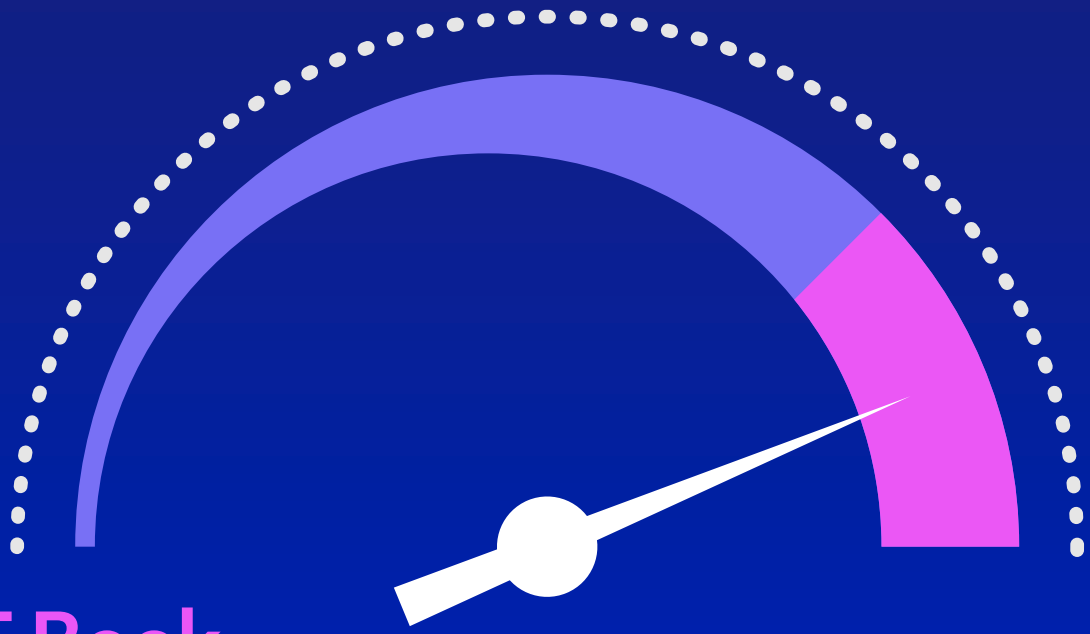


E Book

THE NEED FOR SPEED

Fast, Effective, Affordable Quality Management System (QMS) Deployment in the Life Sciences

Dot Compliance

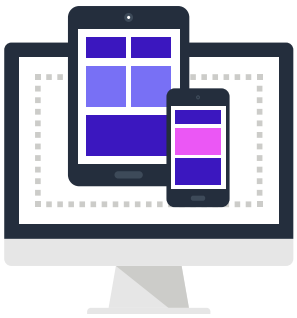
Table of Contents

Don't believe that quality and compliance must be **complex** and **costly**; deploy a ready-to-use QMS built on industry best practices within weeks at a single subscription price.

MYTH

As a life science company, you need a costly and complex quality management system (QMS) that cripples you financially, takes months to configure and implement, and continuously surprises you with hidden fees for updates, upgrades and validation.

Wrong. Don't fall for the lies and outdated technology.



REALITY

Within weeks you can be up and running with a ready to use, cloud-based QMS that is preconfigured based on industry best practices to support the quality and compliance processes you need when you need them.

Single subscription fee, no customization required, easy to use, no hidden fees, no surprises.

Conventional QMS:

Designed for Cost and Complexity

There has always been a need for quality management in the life sciences; therefore, QMS solutions have been around for a long time.

While many QMS vendors have transitioned from traditional on premise (on-prem) software installed on computers to software as a service (SaaS) delivered via the cloud, their basic offerings have remained the same, as have the associated costs and complexity of implementation and support.

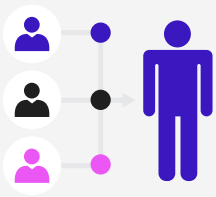
Don't waste your time and money on customization

Conventional QMS providers typically start with a blank canvas, conveying to each customer that unique customization is required.

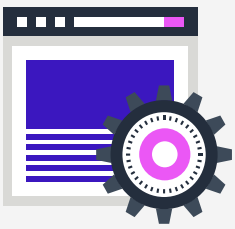
Even for configurable, point and click solutions, there is still an element of customization that is necessary, especially if there is a delta between the customer's requirements and how the system is pre-configured.

Customization adds complexity and costs, and significantly prolongs the implementation process.

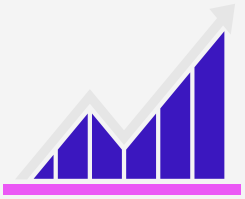
Here is how it typically plays out:



The QMS provider asks the customer for their requirements, gathers that information, customizes/configures their standard solution, and presents it to the customer, all of which results in costly solution delivery and professional services costs.



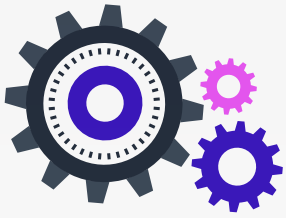
If the customer decides they want a different configuration, the QMS provider must go back to the drawing board, conduct a redesign, and present it again and again until it is right. With each round adding additional time and expense.



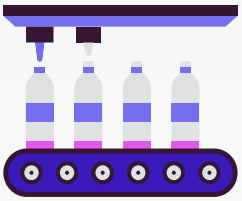
What many life science companies don't know is that each time a change is made to a blank canvas QMS configuration, the provider must re-validate it. These changes often result in months and months of professional services - raising costs significantly.

THIS PROCESS FROM START TO FINISH CAN TAKE:

6 MONTHS → **9** MONTHS → **12** MONTHS



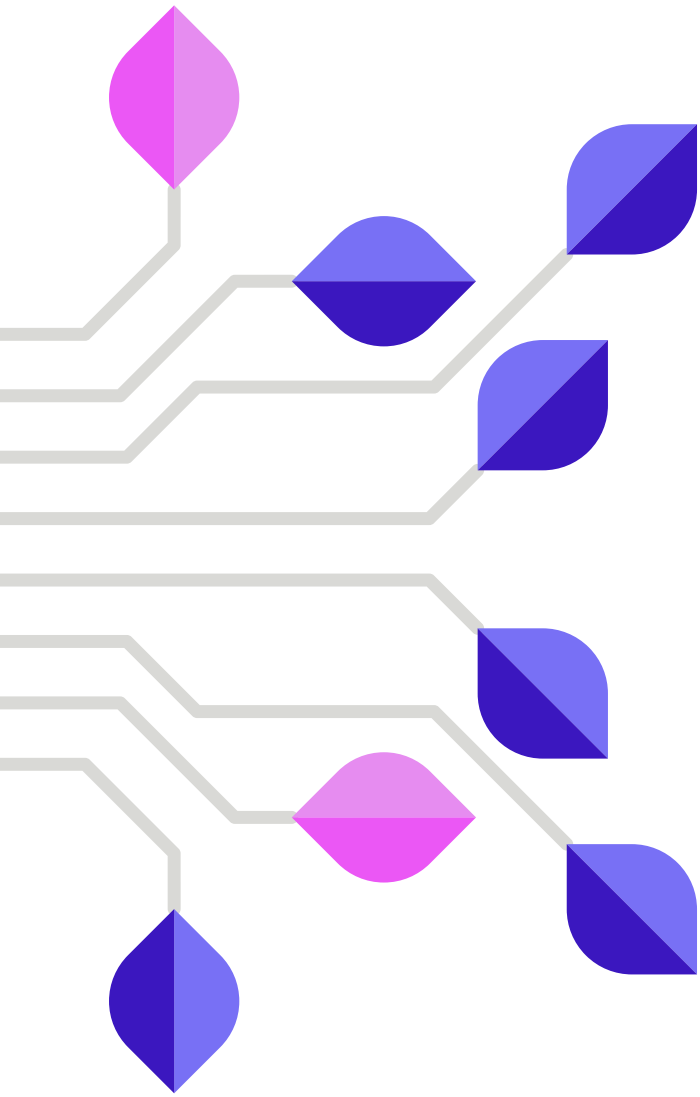
While the life science company is waiting for its QMS, its team often struggles to manage quality using manual processes, Excel, or some other homegrown solution that is not only labor and time intensive, but also presents a high risk for errors.



Operational efficiencies are impacted too. All of this takes time away from what the company should be focused on: The products they are developing or the ones they are working to get out the door in the safest and fastest manner.

Furthermore, the more configuration that is performed, the more maintenance that will be required down the road. A life science company with a customized QMS solution must invest significant information technology (IT) resources to adapt vendor upgrades and updates to meet its unique solution configuration.

Don't Fall Prey to the Dangers of a Homegrown QMS



Small-to-medium sized life science companies don't have the time, resources or money for a long, drawn out, complex QMS implementation.

Facing this challenge, some choose to stay with manual, paper-based processes (e.g., Excel) or other homegrown QMS solutions.

If you are a small-to-medium sized business (SMB) with 10-15 employees and 20, 30, 40 documents you might be able to get by with managing processes in an Excel spreadsheet. But as your company grows and these numbers scale, quality processes become impossible to manage in this way.

Another challenge presented by homegrown solutions and processes is that the knowledge around these approaches is often held by a single individual, likely the person who developed them.

If that person leaves the company, all of that knowledge can disappear overnight. Those left at the company in charge of quality can't figure out why processes have been set up in a certain way, where to find specific information, etc. It is all out the door, leaving them to struggle with what they have in place or start from scratch.

Fortunately, a ready to use QMS solution can get you quickly, effectively and affordably up and running with quality and compliance processes to meet your needs today, and scale as you grow and evolve.

Let's Shatter the Status Quo

We are in an age of digital transformation where practically every industry has leveraged digital technology to streamline processes, reduce costs and work more efficiently. Why should the life sciences be any different? It's not.

Costs and complexity in quality management shouldn't be the norm anymore.

You can shatter the status quo on QMS through a truly off-the-shelf solution for fast, easy and cost-effective deployment.

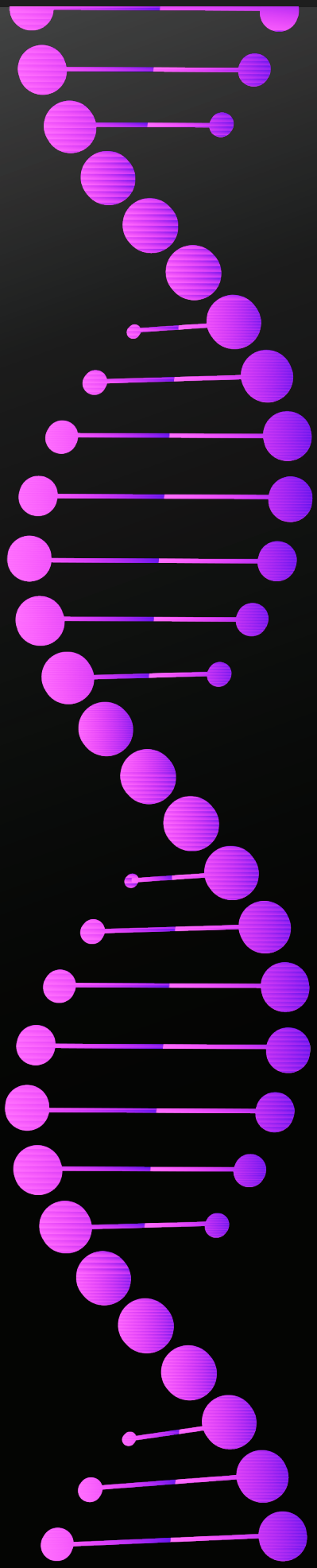
While conventional QMS vendors would like you to think your company's needs are unique and require costly customization you likely don't.

Fundamental quality management processes are the same regardless of whether you are developing and producing pharmaceutical, medical device, biotech or cannabis products. A CAPA is a CAPA is a CAPA.

With an out of the box, holistic, cloud-based solution configured with best practices that meet FDA, ISO, and GxP regulations, you can adhere to even the most stringent quality and compliance requirements quickly and with no heavy lifting.

But if for some reason you need tailored solutions as you grow, a QMS solution should also have the capabilities and flexibility to accommodate your changing needs.

With a ready to use QMS for the life sciences you can:

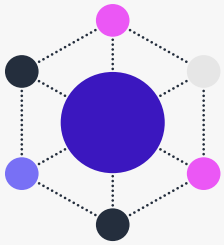


1

Get up and running fast:

Implement a comprehensive QMS with the processes you need within a matter of weeks versus months for a conventional QMS deployment.

2



Have what you need when you need it:

Take a phased approach to digitizing quality and compliance processes, implementing what you need when you need it.

3

Integrate for ease of use:

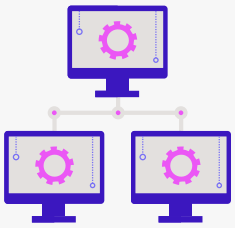
With a QMS built on Salesforce.com, the most integrated and collaborative platform in the world, you can seamlessly integrate with existing enterprise systems and eliminate workarounds.

4

Eliminate excess IT infrastructure:

A solution with broad process coverage and integration capabilities enables you to eliminate redundant systems (e.g., QMS, DMS, LMS, SQM, EBR, PLM, LIMS, ELN, RA & RIM, etc.).

5



Gain enterprise-wide visibility:

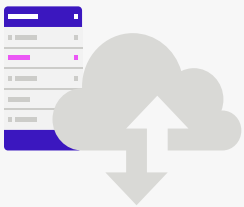
A QMS that unites all departments and individuals who impact quality, from your internal quality team out to third party suppliers and partners. Gain visibility and control over your overall quality operations.

6

Access insights to act quickly:

With a single source of quality data and the ability to perform advanced analytics through AI and machine learning, you can proactively predict quality issues and address root causes.

7



Seamlessly integrate updates:

With a ready to use solution, the QMS vendor can simply upgrade or make value-added updates to its solution via the cloud at regular intervals: No heavy lifting required on your part.

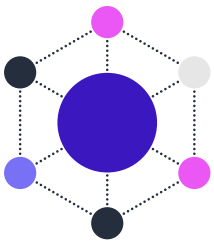
8

Pay one price for it all, really:

A single subscription fee covers everything, including upgrades, updates, validation and as many users as you require.

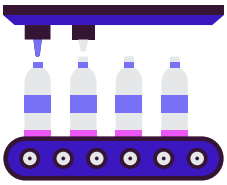
Your QMS Environment: Move-in Ready, Everything Included

1



Core Quality Processes

Your life science company can set the foundation for quality management best practices by deploying core quality processes. These include Document Management, Training Management, Change Control, Deviation / CAPA, Customer Complaint, Risk Management, Audit Management and Supplier Quality.



Expansion into Manufacturing and Compliance Specialty Areas

You can also expand beyond the core and integrate additional processes as you grow and require more capabilities. These include Regulatory Affairs, Product Lifecycle Management, Electronic Batch Records, Equipment Management and Clinical Trial Management.

3

Options for Customization

If your company has unique needs that are not addressed by the pre-configured offerings on the first and second levels, you have the option to have customized offerings built for you.

It is fast, easy, affordable and flexible – everything conventional QMS is lacking and what life science companies need in today's demanding and competitive business environment.

Yes, You Can Deploy a QMS Today. Let's Get Started!

The unfortunate reality is that some legacy companies keep their technologies and processes complex. This confuses customers into thinking they must spend a lot of money, invest significant resources and wait months for solution implementation.

While that was the way it used to be, technology has advanced and it doesn't have to be that way anymore.

Regardless of your company's size and stage, you can deploy compliant and validated quality management processes quickly, easily and affordably.

Don't just take our word for it. Test it yourself with a free trial

www.dotcompliance.com