Highstage

ELECTRONIC QUALITY MANAGEMENT SYSTEM

# TOP 5 QMS FEATURES EVERY QA MANAGER SHOULD DEMAND

## A PRACTICAL GUIDE FOR MEDICAL DEVICE COMPANIES NAVIGATING COMPLIANCE

# Introduction

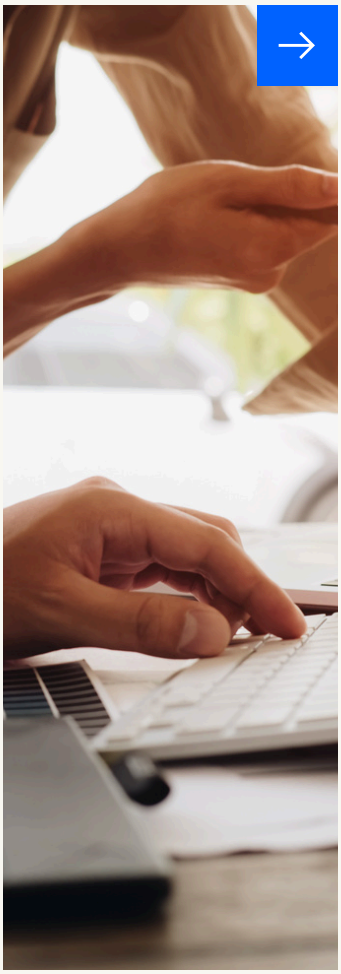
## The Modern QA Manager's Dilemma

Quality managers in the medical device industry face stringent regulatory requirements and complex quality processes. A robust Quality Management System (QMS) is essential to ensure compliance with standards like ISO 13485 and regulations such as the EU Medical Device Regulation (MDR), while also improving efficiency.

**"This guide highlights the five must-have eQMS features that make compliance easier, and quality stronger."**

# Feature 1: Deployed procedures - Automatic records

No QMS is working until you can prove it. And the way to prove that your QMS is actually working is by presenting unambiguous records that it IS being used.



## 01 Forms and Records

In the past, forms were filled out, signed, and stored as records, usually only for regulatory needs and by specific roles.

Today, this should be fully digital and involve the whole organisation. For that to work, the eQMS must deliver more value than effort for every user, offering clear, everyday benefits that make it the go-to place for storing and managing all documents.

When everyone uses the same system, contributing becomes effortless, and the path to certification and product approvals is far smoother.
You'll find more details on this later in the document.

# 02 Deployed processes

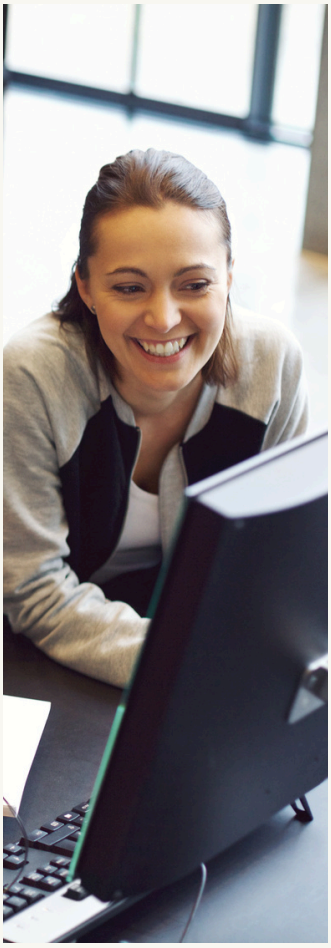

An eQMS should not be a map; it should be the road. The eQMS should lead you by the hand to make sure that records are produced timely.

The eQMS should help you to

- Produce the correct document with the correct template or form in the correct step of the process.
- Produce evidence that a checkbox is checked.
- Collect and store vital data.
- Make sure relevant documents and records are properly reviewed and approved before progressing to the next step of a process.
- Have a clear overview of the activities going on in your business.

Ultimately, an eQMS hand-holding the entire team must ensure adherence to your processes and produce all the records you need for smooth quality and regulatory tasks

The eQMS processes should also be designed to make sure that all data, documents and records required by each process is collected and produced.



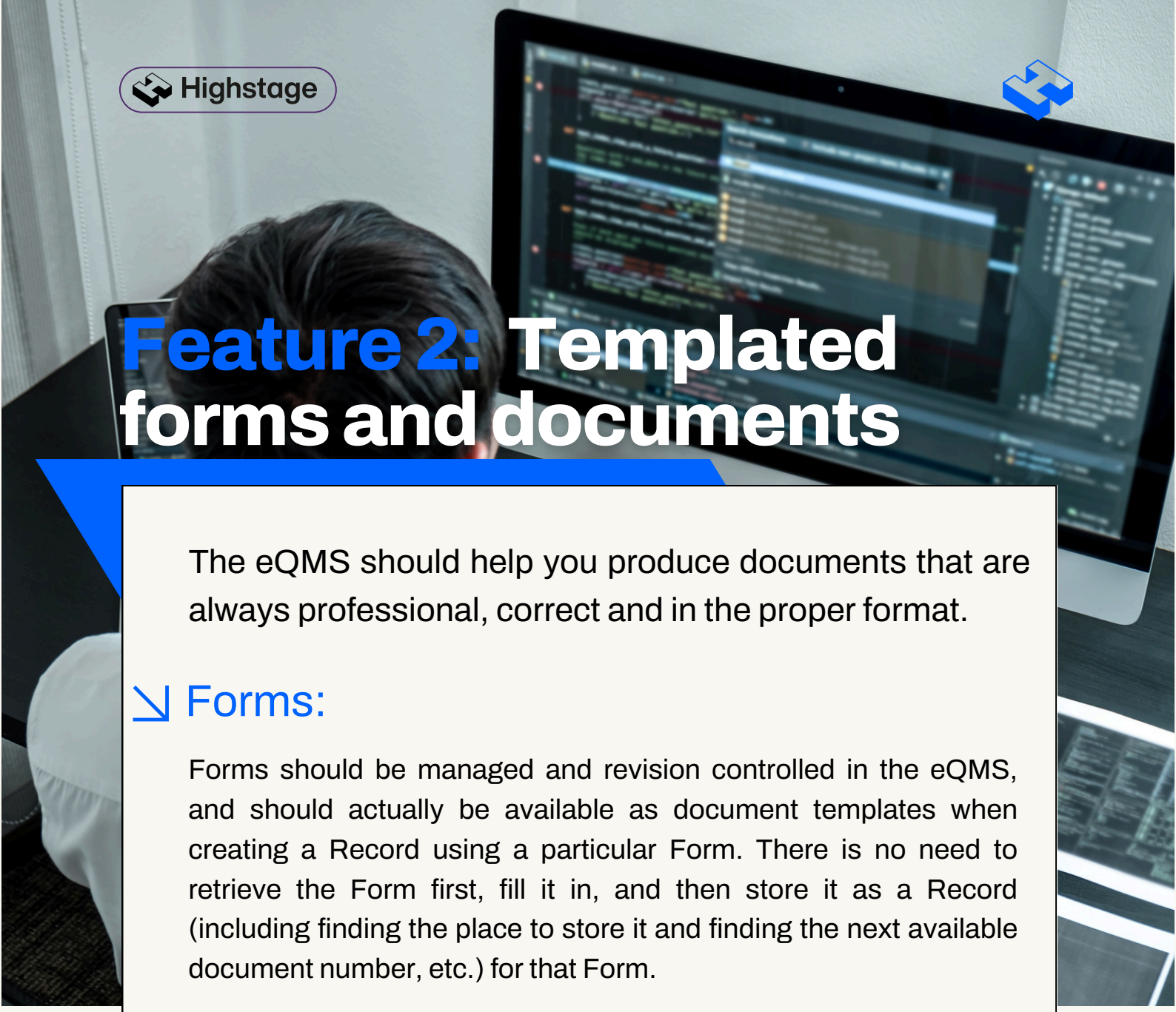
# 03 Design for data collection

It should be possible to design each process type with the number of steps and gates you require, and for each step:

- The data to be collected
- The documents to be produced
- The rationales to be described
- The signatures to be collected

In this way, data and documents are collected and produced in a natural way throughout the process, eliminating the need to find or even re-create them afterwards.

**The result?** Less rework, fewer errors, and everything stored exactly where it should be. Smart templates keep documents clear, consistent, and professional, making compliance part of everyday work.



# Feature 2: Templated forms and documents

The eQMS should help you produce documents that are always professional, correct and in the proper format.

## ↘ Forms:

Forms should be managed and revision controlled in the eQMS, and should actually be available as document templates when creating a Record using a particular Form. There is no need to retrieve the Form first, fill it in, and then store it as a Record (including finding the place to store it and finding the next available document number, etc.) for that Form.

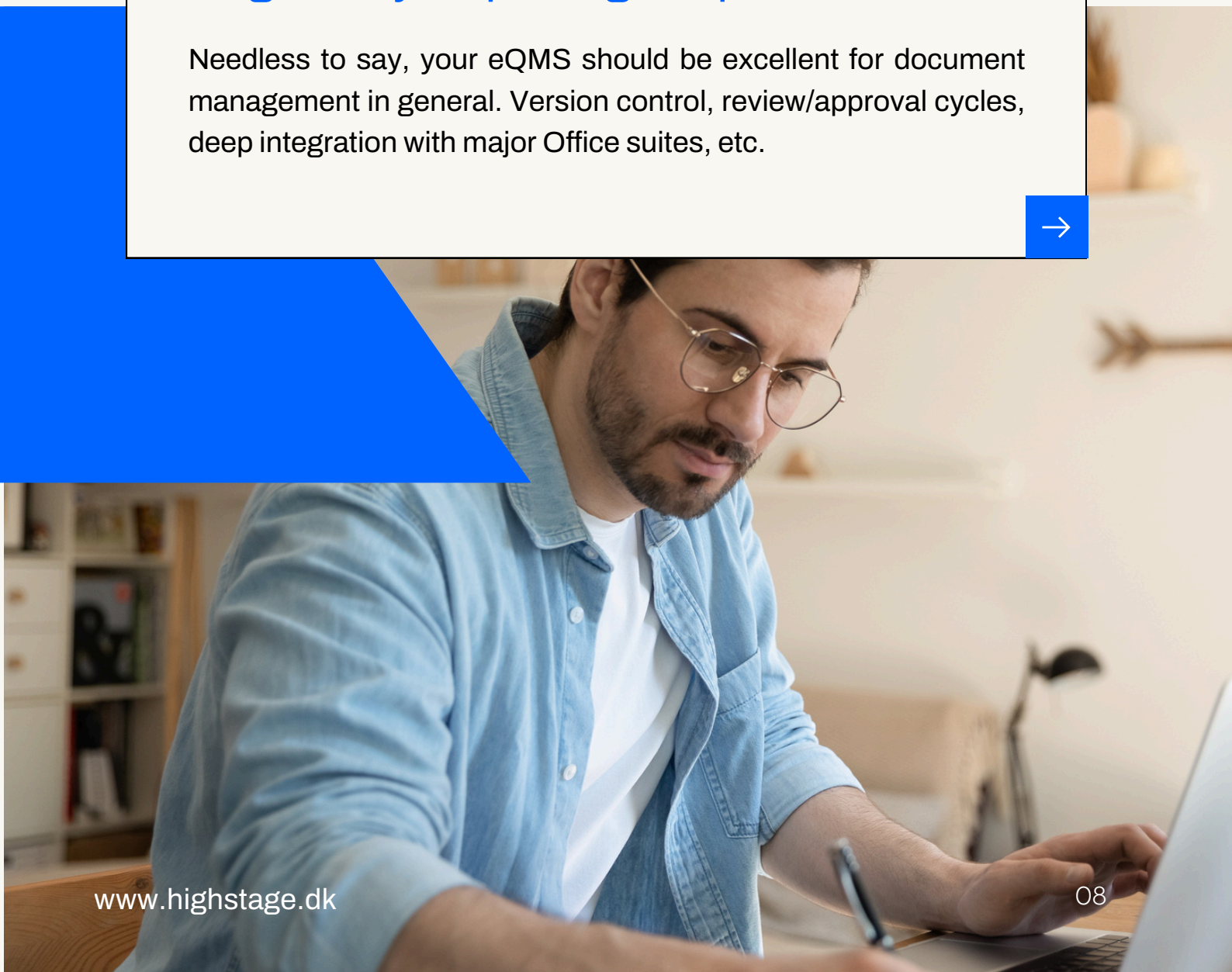
To e.g., make a Design and Development Plan (DDP), **it should be as simple as clicking «Create new DDP»**, and the user should get a new document, with the correct doc id, and with the correct format, layout and even content framework, directly from the DDP Form (which is actually a document template in the system).

## Documents:

The same goes for any document, being it relevant for regulatory purposes or not. It should be as simple as clicking «New» on the document type you want to write, and it should produce a wonderfully perfect document, ready for you to write or make your modifications in. Do it for all your documents. Make a consistantly professional appearance by always producing professional documents, presentations and reports. Consequently, the eQMS should be file-agnostic, and handle any file types.

## Regulatory Reporting & Updates:

Needless to say, your eQMS should be excellent for document management in general. Version control, review/approval cycles, deep integration with major Office suites, etc.



## Synchronised data and documents:

It is a nightmare to keep documents current and updates. Documents typically refer to other documents, often also referring to specific versions of documents. When one document is updated, what are then the impact on the references inside other documents. Two main questions arises:

1. Evaluating the impact; where is this updated document referenced?
2. Should the reference in each of these documents be updated, and how to perform it.

The eQMS should clearly indicate this for you. It should show you «Where referenced» to help you evaluate the impact. It should also help you automatically update the references inside each impacted document.

However, this must be controlled by you, as you are the one knowing IF the reference is going to be updated, or kept to refer to the previous version.

# Feature 3: Integrate product development in the regulatory and quality processes

There should NOT be walls between product development and QA/RA activities and departments. Rather, there should be strong collaboration, shared tools and processes, and common objectives and key results.

## ↘ Integrate the BOM in the eQMS:

To make more sense to users, and to improve traceability considerably, choose an eQMS which has also got PLM (Product Lifecycle Management) capabilities.

This means that the original design data are managed in the same system, giving multiple benefits «for free»:

1. Reference the design (component, assembly, etc.) directly from a quality document or record, e.g. reference the component with version directly from the verification record for that component.

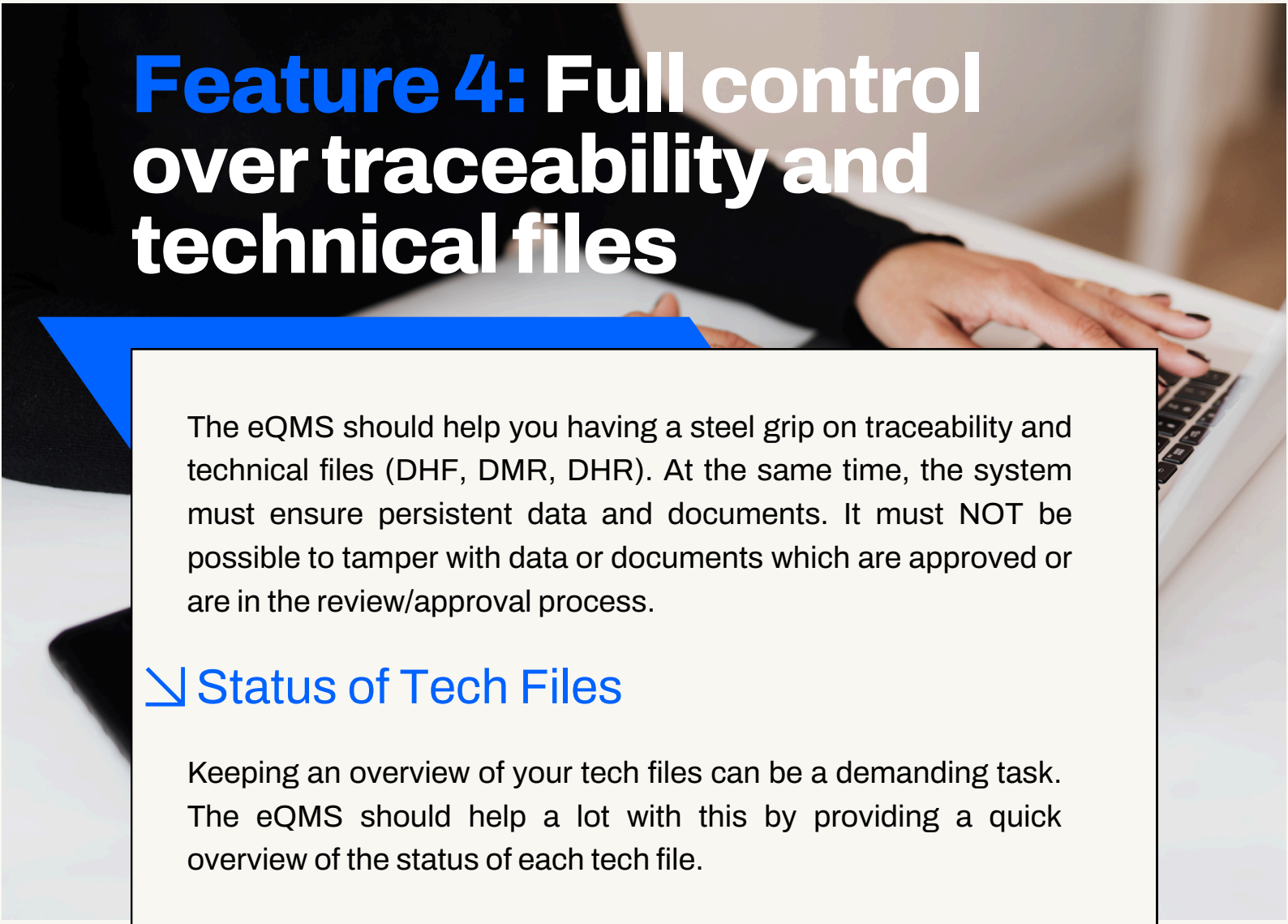
2. You can quickly see which documents and records are related to a design, including the history over the design versions.
3. You can automatically list the referenced designs directly from inside a document or form
4. When engineering produces a document releting to a design, it automatically becomes a record for the DHF.

## ↘ Involve all in the quality processes:

It should be possible to make processes across departments and disciplines. E.g. the Design Controls process should span everybody working on developing a product, irrespective of organisation, department or locations.

Hence, it should be possible to assign different resources to different steps of the the process. It is natural to have other resources in the Design Output phase than in the Design Transfer phase.

Consequently, it should also be easy for each individual to see which are their tasks and responsibilities, and what documents and records are to be produced per step of the process.



# Feature 4: Full control over traceability and technical files

The eQMS should help you having a steel grip on traceability and technical files (DHF, DMR, DHR). At the same time, the system must ensure persistent data and documents. It must NOT be possible to tamper with data or documents which are approved or are in the review/approval process.

## ↘ Status of Tech Files

Keeping an overview of your tech files can be a demanding task. The eQMS should help a lot with this by providing a quick overview of the status of each tech file.

First, it should not allow for approving a tech file unless all referenced documents are first approved separately.

Second, it should present a clear overview of the approval status of each referenced document, who is working on it, and where there are review/approval bottlenecks.

Finally, it should show which documents are missing to complete the tech file. The Tech File front page (e.g., the DHF Index document) shall, of course, be version-controlled and refer to a specific version of the Design Output.

## Submissions

When submitting tech files for e.g. product approvals, it is vital that the correct version is submitted, and that the data and documents contained therein cannot be changed or tampered with.

It must also be easy to find the exact data and document set that was submitted, and it must be possible to continue to work on a new version of the data and document set without compromising what was submitted.

Full persistence of data, documents and data sets is a vital criteria to any eQMS. The eQMS should also support the actual submission, documenting what was sent, by whom, to whom, when, for traceability

## Always Audit Ready

A well-functioning eQMS will have happy users accross departments and disciplines. Lojalty to the system will be high, as it delivers tangible value back to everyone (!) who uses it (!).

When this is the case, all documents are version controlled and properly signed, all data and documents are persistent and unambiguous, and your Notified Body will be impressed.

Bottom line, your eQMS should make you look forward to the next audit. No preparations should be required, except logging into your system and setting up a screen.

# Feature 5: Context-based environments

To leave the well-known folder structure and your Excel-files can be perceived as a hurdle. But once you realise the beauty of contextual data, you´ll embrace it as your «secret sauce» to get on top of all your regulatory and compliance issues.

## ↘ Traceability end-to-end and all accross:

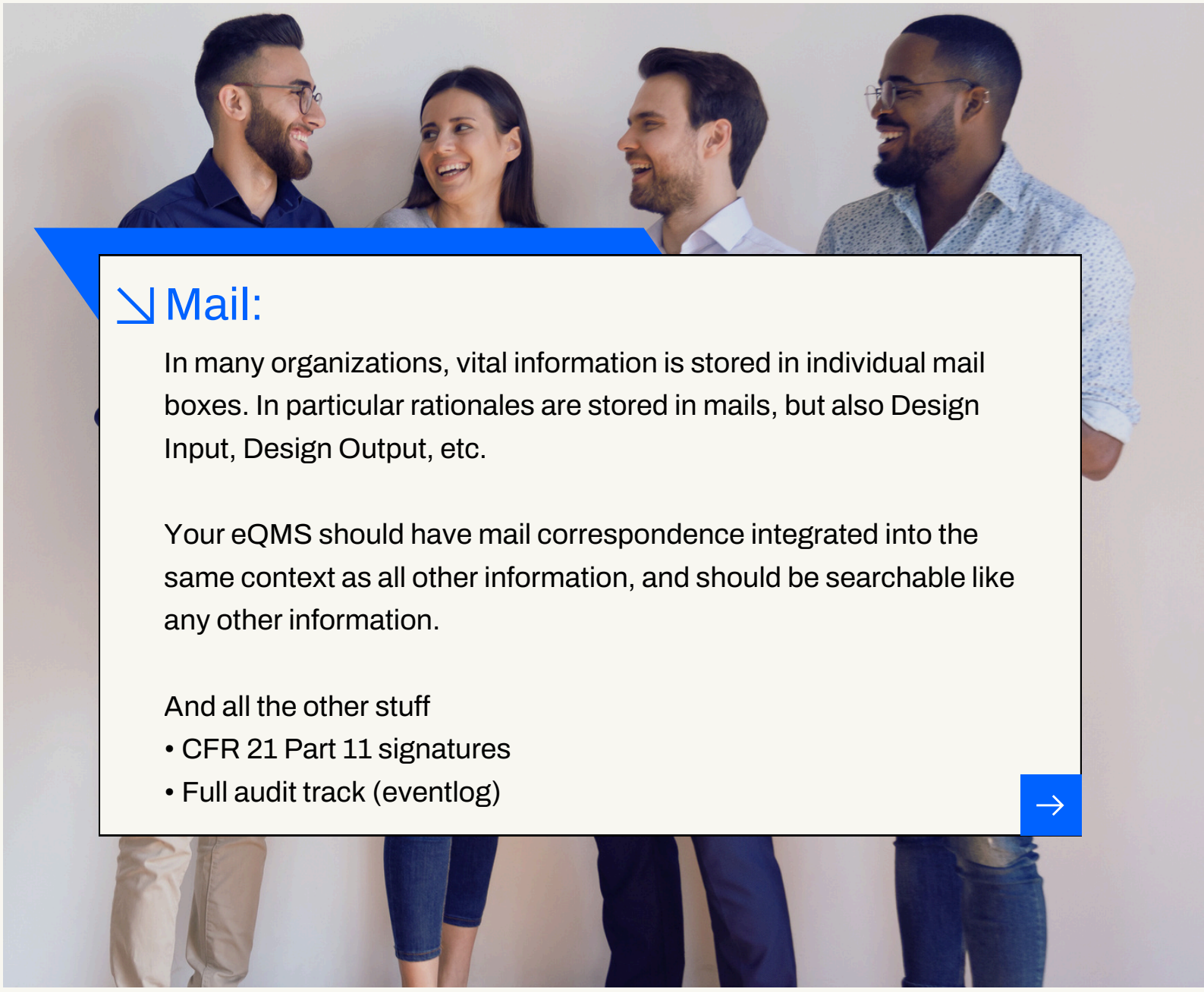
Imagine being able to easily follow the traces

- From idea to released product
- From non-conformity, via CAPA, to an updated procedure
- From a customer complaint to a design
- From a design to the competency of the engineer making the design - Etc
  Your eQMS should ideally span from prototyping and early feasibility studies, to post-market activities and end-of-life for your products.

This implies that it must be possible to reference any information (document, record, design, action, etc.) to any other information. To make advanced information structures that make a lot of logical sense, group information logically, and open up for context-based search and navigation.

## ↘ Re-use:

Your eQMS should allow for re-use of information. This cannot be done at all in a folder structure, but with references it can. Imagine a sub-assembly already properly documented and released in one product, being reference into another product. It saves work and simplifes the data and document management.



## ↘ Mail:

In many organizations, vital information is stored in individual mail boxes. In particular rationales are stored in mails, but also Design Input, Design Output, etc.

Your eQMS should have mail correspondence integrated into the same context as all other information, and should be searchable like any other information.

And all the other stuff

- CFR 21 Part 11 signatures
- Full audit track (eventlog)

# The Secret Sauce in Highstage

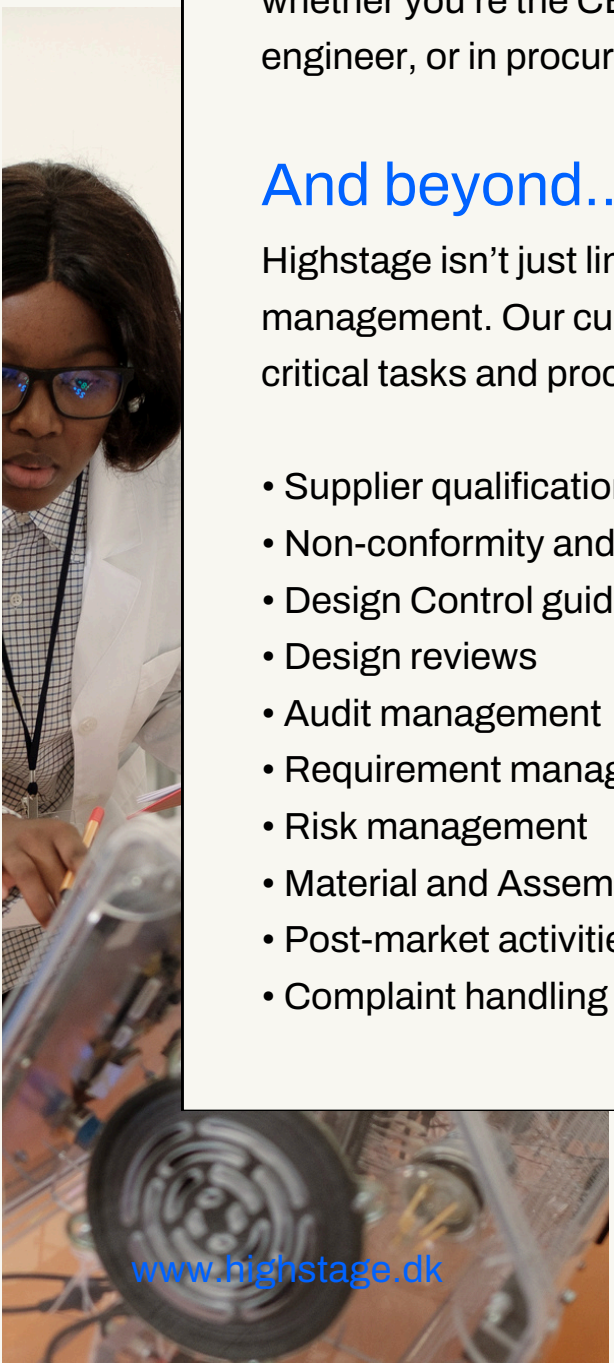
## Built for Everyone

We believe in simplicity with purpose. With Highstage, you enter data once, in a logical context, and it works for everyone, whether you're the CEO, compliance officer, project manager, engineer, or in procurement.

## And beyond....

Highstage isn't just limited to PLM, eQMS, or document management. Our customers trust us with some of their most critical tasks and processes, including:

- Supplier qualification and management
- Non-conformity and CAPA management
- Design Control guidance
- Design reviews
- Audit management
- Requirement management
- Risk management
- Material and Assembly traceability
- Post-market activities
- Complaint handling



Highstage

**See how Highstage helps Medtech companies achieve compliance effortlessly.**

**Schedule a walkthrough!**

**www.highstage.dk/qms**