

Product catalog

GxP-compliant solutions for your digital documentation

Content

Company Digital Life Sciences	3
Facts and figures	5
Modular eDMS & eQMS	7
Cloud, on-premises, or hybrid?	9
Addressed Regulations	10
Document Control	11
Training Management	17
E-learning	23
QM Processes	27
Reporting	31
Supplier Qualification	33

Technical Documentation..... 35

References..... 37





Company Digital Life Sciences

Digital Life Sciences GmbH was founded in April 2007 by Mr. Thilo Gukelberger, Co-Founder of d.velop AG.

We are a provider of digital and GxP-compliant documentation solutions and have focused on the specific requirements of the life sciences industry since our foundation. Our solutions build on the ECM/DMS system of d.velop AG, namely

d.velop documents (formerly d.3ecm), and extend the platform with the special aspects of controlled document and quality management. With many years of experience as a digitizer in regulated environments, we offer our customers not only a broad portfolio of solutions but also a comprehensive range of services (e.g., customer-oriented process consulting, validation services, specific migration consulting, and much more).

Compliance our mission

The concepts of life sciences solutions for quality management of GMP-relevant processes can be found in the GMP Advisor published by Peither, among other sources. Thilo Gukelberger and other employees of the company are authors for the GMP Advisor and have published the following chapters, among others:

- Chapter 1.H: IT systems for the optimisation of quality management processes
- Chapter 2.C: Training management
- Chapter 9.B: Regulatory requirements for computerised systems and the validation process
- Chapter 9.D.2: Risk management in the validation of computer-based systems
- Chapter 9.E: Qualification and validation of computerised systems
- Chapter 15.G: Document management systems



Facts and figures



Founded in 2007

... and thus with nearly 20 years of experience in the (GxP) regulated environment



more than 90
employees



Our services

Validation Services

Professional Services

Support Services



Industries in a regulated environment

Bio technology

Pharma

Food

Medical technology

Chemistry

Cosmetics

Laboratories

...and other companies with a strong focus on quality management



more than 65.000
happy users use our software every day



Certified according to
ISO 9001:2015



more than 165
...customers in a regulated environment



GAMP audits
Successfully audited as a supplier to our customers
(by mail, in person, remotely)

Modular eDMS & eQMS

Comprehensive DMS and QMS solution



Solutions

Our digitization solutions primarily address document-based processes in quality management and manufacturing/production.

The basis of dls | eQMS is a comprehensive ECM/DMS. All software solutions can be introduced as modular building blocks and can be expanded like a building block model to a complete GxP-compliant eQMS suite. The blocks highlighted in turquoise illustrate this aspect.

The ECM/DMS system can also be extended to include non-GxP applications and can be linked to your existing ERP system (e.g. SAP), thus enabling you to implement almost all document-based processes in your company.

You already have an ECM/DMS in use? No problem, it is also possible to deploy only the eQMS modules. Please feel free to contact us.

Let us introduce ourselves

Immerse yourself in the world of digital transformation with the eQMS Suite. Find out more about Digital Life Sciences and our solutions in this video. Learn how you can redesign your document-based processes with customised GxP-compliant software solutions and discover the possibilities of digital transformation.



Brief overview in the video



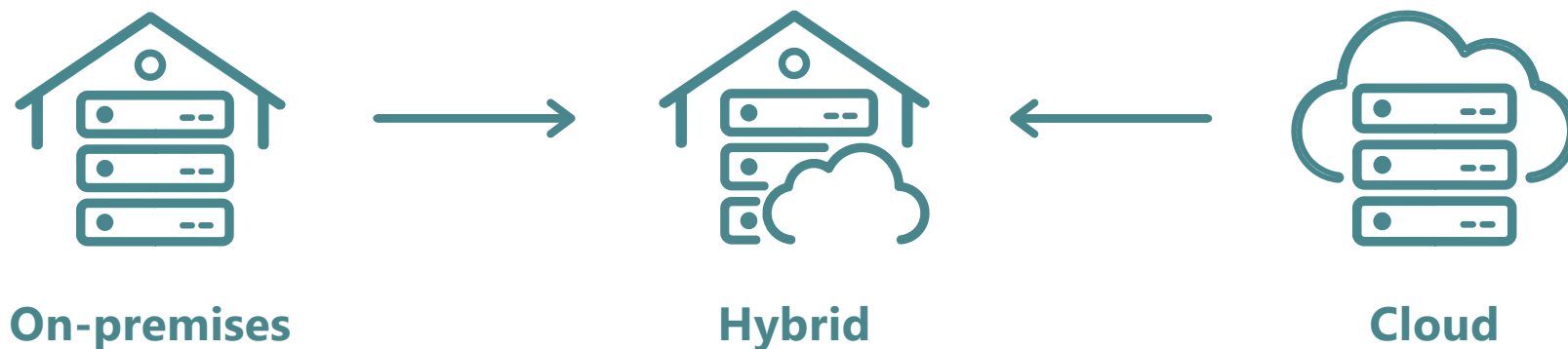
Cloud, on-premises, or hybrid?

Our delivery options

In order to be able to offer you the ideal mode of operation for our software solutions, we are strategically aiming to give you, our customers, the choice. We want you to be able to decide for yourself which delivery method is best for your needs. In addition to the classic on-premises operation, in which the eDMS | eQMS Suite is operated in your own infrastructure, we offer you the use of our Suite in the cloud as an alternative, either as software as a service (SaaS) or as an application service provider (ASP) in a state-of-the-art and secure data centre, or in combination as a hybrid model that flexibly combines cloud and on-prem-

ises solutions. Our data centre partner is accessible to customers and interested parties and has many years of GxP know-how. The data is of course stored and mirrored in Germany. The qualified data center meets all current IT security standards and has been awarded certifications and conformities such as ISO 27001, FDA 21 CFR Part 11, Compliance, GxP Compliance, and many more.

Three ways to use the system:



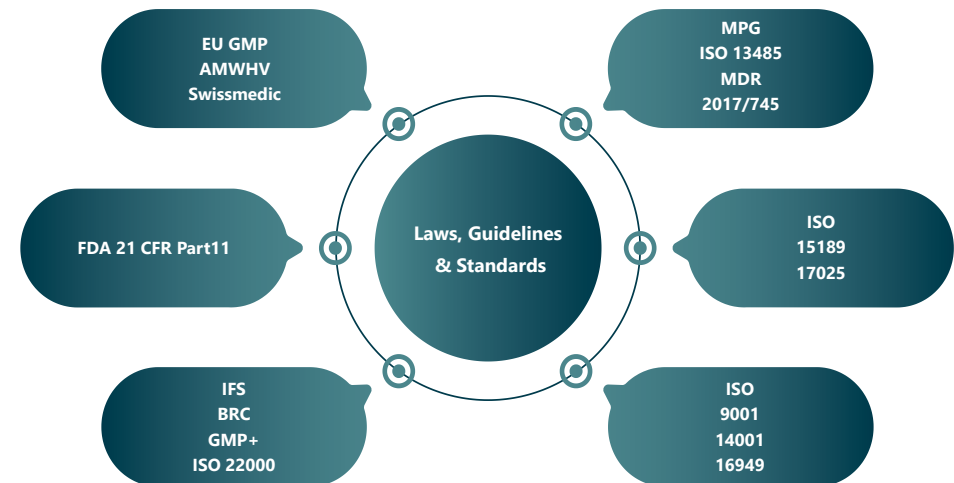
Addressed Regulations

Regulatory requirements

The product development process with respect to regulatory requirements demands a very high level of quality. Our software solutions take into account the relevant laws, guidelines and standards in the regulated environment and have been developed specifically with this in mind. Our products have also been introduced and successfully validated by numerous companies in the life sciences sector.

Audits

As a supplier of software for companies in the GxP environment, conducting supplier audits is standard practice (e.g. in accordance with GAMP® 5). In addition, our products have been successfully inspected by regional and district authorities as well as during TÜV audits in accordance with ISO standards 9001 and 13485. Regular audits by our customers and interested parties also contribute to the continuous improvement of our process and product quality.



Document Control

dls | document control

Whether SOPs, work and process instructions, test specifications, operating instructions, guidelines, manufacturing documents, contracts or any other type of document - you can create, revise and sign them all completely digitally with our "dls | document control" module.



Your benefit

- Create new documents based on approved templates or use existing documents as templates
- You confirm the review, approval and release of your documents with the integrated and GxP-compliant signature
- The system provides further applicable documents and links to other documents as well as the "Periodic Review" function
- Compare the different versions of a document and view the changes directly
- Your paper printouts (if necessary) are controlled and logged by the system depending on the process. Of course, printouts will be marked with a meaningful watermark.
- The integrated reporting facilitates your evaluations and provides an overview of documents and processes (e.g. process cycle times)

Regulatory requirements

- ISO 9001:2015, chapter 7.5
- ISO 13485:2016, chapter 4
- EU-GMP guideline, annex 11
- FDA 21 CFR Part 11
- WHO: "Guidance Document on Good Data and Record Management Practices"
- EFG Vote V11002: Requirements regarding the electronic data storage
- EFG Vote V11003: Requirements regarding electronic signatures and initials

Document Control

From the paper document...

STANDARD OPERATING PROCEDURE		Department: QS
SOP Title: Test Erinnerung Dokument in Bearbeitung		SOP No: SOP-00026
		Author: Abteilungsleiter A
		Qualitätssicherung (aaq)

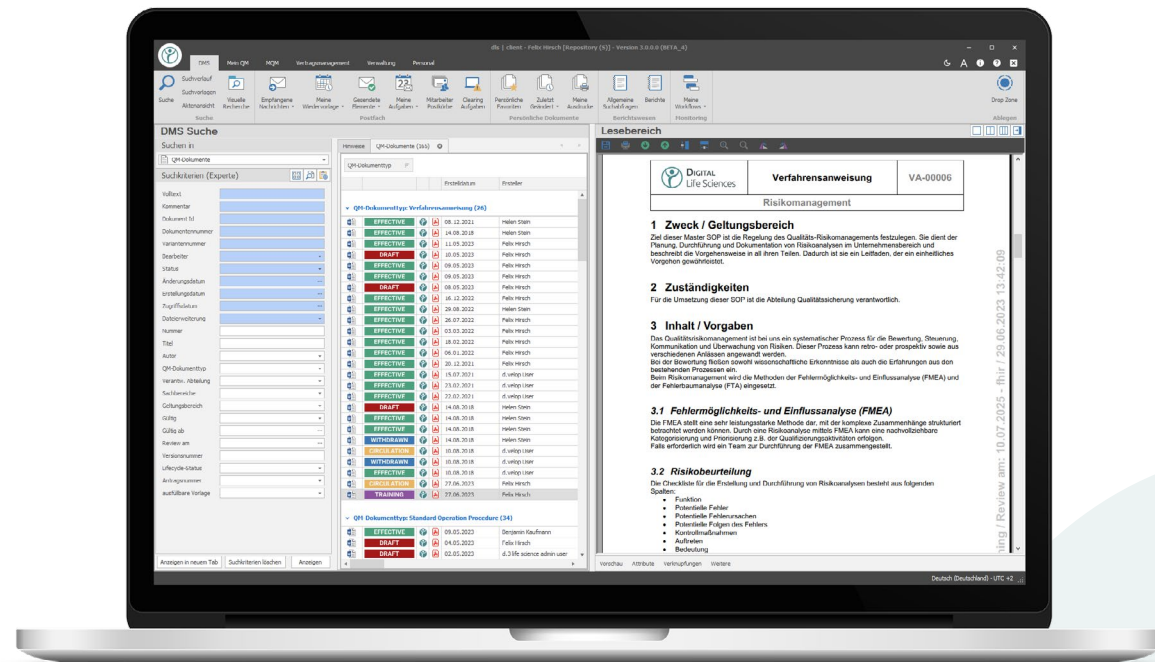
Contents

- PURPOSE 1
- INTRODUCTION 1
- SCOPE 2
- DEFINITIONS 2
- RESPONSIBILITIES 3
- SPECIFIC PROCEDURE 3
- FORMS/TEMPLATES TO BE USED 3
- INTERNAL AND EXTERNAL REFERENCES 3
- CHANGE HISTORY 3

- PURPOSE**
 A brief description of the purpose of the SOP, it should describe why the SOP is required (e.g. compliance with GCP and other internal procedures and guidelines).
 Any regulations or procedures referred to in "Purpose" section should be identified. The source should be given in the reference section rather than direct quotes.
- INTRODUCTION**
 A general introduction, with a statement of rationale.
- SCOPE**
 A statement that outlines the areas and context covered by the SOP.
 If there are any areas in which this SOP specifically does NOT apply, these should also be mentioned.
- DEFINITIONS**
 When appropriate, a list of definitions should be included for terms used in the SOP. Acronyms and abbreviations should be explained at the point of use within the SOP and not listed in this section.
- RESPONSIBILITIES**
 A summary of the roles listed in the procedure and the responsibilities of each role holder for the procedures detailed in the SOP.
 The details of the responsibilities should be a brief list of the key tasks performed. This section should not be a complete summary of the SOP.

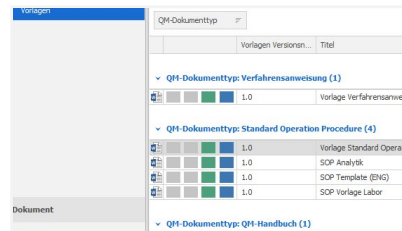
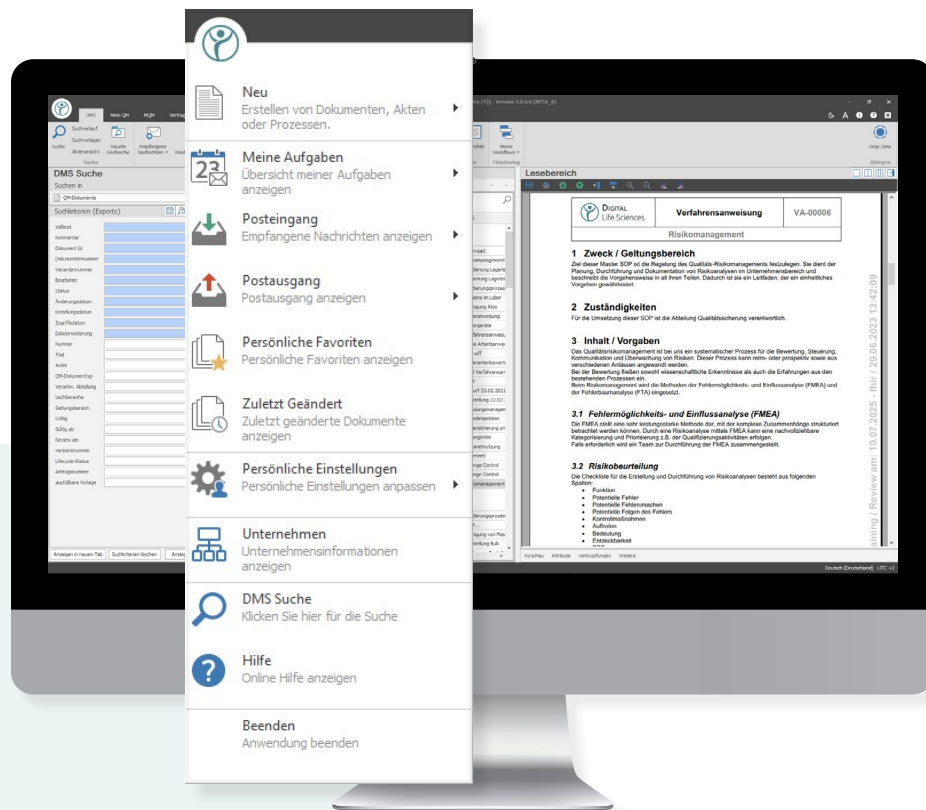
Page 1 of 4

... to the digitally controlled document!



Document Control

Creation via integrated template management

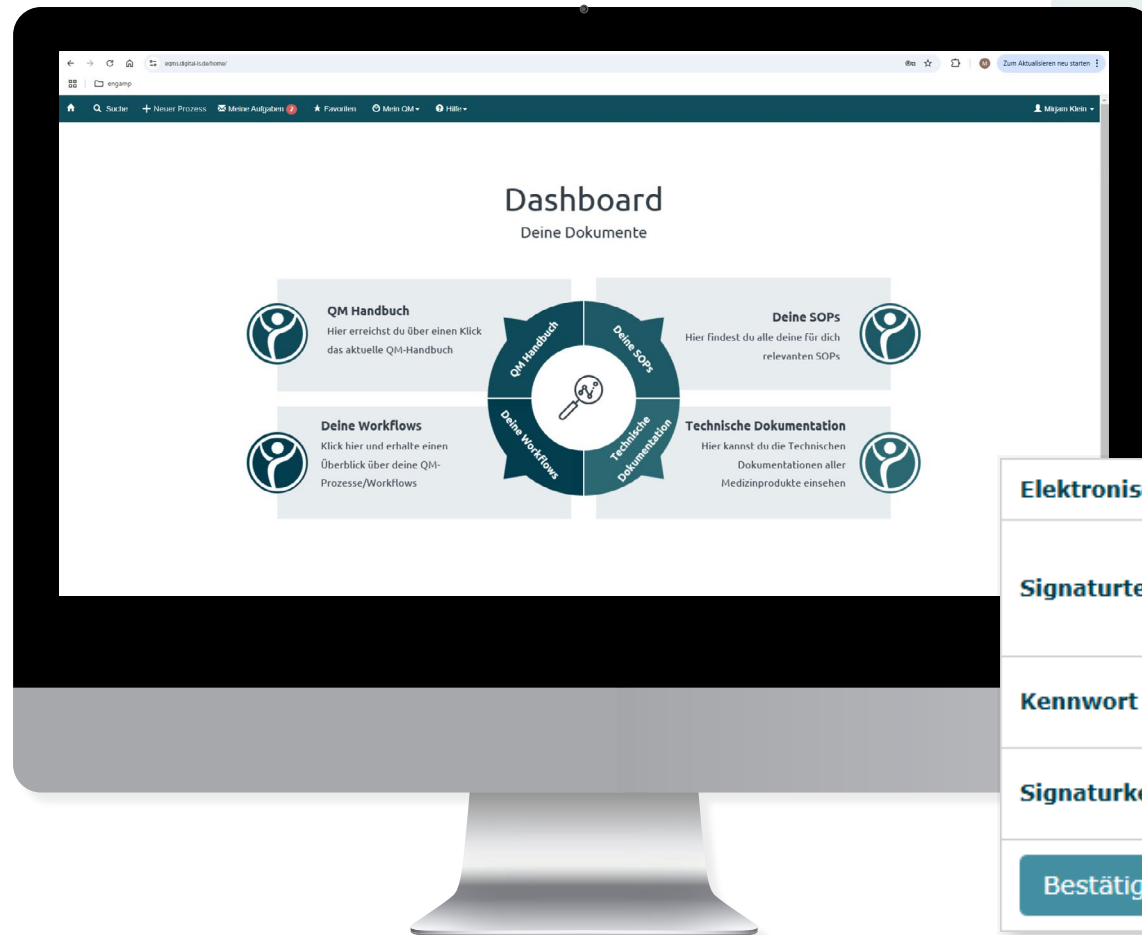


QM-Dokumente von Vorlage erstellen.
Bitte geben Sie die notwendigen Informationen an.

Nummer	AA-00063
Titel	Erstellen einer Arbeitsanweisung
QM-Dokumenttyp	Arbeitsanweisung
Verantw. Abteilung	Qualitätssicherung
Sachbereiche	
Geltungsbereich	Unternehmensweit/alle Standorte
Antragsnummer	
ausfüllbare Vorlage	

Document Control

Document circulation: Review, Approval, Release



Elektronische Unterschrift	
Signaturtext	200: Hiermit bestätige ich, Helen Stein (hste) signiert als Head of Quality Management, das Dokument "Change Control (VA-00001)" erfolgreich geprüft zu haben.
Kennwort	
Signaturkennwort	
Bestätigen	

Use document circulations/workflows that can be adapted to your needs and procedures. Different (single or multi-level) document circulations can also be used for your different document types, if required. Participation in the automated document circulation is confirmed by means of a digital and GxP-compliant signature. Periodic Review tasks as well as other task types are sent automatically by the system, of course also with corresponding notification by e-mail. An integrated deputy function as well as reminder and escalation management ensure that tasks are completed on time and that your documents are made available to the relevant employees as quickly as possible.



Increase in efficiency



Increased transparency



Time & cost savings



Ensuring compliance



Improving collaboration



Risk minimization



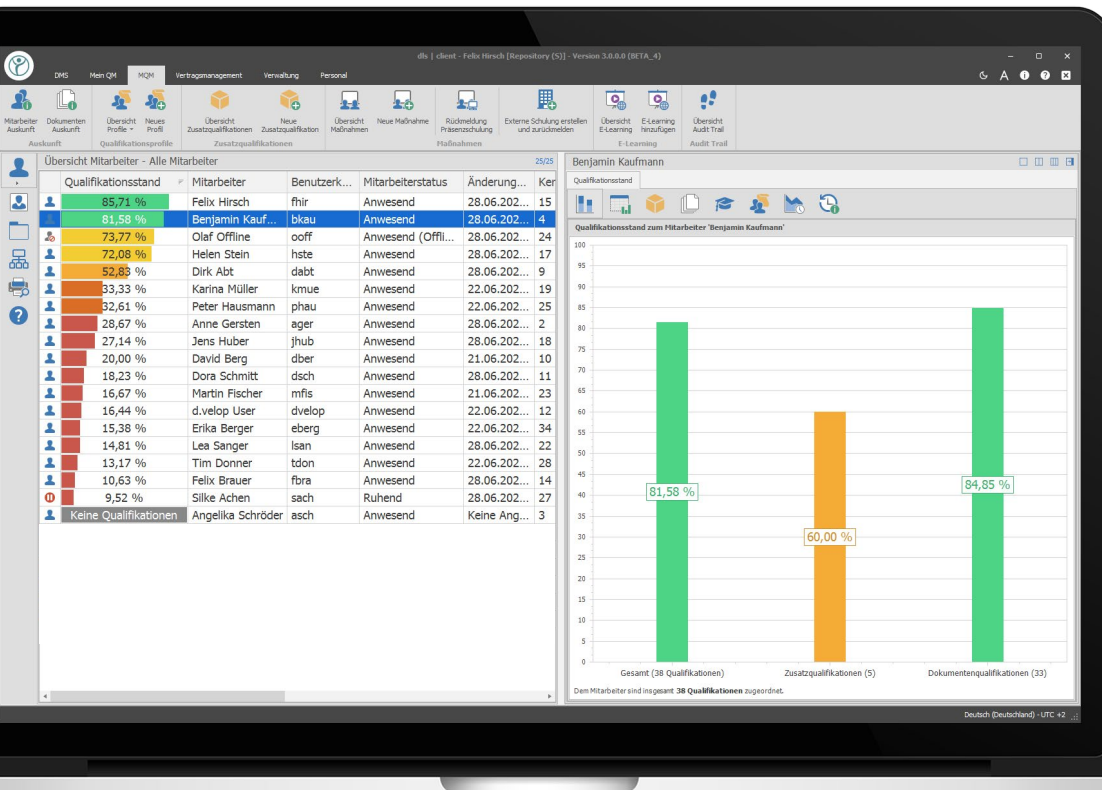
Flexibility and scalability



Increased data security

Training Management

dls | training management



Expand the document control module to actively schedule and log training for your employees. This task is performed by our solution "dls | training management".

Regulatory requirements

- ISO 9001:2015, chapter 7
- ISO 13485:2016, chapter 6
- EU-GMP guidelines Part 1, chapter 2
- EU-GMP guidelines Part 2, chapter 3
- Medicinal Products and Active Ingredients Manufacturing Ordinance (AMWHV) section 2, §4
- FDA 21 CFR 211 Subpart B

Your benefit

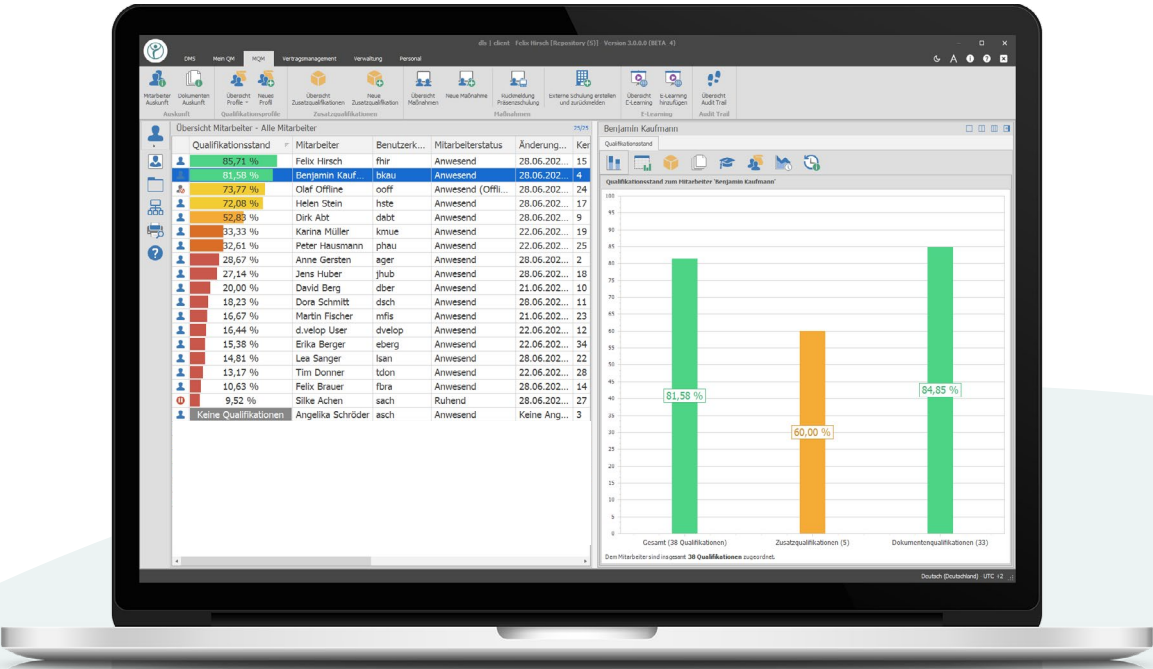
- Make sure that all employees have the necessary qualifications for their job
- Update the qualification level of your employees due to successful document trainings or (externally) completed trainings
- Training management supports you in the planning and confirmation of your in-house training or classroom training, including the creation of automatically generated participant lists and other training documents
- Automatically assign training tasks to affected employees when a new document version is released
- Complete comprehension questions on selected documents and use an electronic exam
- Configure different repetition intervals for your classroom training as well as external advanced and further training courses
- Check the qualification level of your employees at the push of a button - based on a document, an employee or a job, role, department, etc. The resulting qualification matrix and integrated reporting tools provide you with information at a glance

Training Management

From training list...

Schulungsliste							
Pos.	Abt.	Name	Vorname	Inhalt	Dozent	Datum	Raum
1	Qualif.	Mende	Anny	Biostatistik Dr. Müller	2023-10-11	Konferenzsaal	09:00
2	Qualif.	Lübs	Hermann-Josef	GMP-Rich Dr. Fischer	2023-03-30	Labor 202	08:00
3	Qualif.	Schöten	Maurizio	GMP-Rich Dr. Fischer	2023-12-31	Raum 404	10:00
4	Pharm	Scholz	Leszek	Dokumen Dr. Müller	2023-05-31	Labor 202	09:00
5	Forsc	Weiß	Sunnar	Biostatistik Prof. Schmidt	2023-07-04	Labor 505	11:00
6	Forsc	Vollbrecht	Cora	Qualitäts Dr. Fischer	2023-08-08	Raum 101	10:00
7	Qualif.	Hellwig	Veronique	GMP-Rich Dr. Fischer	2023-09-24	Raum 101	13:00
8	Forsc	Frohlich	Charlotte	GMP-Rich Dr. Fischer	2023-04-12	Labor 202	13:00
9	Biote	Schneibach	Roderich	Qualitäts Dr. Weber	2023-11-13	Labor 505	13:00
10	Biote	Reuter	Walfried	Biostatistik Dr. Fischer	2023-02-13	Konferenzsaal	09:00
11	Qualif.	auch Schlauch	Kristin	Laborger Dr. Weber	2024-02-13	Konferenzsaal	10:00
12	Biote	Frohlich	Norma	Dokumen Dr. Müller	2023-08-11	Raum 404	13:00
13	Biote	Conradi	Hans-J.	Qualitäts Dr. Müller	2023-10-06	Labor 202	11:00
14	Biote	Hethur	Liesel	Qualitäts Dr. Müller	2023-11-22	Labor 505	13:00
15	Forsc	Hornich	Bernd	GMP-Rich Dr. Müller	2023-04-02	Labor 505	09:00
16	Produ	Koch II	Wladimir	Dokumen Dr. Müller	2023-02-25	Raum 101	11:00
17	Biote	Albers	Adam	Biostatistik Prof. Schmidt	2024-01-05	Raum 101	09:00
18	Qualif.	Schulz	Klaudia	Biostatistik Dr. Weber	2024-02-11	Raum 101	13:00
19	Biote	Ladeck	Mary	Biostatistik Dr. Müller	2023-05-14	Konferenzsaal	08:00
20	Produ	Klingelhöfer	Jeanette	Laborger Dr. Fischer	2024-01-25	Raum 404	10:00
21	Biote	Pechel	Sigfried	Laborger Dr. Fischer	2024-01-25	Raum 404	10:00
22	Qualif.	Weismann	Knud	Dokumen Dr. Fischer	2023-10-13	Raum 404	08:00
23	Qualif.	Herrmann	Jenny	Qualitäts Dr. Fischer	2023-11-05	Konferenzsaal	08:00
24	Pharm	Jopich	Gereon	Qualitäts Dr. Fischer	2023-11-22	Labor 505	09:00
25	Biote	Kroker	Imme	GMP-Rich Prof. Schmidt	2023-05-25	Raum 101	08:00
26	Biote	Wesack	Thoralf	Laborger Dr. Fischer	2023-08-19	Raum 404	11:00
27	Pharm	Rogge	Bertold	GMP-Rich Dr. Fischer	2023-06-19	Konferenzsaal	11:00
28	Produ	Ring	Edda	Dokumen Dr. Fischer	2023-12-29	Raum 404	09:00
29	Pharm	Wagner	Jolanta	GMP-Rich Dr. Fischer	2023-03-24	Raum 101	09:00
30	Forsc	Pergande	Hartmut	GMP-Rich Dr. Fischer	2023-03-24	Labor 505	09:00
31	Biote	Harloff	Anton	Laborger Dr. Fischer	2023-07-02	Labor 202	09:00
32	Forsc	Stiebitz	Hassan	GMP-Rich Dr. Weber	2023-11-04	Labor 202	10:00
33	Biote	Döring	Anbert	Qualitäts Dr. Müller	2023-10-21	Konferenzsaal	10:00
34	Produ	Thanel	Romana	Laborger Prof. Schmidt	2023-08-26	Raum 404	08:00
35	Forsc	Junk	Brunhilde	Dokumen Dr. Weber	2023-06-09	Labor 202	11:00
36	Forsc	Trub	Knud	Dokumen Prof. Schmidt	2023-03-15	Labor 505	11:00
37	Produ	Eberth	Jörgen	Dokumen Dr. Fischer	2023-11-28	Raum 404	09:00
38	Qualif.	Trommler	Paul-Henry	GMP-Rich Dr. Weber	2023-11-25	Labor 505	08:00
39	Pharm	Heldrich	Bertold	Biostatistik Dr. Weber	2023-04-23	Raum 404	08:00
40	Biote	David	Moritz	Laborger Dr. Fischer	2023-07-16	Labor 202	08:00
41	Produ	Ilussek	Max	Biostatistik Prof. Schmidt	2023-09-24	Konferenzsaal	11:00
42	Forsc	Ladeck	Anni	Qualitäts Dr. Müller	2023-07-16	Labor 202	08:00
43	Qualif.	Rosenow	Aurelia	Dokumen Dr. Fischer	2023-11-06	Labor 505	09:00
44	Pharm	Dehmel	Cemil	Dokumen Dr. Weber	2023-05-23	Konferenzsaal	13:00
45	Biote	Barth	Ayattoli	Qualitäts Dr. Fischer	2023-12-04	Konferenzsaal	11:00
46	Produ	Kuhl	Joerg	Dokumen Dr. Weber	2023-02-27	Labor 202	11:00
47	Biote	Subeier	Helmud	GMP-Rich Dr. Fischer	2023-09-28	Labor 505	09:00
48	Pharm	Mies	Michail	GMP-Rich Dr. Müller	2023-11-07	Labor 101	11:00
49	Biote	Keudel	Sepp	Laborger Prof. Schmidt	2023-05-26	Raum 404	10:00
50	Forsc	Karz		Laborger Dr. Weber			

... to digital training management



Training Management

Training task & qualification matrix

The screenshot displays the Training Management software interface. The top section shows document details for 'Umgebung mit elektronischen Unterschriften' (Environment with electronic signatures), including author, title, version, and creation date. The bottom section shows the 'Meine Qualifikationsmatrix' (My Qualification Matrix) for user 'Tim Dönnebrink'. The matrix is titled 'Meine Qualifikationsmatrix - 100,00 % (47 / 47)' and lists three training tasks with their status, number, name, version, training type, and completion date.

Status	Numer	Name	Version	Schulungsart	Nachweiszeit
EFFECTIVE	RL.00006	Abwesenheit	3.0	Leseschulung	02.04.202...
EFFECTIVE	BA.00010	Arbeitszeiterfassung und Überstundenregelung	3.0	Leseschulung	02.07.202...
EFFECTIVE	AN.00044	Auditprogramm 2025	6.0	Leseschulung	16.01.202...

Define which employees should have which qualifications and easily assign them the relevant documents and further trainings. Choose from a variety of training types (Informative, Read and Understood training (including electronic exam), classroom training, e-learning, etc.) and plan customized training for your workforce. The constantly updated qualification matrix provides you with information about the current qualification status of your employees at the click of a button, based on proofs of qualification (target/actual comparison). Your employees are automatically informed about your training tasks. Benefit from features such as repetition intervals for trainings and individual training events (e.g., re-trainings).



Training Management

Electronic exam

Test your employees' knowledge with the electronic exam function. This allows for the creation of individual question catalogs. After successful completion of the exam, e.g. multiple choice, the qualification status of your employees is automatically updated and immediately displayed in the qualification matrix.

dls | client

Frage erstellen Frage entfernen Lernkontrolle testen Ansicht Drucken Antwort erstellen Antwort entfernen

Verwaltung Information Antworten

Einstellungen zum Fragebogen

Titel
Test zur Arbeitsanweisung

Anzahl der zu beantwortenden Fragen:
7

Prozentzahl (in %) zum Bestehen des Tests:
70

Es müssen 5 Fragen von insgesamt 7 Fragen korrekt beantwortet werden.

☒ Als Multiple-Choice-Katalog behandeln

dls | client

Frage erstellen Frage entfernen Lernkontrolle testen Ansicht Drucken Antwort erstellen Antwort entfernen

Verwaltung Information Antworten

Übersicht der Fragen

Nr.	Thema
1	Aufgabe Organisation
2	Interne Audits
3	Auditprogramm
4	Prozesse und Produkte
5	fehlerhafte Produkte
6	Datenanalyse
7	Personenbezogene Daten

Bearbeitung der Frage

Thema: Personenbezogene Daten

Calibri 11

Welches Gesetz regelt den Umgang mit personenbezogenen Daten?

Antworten

Nr.	Text
1	☐ Das Bürgerliche Gesetzbuch (BGB)
2	☒ Das Bundesdatenschutzgesetz (BDSG)
3	☐ Das Strafgesetzbuch (StGB)

Speichern Hilfe Abbrechen

Elektronische Lernkontrolle - Testmodus

Elektronische Lernkontrolle
Bitte beantworten Sie die folgenden Fragen.

Frage 1 von 7

Welches Gesetz regelt den Umgang mit personenbezogenen Daten?

Antwort

☐ Das Bürgerliche Gesetzbuch (BGB)

☒ Das Bundesdatenschutzgesetz (BDSG)

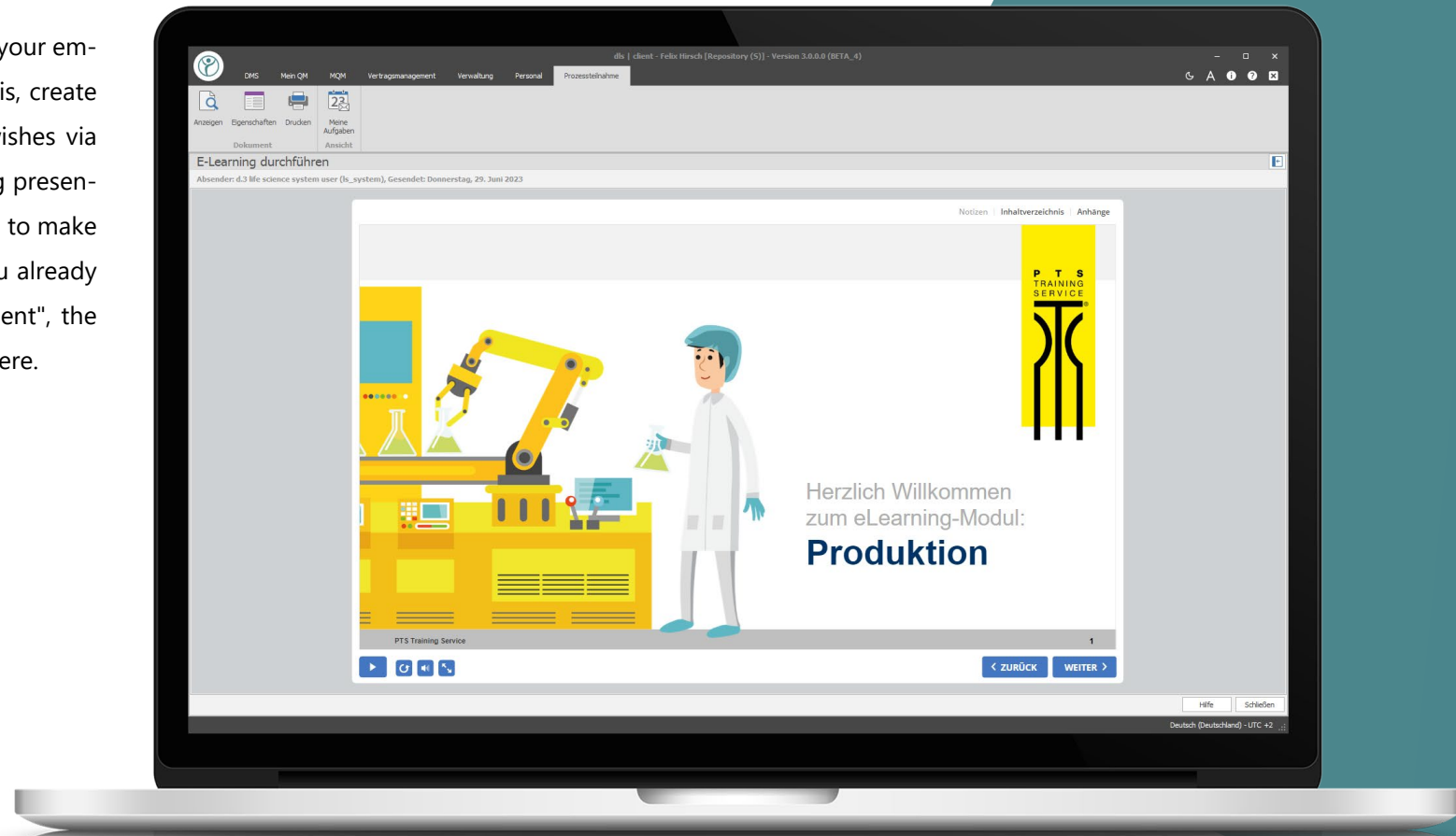
☐ Das Strafgesetzbuch (StGB)

< Zurück Weiter > Abbrechen Hilfe

E-learning

dls | e-learning

Use our module "dls | e-learning" to train your employees even more interactively. To do this, create an e-learning freely according to your wishes via Microsoft PowerPoint or integrate existing presentations. In addition, use audios and videos to make your trainings even more engaging. If you already use our module "dls | training management", the new training type e-learning is available here.



Your benefit

- Easily integrate content from the eDMS / eQMS, such as default and specification documents, into the e-learning
- In addition to documents, integrate audio files and videos to illustrate your learning content
- Participate in your e-learning via delivered tasks within the system or via the web-based training portal
- If our "dls | training management" module is also used, the successful processing of the exam automatically updates the qualification status of your employees
- Design your electronic exam individually using a variety of options directly in PowerPoint

To the e-learning example



E-learning

Electronic exam

Question 1 - Puzzle

Frage 4 von 4 | Ihre Punkte: 30 von 40 | [Inhaltsverzeichnis](#) | [Anhänge](#)

Thema: **Produktion** | Kapitel: **Erfolgskontrolle** | Unterkapitel: **Testen Sie Ihr Wissen!**

Die Produktionsvorgänge müssen nach klar definierten Verfahren erfolgen. Diese Verfahren in schriftlicher Form. Verfahren müssen den der Guten Herstellungspraxis (GMP) entsprechen, um zu Produkten zu führen, die die besitzen und die mit der und den jeweiligen übereinstimmen.

Richtig ✓
Stimmt! Sie haben die richtige Antwort gewählt.

Ziehen Sie die Wörter und lassen Sie sie an der richtigen Stelle fallen!

PT S Training Service 14 [ERGEBNISSE ANSEHEN](#)

[EINREICHEN](#)

Question 2 - Multiple Choice

Frage 1 von 4 | Ihre Punkte: 0 von 40 | Inhaltsverzeichnis | Anhänge

Thema
Produktion

Kapitel
Erfolgskontrolle

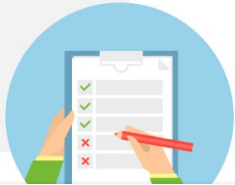
Unterkapitel
Testen Sie Ihr Wissen!

Ein Fertigarzneimittel soll produziert und in den Verkehr gebracht werden.
Welche Voraussetzungen gibt es?

☐ Ausreichend Mitarbeiter, die Qualifikation ist nicht entscheidend, Hauptsache die Anzahl stimmt

☒ Herstellungserlaubnis

☒ Zulassung



Inhaltsverzeichnis | Anhänge

Thema
Produktion

Kapitel
Erfolgskontrolle

Unterkapitel
Testen Sie Ihr Wissen!



Glückwunsch, Sie haben bestanden!

Ihr Ergebnis: **100% (40 Punkte)**

Notwendige Punktzahl: **80% (32 Punkte)**

[ERGEBNISSE ANSEHEN](#)

PTS Training Service

14

[< ZURÜCK](#)

You have a wide range of options:

Use a variety of question types to create your performance review according to your preferences:

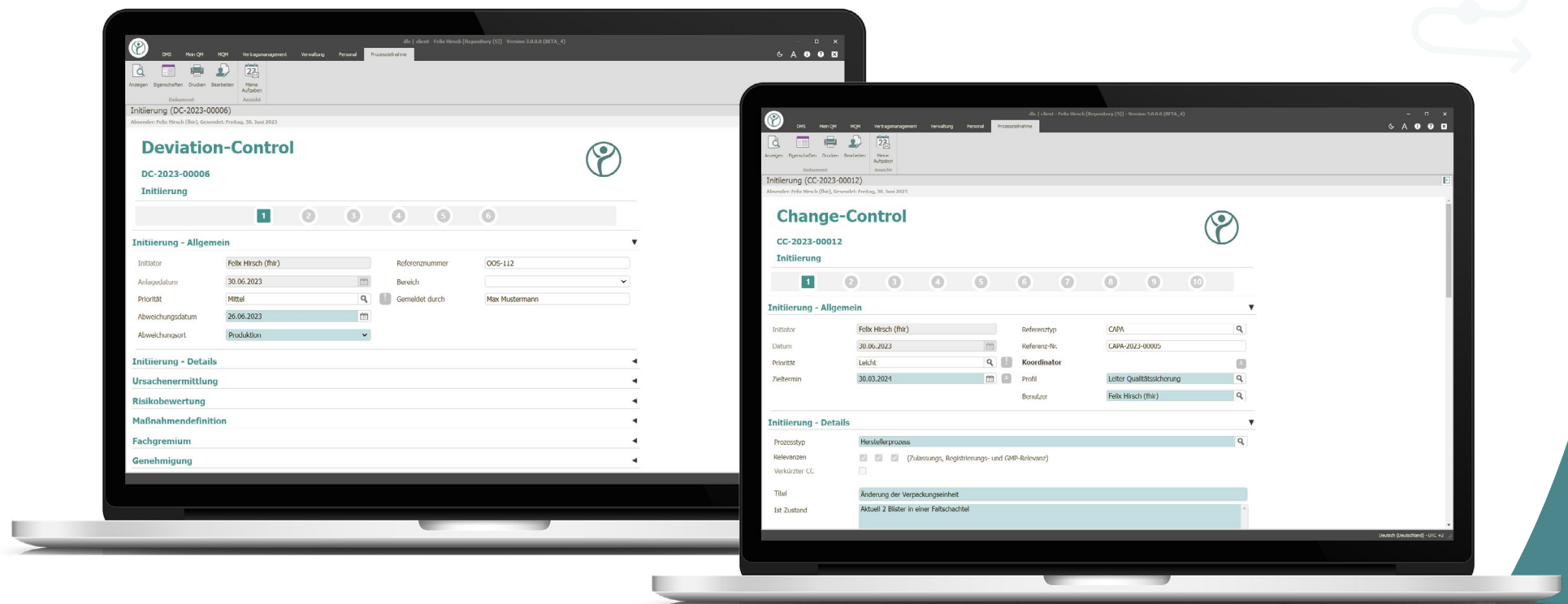
- Multiple-choice
- Text responses
- True/False
- Cloze tests
- Puzzle
- Drag and drop
- Rating matrix
- Hotspot
- Order

QM processes

Complaint, Deviation Control, CAPA, Change Control

Control your production-related QM processes such as complaints, deviation control, corrective and preventive actions (CAPA) or change control with our digital workflows. Our integrated solutions manage your previously paper-based process from capture to completion completely digitally. The workflow system automatically forwards the digital form to the next instance; if deadlines are

exceeded, the reminder and escalation management system intervenes. Of course, an absence management is also included for the task routing.



Your benefit

- Records that you keep today in paper forms will no longer be lost, as they are stored digitally from the start
- The administration costs and runtime of processes are reduced and the quality of results is increased
- Generate interconnected process chains, consisting of individual processes, to increase traceability
- Create reports and statistics and keep track of your quality-relevant processes, even if you are not involved in the process
- Of course, we have also added the electronic and GxP-compliant signature to these solutions

Regulatory requirements

- ISO 9001:2015, chapter 5.1.2
- EU-GMP guidelines Part 2, section 15
- FDA 21 CFR Part 211 & CFR 7 Subpart C
- AMWHV §19
- ISO 9001:2015, chapter 8
- ISO 13485:2016, chapter 8
- EU-GMP guidelines Part 1, chapter 8
- ISO 9001:2015, chapter 8.5.6
- ISO 13485:2016, chapters 4 and 7
- EU-GMP guidelines Part 2, section 13

QM processes

Complaint, Deviation Control, CAPA, Change Control

From a paper form...

Reklamation / Beschwerde (Complaints)

Referenz-Nr.:

Meldung von Beanstandungen und Verbraucherbeschwerden

Diese Meldung ist vom Empfänger der Beanstandung auszufüllen und unverzüglich weiterzuleiten.

Bearbeiter: Funktion: Tel. Eingangsdatum, Uhrzeit:

Beschwerdeführer: Kunden-Nr. Name, Anschrift: Nähere Angaben zum Beschwerdeführer:

Art der Nachricht: (bitte Tel.-Notiz, FAX oder E-Mail-Ausdruck anhängen) Telefon FAX Email

Informationen über die Beanstandung/Verbraucherbeschwerde:

Betroffenes Arzneimittel: Zul./Reg.-Nr.:

Charge: Haltbarkeitsdatum: Menge: Kühlware ☐ Ja ☐ Nein

Beanstandungsmuster

Der Beanstandung ist ein Muster beigelegt. ☐ Ja ☐ Nein

Der Beanstandung ist Bild-/Beweismaterial beigelegt. ☐ Ja ☐ Nein

Beanstandung/Verbraucherbeschwerde:

Eingang bestätigt; Datum/Uhrzeit/Unterschrift:

Seite 1 von 1

...to the digitally controlled process

db | client - Felix Hirsch | Repository (32) - Version 3.0.0.0 (BETA_4)

Ansagen, Gesprächsplan, Drucken, Bearbeiten, Neue Aufgaben, Ansicht

Initiierung (CP-2023-00002)

Abandon Felix Hirsch (thir), Created: Donnerstag, 29. Juni 2023

Complaint

CP-2023-00002

Initiierung

1 2 3 4 5 6 7 8

Initiierung - Allgemein

Initiator: Felix Hirsch (thir)

Datum: 29.06.2023

Erstinformation: 29.06.2023

Ereignisdatum: 27.06.2023

Priorität: 1 Hoch

Koordinator: Leiter Qualitätssicherung

Benutzer: Helen Stein (hste)

Initiierung - Einsender

Einsendort: Apotheke

Name: Arker-Apotheke

Anzahl der Fälle: n.a.

Ansprechpartner: Petra Schwilke

Strasse: Österreich Str. 25

PLZ: 01279

Stadt: Chemnitz

Deutsch Deutschland - UTC +2

QM processes

Control your QM processes digitally

More features

- Adding documents/attachments
- Audit trail and master data reference
- Addressing roles and users
- Connection to document control
- Automatic PDF creation and storage
- Consistent design elements and functions
- Clear status tracking

The screenshot shows a web application window titled "dk | client - Felix Hirsch [Repository (5)] - Version 3.0.0.0 (BETA_4)". The interface includes a top navigation bar with tabs like "DMS", "Mein QM", "HQM", "Vertragsmanagement", "Vorschau", "Personal", and "Prozessabläufe". Below this is a sub-navigation bar with icons for "Anzeigen", "Eigenschaften", "Drucken", "Bearbeiten", and "Neue Aufgaben". The main content area is titled "Initiierung (CAPA-2023-00005)" and "CAPA-2023-00005". It features a progress bar with steps 1 through 8, where step 1 is highlighted. The form is divided into two sections: "Initiierung - Allgemein" and "Initiierung - Details".

Initiierung - Allgemein

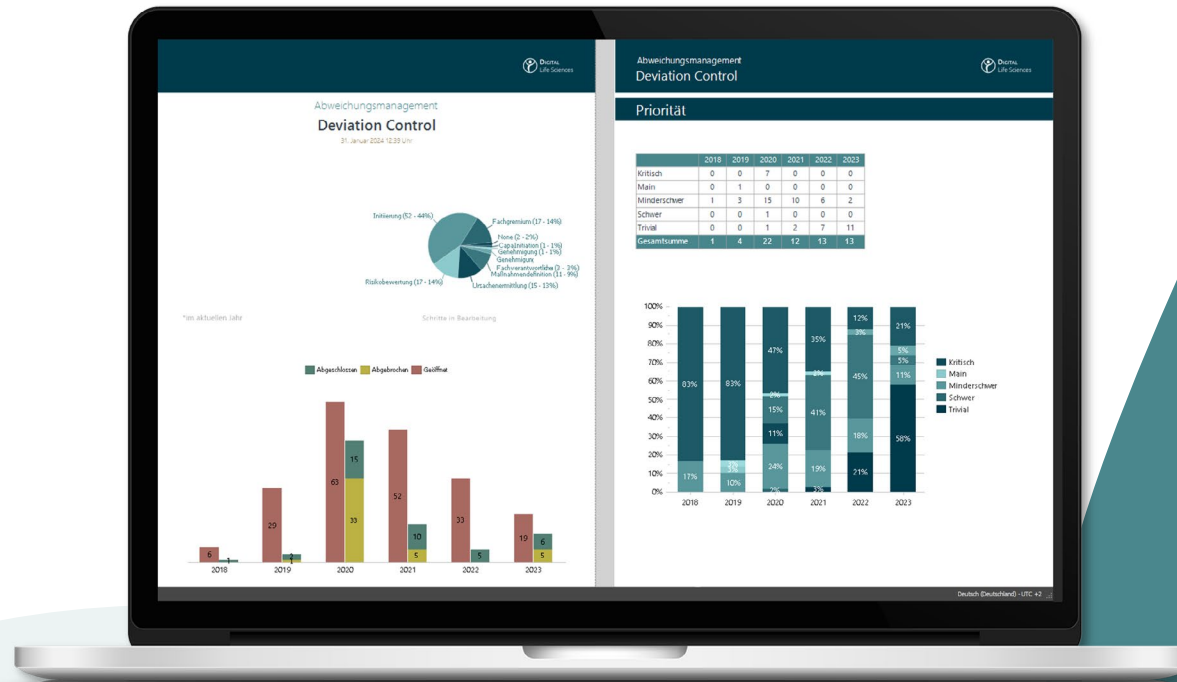
Initiator	Felix Hirsch (fhir)	Referenznummer	Audit-Bericht 23-06
Anlagedatum	30.06.2023	Koordinator	
Priorität	Mittel	Profil	Leiter Qualitätssicherung
		Benutzer	Felix Hirsch (fhir)

Initiierung - Details

Typ	Vorbeugemaßnahme - Preventive action
Auslöser	Audit
Titel	Risiko zur Kreuzkontamination an Abfülllinie A
Beschreibung	Während eines Behördenaudits wurde bemängelt, dass das Reinigungskonzept der Abfülllinie A unzureichend ist.
Betroffene Abteilung	Fertigung/Produktion/Herstellung

Reporting

In the dynamic world of quality management processes, it is crucial not only to maintain an overview, but also to be able to respond proactively to changes and challenges. Our standardised and integrated reports are designed to support your decision-making with accurate, timely, and meaningful data.



Your benefit

- Clear quality management metrics for immediate insights into your quality metrics
- Detailed QM reports that provide specific insights for every aspect of your QMS
- Time savings and cost efficiency thanks to automated analyses
- Assured decision quality through access to your precise real-time data
- Quality improvement through targeted identification and management of potential for improvement

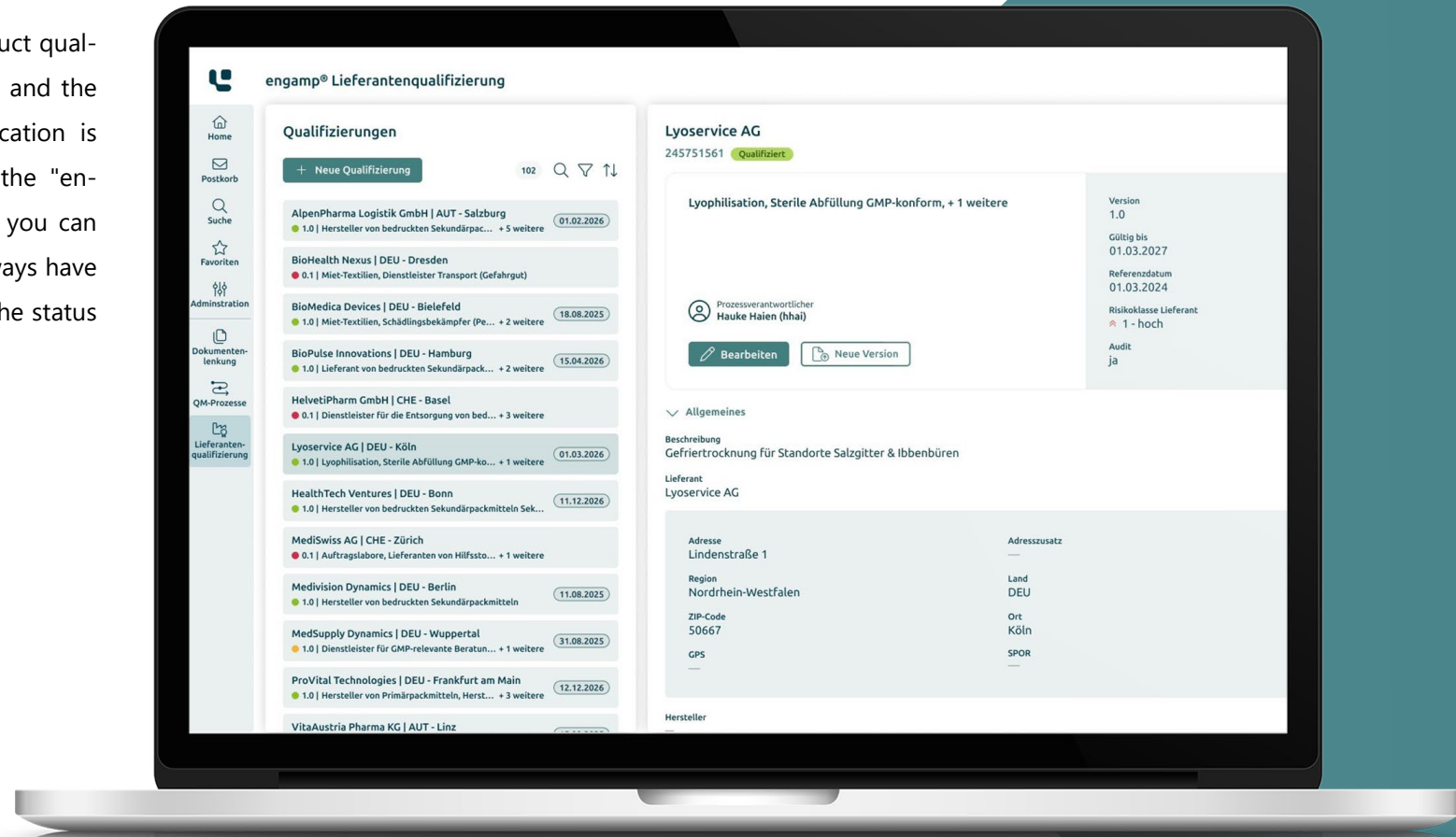
Integration

Our reporting module integrates seamlessly with all core functions of your eQMS to ensure a smooth flow of data and a consistent user experience.

Supplier Qualification

engamp® | supplier qualification

In order to limit negative effects on product quality caused by international supply chains and the outsourcing of services, supplier qualification is becoming increasingly important. With the "engamp® | supplier qualification" module, you can document the risk-based process and always have access to up-to-date information about the status of your suppliers.



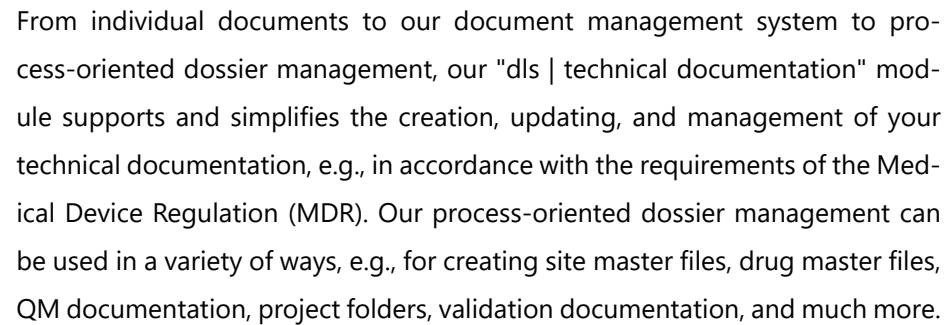
Your benefit

- 'Single point of truth' about the status of your suppliers
- Representation of the supply chain based on your material numbers with reference to your end products
- Specification of the required documents according to the risk classes of your suppliers
- Templates for questionnaires, audit reports, evaluations and much more.
- Document dossier per qualification
- Efficient planning and management of audits
- Monitoring the validity of certificates and qualifications

Regulatory requirements

- GMP guideline chapter 1 & 5
- MDR 2017/745 article 10(9) d
- ISO 13485:2016 7.4.1
- FDA 21 CFR 820.50
- AHMWHV §11
- ICH Q10 2.7

dls | technical documentation



dlb | Technical documentation - Elvira Network [Repository #0] - [Schreibgeschützt]

Start

Überprüfen

Bearbeitung

Status anzeigen

Dossier anzeigen

Geschichte anzeigen

Vollzeit Suche

Dossier Drucken

Exportieren als PDF Datei

Exportieren als XML Datei

Kommentar anzeigen

Neuer Kommentar

Dokumente Erstellen

Dokument zuordnen

Lösche die Anlagen

Aufgaben

Status

Anzeigen

Kapitelstruktur

- Erfolgung neuer Eigenschaften •
 - UCL (neuen angestrichelten) Erfolg
 - Nachführung und Nachbearbeitung
 - Vertrag übernahmungsprozess
 - Konformitätsüberprüfung
 - Berechnung der Punktzahlwerte
 - Schrittweise, Komponenten und nach:
 - Übersicht über alle Fähigkeiten (F)
 - Spezifischer Konstruktionsbau
 - Spezifizierung des Produktes (P)
 - Objekt, auszuführende Analyse
 - Identifikation der Schritte
 - Einführung zu besonderen Substanzen
 - Formale Erklärung zur Vermeidung
 - Formale Erklärung zum Vervielfachen
 - Formale Erklärung zu Bestandteilen
 - Fächer Generationen
 - Übersicht über das vom Hersteller
 - Übersicht über abgeleitete Modell
 - Kennzeichnung/Sicherheitsanweisung
 - Kennzeichnung im Datenblatt
 - Gebrauchsanweisung in allen Sprachen
 - Gebrauchsanweisung
 - Berechnung der Auslegung und Herstellung
 - Berechnung der Abmessungen
 - [SA-000001 RHA]
 - Anforderungen über den Lieferanten
 - Nachvollziehbare Beschreibung
 - Adresse oder Produktionsstätte
 - Angeben zu speziellen Prozessen
 - Angeben zu kontrollierten Bedingungen

Inhaltsselemente (4 von 4)

Zusammenfassung	Dossiersinhalt
IAA-000001_RNA	Dokument
H0000000007	Dokument
H0000000008	Dokument
M0000000086	Dokument

Lesebereich

cells with 9 Supplements

General information:
Endothelial cells from blood and lymphatic vessels or the internal cavities of the heart play a key role in many physiological and patho-physiological processes. Adhesion among the cells is enabled by desmosomes and tight junctions. A huge number of soluble factors circulating in the blood or released by neighbouring cells control proliferation or apoptosis of endothelial cells and the invasion of leucocytes to the endothelium. Evidence regulating the maintenance, degeneration, or regeneration of blood vessels.

Product Information:
Endopass 3 ready-to-use is a medium specially developed for the in vitro culture of human endothelial cells containing all components necessarily required for optimal growth. It is designed for use in an incubator at 37°C with a 5 % CO₂-atmosphere.
Endopass 3 kit is provided with FBS and supplements in separate sterile packaging. This will enable the user to prepare a medium for specific applications. For example FBS, VEGF, FGf-2 or other components may be omitted from the complete medium for specific experimental settings. Please note that such a formulation will not promote optimally cell growth.

Storage conditions:
Storage: Complete and basal medium: 2 – 8 °C in the dark;
Supplements: - 20 °C
Stability: Basal Medium: 12 months
Complete Medium: 3 months
Filling: 500 ml, other sizes on request

Composition
Endopass 3 kit contains the following single packaging:

- ECGF (human recombinant Epidermal Growth Factor)
- FGF-β (Basic Fibroblast Growth Factor)
- VEGF (Vascular Endothelial Growth Factor)
- Vitamin C (Ascorbic acid phosphate)
- IIG-IgG-1 (human recombinant Insulin-like Growth factor)
- FBS (Fetal Bovine Serum)
- Cx-A (Santenamin/Ampicillin)
- Hydrocortisone
- Heparin

Suitability
FOR RESEARCH USE ONLY!
Not approved for human or animal diagnostic or therapeutic procedures.

Aktuelles Dossier Technische Dokumentation nach MDR 2017/745 Anhang IV [H0000000009], S. L.O

Your benefit

- Manage templates for different structures of your dossiers
- Manage tasks for the editors of individual chapters of a dossier (work-flow)
- Seamless integration into our Document Control module
- Control of the current editing status of your dossier
- Versioning of your dossiers and easy access to all previous version statuses
- Create comments with different priorities
- Export of the entire dossier or selected parts of it to a PDF or ZIP file
- Print of the entire dossier or selected parts of it
- Integrated electronic and GxP-compliant signature as well as an audit trail feature
- Classification of files based on characteristics relevant to you

References

Excerpt

 MEDICE THE HEALTH FAMILY	 ARISTO	 Corden Pharma	 SCHOTT glass made of ideas	 Bionorica®	 ROTTENDORF PHARMA
 DR-WOLFF-GROUP	 ROMMELAG CMO	 solu pharm	 Nordmark Wir gestalten gesunde Zukunft.	 Dentsply Sirona	 amedes
 raumedic	 Eckert & Ziegler <i>wir helfen zu helfen.</i>	 Similasan	 HENNIG ARZNEIMITTEL Seit 1899 im Dienste der Gesundheit	 WELDING GROUP	 wiewelhove Auftragsherstellung fester Arzneiformen
 stratec	 SIDROGA PHARMA	 DMG	 Goerlich Pharma	 esparma PHARMA SERVICES	 Luvos® HEILERDE
 PFLÜGER	 BOLDER Your expert in pharmaceutical pastilles	 GfM	 formycon®	 AMANNGIRRBACH	 Pharma Bavaria International
 DROSSA PHARM	 neovii	 STÖCKERT medical solutions	 Alpinamed	 LICHTENHELDT	 METASYS
 Labor LS	 Dr. Loges Naturheilkunde neu entdecken	 BA-Unternehmensgruppe Gesundheitswesen Team Erfolg	 UNIVERSITÄTS- KINDERSPITAL ZÜRICH	 BAG HEALTH CARE	 Denk Pharma



Success Story
ChemCon GmbH

ChemCon saves up to 40% of working time on documentation with digital document management.



HENNIG ARZNEIMITTEL
Seit 1898 im Dienste der Gesundheit

Success Story
Hennig Arzneimittel

Family-owned company Hennig Arzneimittel successfully migrates its legacy system and now benefits from a modern eDMS/eQMS.

**To our
success stories:**



References

Excerpt



"We have been customers from the very beginning, and Digital Life Sciences provides us with reliable, long-term support with its products, helping us to further develop our QMS and map electronic solutions/workflows while taking data integrity requirements into account."

Silke Schwiertz, Head of QM/QA/QP - MEDICE Arzneimittel Pütter GmbH & Co. KG



"Digital Life Sciences GmbH supported us with professionalism and expertise in record time during the transition to a new electronic quality management system. In the process, six independent document management systems were transferred to a harmonized central d.3 eQMS. The support for the implementation of validation requirements for computerized systems according to GxP and ISO requirements is excellent."

Christine Strubel, Head of Management Systems Quality & EHS, SCHOTT AG





"A high level of consulting expertise and the partner-like performance characterize the successful collaboration. We therefore see Digital Life Sciences GmbH as a long-term partner of our company."

Silke Sobek, Group Manager ECS - Holopack Verpackungstechnik GmbH



"Prior to 2016, we did have an electronic document routing system in place, but it was all not as clean and performant as it should have been. For example, we missed a good overview of which employee is trained to what extent. That's what we have today thanks to Digital Life Sciences. This is important, for example, for an external audit. With the old system, we still had to do many things manually. With Digital Life Sciences' eQMS solution, quality and speed have taken a leap upward."

Yvonne Kraska, Head of QM - amedes Group



Digital Life Sciences GmbH offers innovative and practical solutions in the field of digital document management and quality management. With our comprehensive industry knowledge and many years of experience in regulated environments, we can provide you with targeted support for your digital transformation. In doing so, we ensure that your processes meet the latest compliance requirements and meet the highest quality standards at all times.



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