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Automation Of Documentation In Pharmaceutical Industry

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Abstract

Automation in documentation in the pharmaceutical sector revolutionizes the way organizations manage and maintain their records by leveraging advanced technologies such as Electronic documentation, Human-in-the-loop automation (HITL), Intelligent Document Processing (IDP), Windward core, SignDesk, Intelligent Document Automation (IDA), and recently developed Medical Document Automation and Fonto Integrated Authoring Platform (IAP) for pharma healthcare. This approach enhances efficiency, accuracy, and consistency in document creation, management, and retrieval processes. Through automatic document organization and updating, automation systems can minimize human mistake, speed repetitive procedures, and guarantee regulatory compliance. Additionally, these tools facilitate real-time collaboration and integration across various platforms, improving accessibility and information sharing. As a result, organizations experience significant time savings and cost reductions while enhancing their documentation's overall quality and reliability. The adoption of automation in documentation represents a strategic shift towards more agile and scalable operations, positioning companies to handle better increasing data volumes and complexity in the digital age.

Keywords : Automation, documentation, Electronic records

1. Introduction

1.1 Documentation

A document or record is any written, printed, magnetic, or electronic medium containing data or information about a product's manufacturing and production process. In the pharmaceutical industry, the document must be prepared, clearly readable, traceable, and provide sufficient information about the action and a precise historical record of the occurrence. Records and documents offer proof that the products are produced in compliance with previously established criteria and processes. (1)

The pharmaceutical industry uses the phrase "good documentation practice," or "GDP or GDocP," to describe how important it is for data reporting and collection to remain honest to support pharmaceutical product research, registration, commercialization, and lifecycle management. (2)

Following the GDP guarantees that mistakes won't be made in the manufacturing process or when analyzing pharmaceutical products, It might be adverse to the end product's quality, patient safety, the infrastructure of the production process, and associated activities.

Regulations enforced by the CFR (Code of Federal Regulations) of the FDA and the (European Medicines Agency) EMA mandate compliance with GDPs. Apart from the main chapter published by the United States Pharmacopoeia (USP)(3), Specific guidelines about GDPs have been issued by the World Health Organization (WHO), Health Canada (4), and EudraLex (the collection of laws and regulations governing pharmaceutical products in the European Union) (5). However, GDP plays a significant role in the US's current Good Manufacturing Practices (cGMPs) (6). Apart from adhering to regulatory requirements, keeping precise records and documentation of pharmaceutical industry operations for commercial purposes is crucial. This facilitates a critical assessment of internal protocols, enabling enhancements to both products and processes and reduces time spent on redoing studies, when necessary, instead of commencing from start to finish.

The WHO states that the goal of good documentation practices (1) is as follows.

To specify the requirements or protocols for every material with manufacturing and control process
To guarantee that every employee is aware of what has to be done when
•To guarantee that data are available for validation, appraisal, and statistical analysis
•To assure the existence of documented evidence, traceability, and to provide records of an audit trail for investigation
To make sure that authorized persons have all the information required for the release of a product.

Figure 1.1 Goals of good documentation practices

1.2 Automation

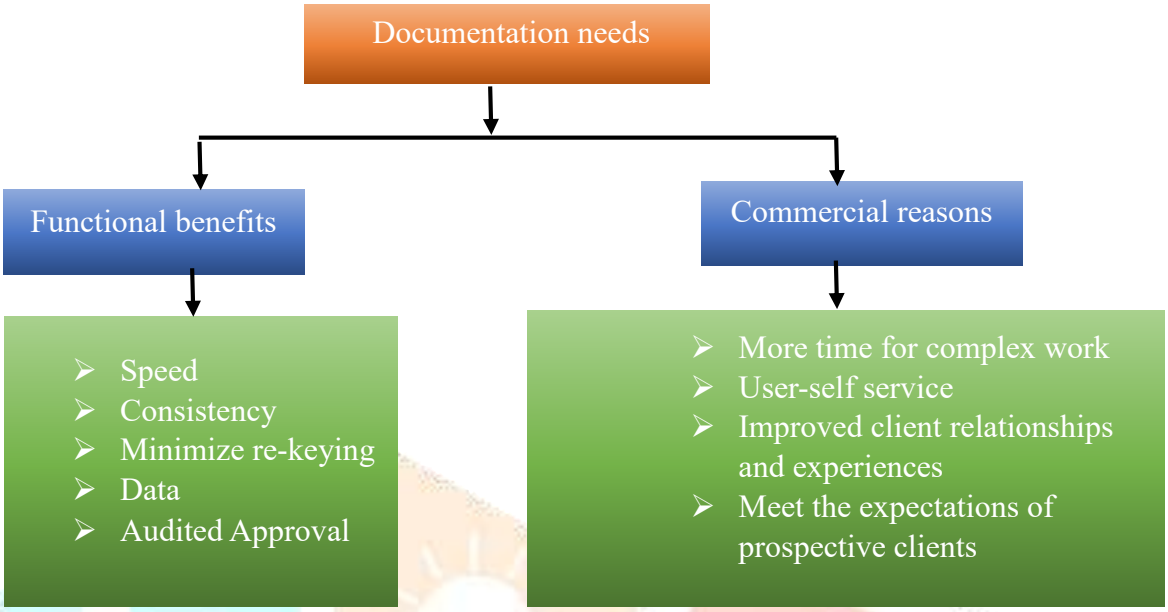
In the pharmaceutical sector, automation refers to the employment of machines to perform the majority of significant and repetitive work. The development of pharmaceutical companies has been accelerating, and the pharmaceutical sector is no exception. Regulations are becoming more stringent than they formerly were (7). Industrial management can comply with the constantly evolving regulatory requirements with the help of automated processes. For a considerable amount of time now, industries all around the world have been replacing human labour with modern technologies. (8)

There is increase in the use of computer vision systems for quality assurance recently. Consequently, these systems may eventually take the position of human inspectors. Numerous notable advancements have resulted from the advancements in computer hardware and software technology. (9) More flexibility and repeatability at comparatively low costs are made possible by this technology, which allows for higher plant throughput without sacrificing product quality. These systems are currently being developed as an essential component of pharmaceutical processing plants for online and real-time quality evaluation. (10)

1.3 Need for document automation.

Automation ensures that documents are produced flawlessly every time, and it also enables people to work more quickly.

The benefits of document automation fall into two primary categories: functional and commercial.



1.3.1 Functional benefits

The following is a summary of some of the functional advantages that automation offers:

I. **Speed.** It's the reason that most people initially consider automating document processing. The drafting of one or many documents at once is sped up by automation:
   a. The provisions that may or may not need to be included are pre-curated for you, making it quicker to create a single document using an automated template.
   b. Because document automation technologies may generate big batches of comparable papers, authoring several documents using them is faster when employing them. For large transactions, several technologies can even generate many document formats in bulk at the same time.

II. **Consistency.** You can limit user edits in document automation to predefined fields (which may also include validation). Documents created using a computer have fewer errors than those written by hand.

III. **Minimise re-keying**. The data from other sources, such as term sheets, Excel files, or other software, is used to fill out the majority of commercial documents. Such data can be automatically imported from another location into a well-structured automated document. Better productivity, fewer errors, and less double-entry of data are all benefits of automated data importation.

IV. **Data**. You may maintain the structure and orderliness of your documents with their commercial characteristics by using document automation.

V. **Audited approvals**. You can set up your automated papers to expedite and integrate your internal approval procedures. Documents that are safe, compliant, and auditable are made possible by automation.

The main functional advantages are time savings and safe, auditable document generation.

Here are some more commercial reasons for document automation:

I. **More time for complex work**. Teams that have more time can focus more on challenging and important projects. Employees who do more high-impact tasks are better equipped to benefit clients. The company's efficiency will rise, and personnel won't be forced to perform the more tedious tasks.

II. **User self-service**. Business users may swiftly, securely, and auditably put together automated documents on their own. Legal intervention should only be used in cases when drafts deviate from the original. Self-service reduces internal back and forth, speeds up contract negotiations, and eases the strain of legal representation!

III. **Improved client relationships and experiences**. It can be challenging to find a balance between accurately and swiftly doing work for clients, whether you are copying and pasting text or manually creating papers from scratch. Automation offers a highly economical way to produce high-quality documents quickly.

IV. **Meet the expectations of prospective clients**. Document automation software and legal technology have advanced significantly in the last few years. Thanks to technological advancements, a lot of customers are starting to demand a seamless user experience. Providing them with an intuitive online platform to create their documents will guarantee their return visits. (12)

1.4 Scope and role of automation in documentation

1.4.1 Handling and Interpretation of Digital Data

Each component of data in the automated world is digital. Thus, employees should be adequately trained to handle and comprehend them. Information interpretation is the process of evaluating data and coming to a well-informed decision. It is evident how important interpretation is, which is why it must be done correctly. (13)

1.4.2 Innovative Thinking to Design Better Automated Systems

The staff must possess the skills and preparation needed to create automated systems that are hassle-free and effective. The QA team has enough knowledge about the primary characteristics of quality to be able to install the necessary devices to monitor them. Additionally, having sufficient process expertise can aid in designing the equipment in a way that ensures trouble-free manufacturing processes. (14)

1.4.3 Develop Computer Handling Skills

The staff members need to be sufficiently knowledgeable about using computer software to handle data and keep an eye on automated processes. (15) Employees in the pharma industry need to receive sufficient training to adapt to the changing nature of the workplace. ProcessPro, Batchmaster, Response

Pro, Ceecom Manufacturing, and more programs are used. Since this software handles the majority of complex functions, QA staff will be more equipped to deal with automated systems if they possess the necessary knowledge to manage them. (16)

1.4.4 Confidentiality

As more data becomes digitized, concerns about data confidentiality are bound to surface. Because the automated systems adhere to the most recent regulatory standards, the data is stored in a way that makes it only possible to move them with the necessary authorization. The relevant staff has received extensive training to ensure that they don't take any activities that might cause a server data breach. As a result, questions about data confidentiality after automated technologies are implemented might be postponed. (13)

1.4.5 Data Integrity

Similar to data confidentiality concerns, questions regarding data integrity might also arise. Automated technology compliance with 21 CFR PART 11 is the manufacturers' responsibility. It highlights the necessity for electronically storing data in the pharmaceutical industry. It is one of the auditors' top concerns when conducting quality audits. The access to change the information in the industry should be restricted. Using CFR-compliant technology would not present a difficulty with data integrity; instead, it would be up to the QA administration to ensure that only authorized persons have access to the data. The QA staff who were involved in the same had to be trained in CFR 21 part 11. This will ensure that in a completely automated plant, there is no chance of data integrity. The need for all the paperwork in the sector will be rendered obsolete because the majority of the newest technologies use digital data collection. The QA department will have to be trained to use digital data collection systems. (15) Automation in and of itself might not have a significant impact on the roles that QA personnel play in the pharmaceutical industry, but there's a good chance that demand for human QA personnel will decline as technologies advance and new industrial revolutions emerge. (17)

2. Electronic documentation in the pharmaceutical sector

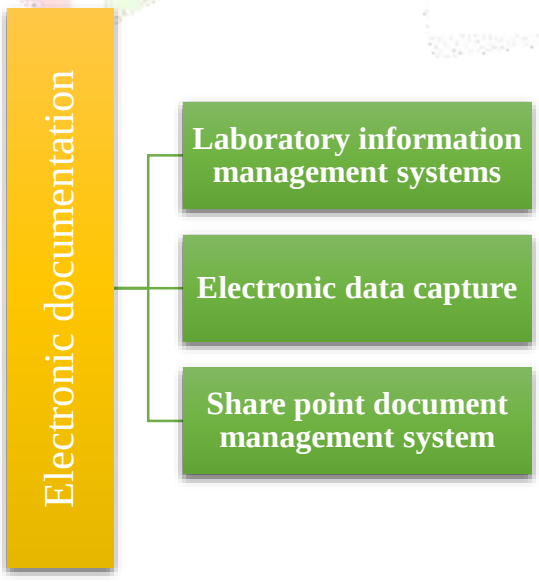


Figure 2.1 Electronic documentation

Because of the development of information technology over the past few decades, the term "document" has undergone significant modification. This comes from a change in perspective from paper-based to electronic document production, which has significant effects on the creation and management of construction documentation.

The primary goal of electronic document management systems (EDMS) is to make it easier for workgroups, projects, and pharmaceutical businesses to handle the papers they need over computer networks. Whether papers are in hard copy or electronic format, EDMSs provide a certain amount of control over the flow of information throughout the construction process. (18)

2.1 Laboratory information management systems (LIMS)

It is a software-based system offering several crucial features to help quality control laboratories run efficiently. There are various key components of LIMS such as assay data management, Workflow, data tracking, data mining, etc. Even though LIMS has been sold commercially for 20 years, numerous modifications have been made to meet modern demands. Laboratory sample data is saved in LIMS, although the specific data that is kept varies greatly throughout user organizations. Certain labs only keep records of the analysis's outcomes. Some make use of the full LIMS, in which every instrument is linked, and All information is sent electronically from the LIMS to the instrument. Various companies have varying functional requirements.

- To ensure that sample findings are within requirements, a production plant's QC laboratory must incorporate specifications.
- Pharmacokinetic testing and stability test results may be required in a pharmaceutical R&D laboratory. (19)

2.2 Electronic data capture (EDC)

It is a computer-based system used to collect e-clinical data. The paper-based data collection has been replaced with EDC. It speeds up the procedure of commercializing medications and medical equipment and simplifies data collection. Clinical research organizations and pharmaceutical corporations are continuously implementing EDC to gather clinical trial data. It is used to gather and organize data during every stage of clinical trials. (20)

2.3 Sharepoint document management system

Microsoft created the web-based application back in 2001. In addition to its many uses, SharePoint offers special features, including system integration, process integration, and workflow automation capabilities. The pharmaceutical industry spends a lot of revenue on content management and documentation, and they are now interested in the possibilities presented by SharePoint systems. One can establish document libraries with the SharePoint document management system, which allows one to store and distribute a range of files. Using their login credentials, team members can access these files, and authorized users can check out and change the files. (21)

3. Techniques of Automation

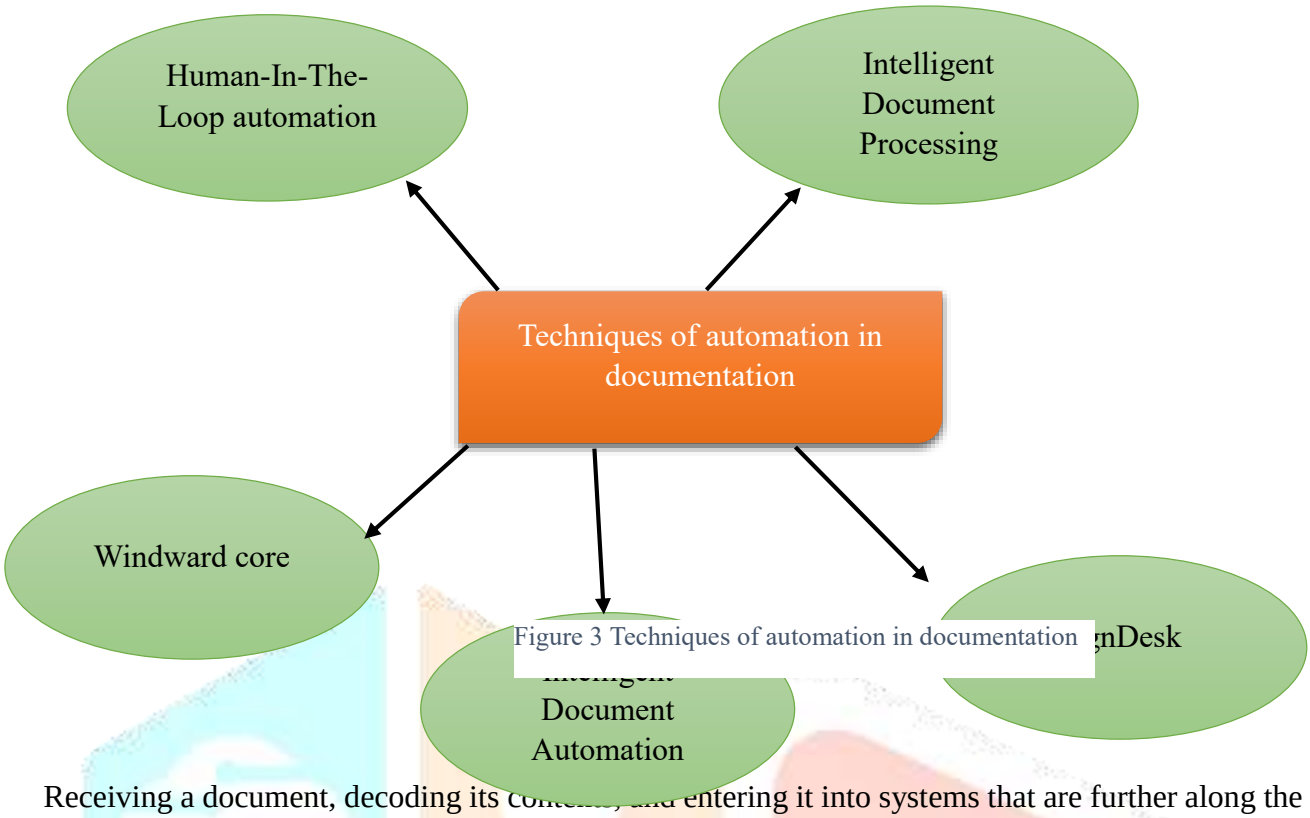


Figure 3 Techniques of automation in documentation

Receiving a document, decoding its content, and entering it into systems that are further along the line is known as document processing. Most business operations require document processing, but it's especially important for the accounts payable, sales, and procurement procedures. Order confirmations, quotations, customer orders, shipment notifications, bills, and other B2B paperwork must all be processed. Manual document and data processing are labour-intensive, time-consuming, labour-intensive, and prone to mistakes and inaccuracies. Automation technologies have helped to streamline company procedures and increase operational efficiency in document processing. The data in these documents is processed automatically by automated document processing, which replaces manual processing with automation software.

3.1 human-in-the-loop automation

One application where human-in-the-loop automation comes in handy is automated document processing. Data extraction, document classification, information interpretation, data comparison, tolerance definition, and handling of exceptions or deviations are some of the responsibilities involved in automatically processing documents. Critical thinking, interpretive abilities, and judgment are needed for each of those jobs. This is the application of HITL. Automated document processing benefits greatly from HITL automation. It successfully handles the requirements and difficulties of document processing by combining human and machine abilities. HITL is a crucial component for improving automated systems in document automation because humans can handle the complexity of documents and respond to unanticipated changes.

An automated solution for human intervention in document flow management, the Netfira Platform streamlines document flows in the Purchase-to-Pay (P2P) and Order-to-Cash (O2C) processes. Using the human-in-the-loop method, this AI-driven automation solution proficiently manages exceptions and

edge cases in automated document processing. Human engagement goes beyond simple interaction; it serves as the basis for AI's ability to learn and develop over time, guaranteeing the highest level of efficiency in document processing systems. (22)

3.2 Intelligent Document Processing

Intelligent Document Processing (IDP) uses cutting-edge technology to automate and digitize unstructured data from business-to-business (B2B) documents. IDP mimics human abilities in document identification, contextualization, and processing since it integrates artificial intelligence (AI), machine learning (ML), and natural language processing. AI, ML, and human-in-the-loop automation are the three main tools used by IDP to transform unstructured data into structured and useful data. Intelligent document processing elevates automation by using orchestration, which combines several automated processes into a streamlined workflow.

IDP's applications are revolutionizing the workplace by streamlining regulatory compliance and enhancing drug research. They also make work more efficient and data-driven.

3.2.1 Use cases of IDP

- Drug Development Optimization

  Researchers can gather and manage data from various sources, such as clinical trial reports and scholarly papers, with the aid of intelligent document processing. IDP expedites the process of identifying possible drug candidates by automating data extraction, which improves efficiency and saves time in the drug development process.

- Regulatory Compliance Assistance

  Pharmaceuticals are subject to stringent rules. Large numbers of legal and regulatory documents can be processed with the help of intelligent document processing, which guarantees that all necessary data is correct and current. This aids businesses in adhering to legal requirements.

- Adverse Event Monitoring

  Data may be quickly extracted and analyzed from adverse event reports that patients and medical personnel have provided using intelligent document processing. Pharmaceutical businesses can ensure patient safety by taking prompt necessary action in response to early detection of potential safety risks.

- Pharmacovigilance Automation

  Monitoring the safety of drug formulation on the market is known as pharmacovigilance. Businesses can more easily detect and address any new risks related to pharmaceuticals by automating the analysis of safety-related data with IDP.

- Clinical Trial Data Management

  Conducting clinical studies produces enormous amounts of data. IDP facilitates the effective management and organization of this data, making it possible for researchers to access and analyze it with ease, producing more accurate and trustworthy trial results.

- Invoice and Payment Processing

  Pharmaceutical companies handle a large volume of partner and supplier invoices and payments. By removing data from invoices and enabling smooth payment processing, IDP expedites this procedure while lowering errors and saving time.

- Patient Data Extraction

  Healthcare providers can retrieve vital information from patient medical data, including diagnosis, medications, and treatment plans, with the aid of intelligent document processing. This improves patient care accuracy and empowers physicians to make well-informed choices.

- Drug Labeling and Packaging

  For the protection of patients, medications must be accurately labelled and packaged. By helping to double-check and validate information on medication labels, IDP lowers the possibility of mistakes occurring during distribution and packaging.

- Supply Chain Management

  Pharmacies and manufacturers must track different parts of pharmaceutical supply chains. Tracking and monitoring inventory levels is made easier with intelligent document processing, which guarantees a seamless transfer of medications from manufacturing to final consumers.

- Contract Management

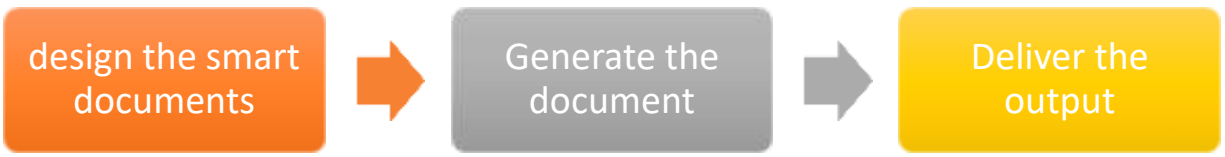
  Contract management can be difficult when dealing with distributors, suppliers, and partners. By automating the processing of contract data, IDP facilitates more efficient business connections by streamlining the review and negotiation process. (23)

3.3 Windward core

For a fully customized document creation solution, ISVs, Enterprises, and System Integrators can integrate document generation into the current application. Business users will gladly take over template design with such robust and user-friendly document features.

Windward does not require programming for each template, in contrast to the majority of competitors. Versions of the engine are available for Java, .NET, and RESTful (any programming language). One can upload their DOCX, XLSX, or PPTX template and get started as soon as Windward Core is integrated into your application. This software generates documents without the need for additional requirements. Users will save a tonne of time because they won't need to add code, test it, stage it, or release it.

3.3.1 Steps involved in Windward core



Design the Smart Documents

- Use all of Microsoft Office's formatting and layout tools to create templates in Word, Excel, or PowerPoint.
- Assemble one or more data sources into your XLSX, PPTX, or DOCX template.
- Create a clever document with the finest Word document generator by using tags and conditional logic to alter content in-line.

Generate the Document

- Give the engine the template, data source (s), and output destination.
- Watch how Windward creates the desired document by combining data with a template.

Deliver the Output

- Produce the report or document in several output formats, including DOCX, XLSX, PPTX, PDF, HTML, and many more.
- Share the document that was created using the application. (24)

3.4 SignDesk

SignDesk provides end-to-end document automation solutions for the healthcare and pharmaceutical sectors, including low-code workflow automation platforms, digital onboarding powered by AI, instant digital stamping, secure electronic signatures, and smart contract lifecycle management.

Healthcare organizations can use these digital document automation technologies to increase productivity and streamline processes.

3.4.1 Streamline operations of SignDesk.

- **Electronic Signature and Digital Stamping:**

  Healthcare workers may now digitally stamp and sign papers, doing away with the need for laborious paper-based workflows, thanks to e-stamping and e-signature systems.

  Document validation can be done securely and effectively while adhering to regulatory requirements with the help of e-signature and e-stamping systems. These automated healthcare document solutions improve accuracy and speed up the processing of agreements.

  With e-stamps, healthcare organizations can speed up the execution of agreements, and new hires, partners, and vendors can sign agreements from a distance.

- **Digital Onboarding:**

  They let healthcare organizations get vital information and documentation from people electronically.

  To guarantee the accuracy and integrity of provided documents and information, these systems incorporate strong identity verification and authentication procedures. Onboarding procedures can be effectively completed online by patients, physicians, healthcare workers, and vendors, allowing hospitals to streamline their onboarding processes and increase operational effectiveness.

  Healthcare digital KYC solutions use cutting-edge technologies like biometrics and artificial intelligence to swiftly and precisely verify identities and authenticate credentials. Medical institutions can improve data security and reduce fraud risks by digitizing the onboarding process.

- **Document Workflow Automation:**

  Healthcare organizations can easily digitize and automate repetitive procedures and processes with the help of workflow automation technologies. These platforms provide document management and onboarding processes that can be created to meet requirements.Healthcare companies can manage their operations more efficiently with the use of document automation solutions, which include centralized storage, personalized alerts for signatures, centralized document droughting, and a complete dashboard.Healthcare companies can process documents quickly and efficiently by using workflow automation, which cuts down processing time considerably when compared to manual methods.These solutions automate repetitive administrative processes and streamline departmental workflows to improve operational efficiency, minimize manual errors, and allocate resources optimally. (25)

3.5 Intelligent Document Automation

Intelligent Document Automation (IDA), a service provided by Salesforce in collaboration with AWS, streamlines document operations and increases operational effectiveness. We will look at how IDA can help Pharma in this piece, as well as how Health Cloud users can gain from it. Three use scenarios are presented to highlight the advantages of intelligent document automation:

Use Case1: Streamlining Prior Authorization: Reducing Delays and Improving Patient Care

Prior authorization is one of the biggest obstacles in the pharmaceutical industry. Complex paperwork, liaising with insurance companies, and delays that affect patient treatment are frequently involved. There is a game-changing option available with Intelligent Document Automation (IDA) to expedite the prior authorization procedure, cutting down on delays and enhancing patient outcomes.

Pharma can effectively handle the prior authorization paperwork with the help of IDA's document processing features. IDA reduces errors and saves time by automating the intake and processing of prior authorization forms. Thus, there's no need for manual data entry anymore.

IDA accelerates the review and approval process by automatically pulling data from prior authorization forms, including patient information, prescribed drugs, and pertinent clinical facts. The retrieved data may be easily incorporated into Health Cloud and other platforms, giving insurance companies and healthcare providers access to real-time insights.

Use Case 2: Accelerating Clinical Trial Processes

Clinical trials frequently entail intricate protocols and copious documentation. Clinical trial procedures can be greatly streamlined using intelligent document automation, allowing for quicker and more effective implementation.

Pharma businesses can develop organized document templates for different stages of the clinical trial process with IDA's Document Workspace and Document Checklists. Clinical trial-related paperwork can be found in these templates. The automated features of IDA make it possible for smooth document collaboration, guaranteeing that all parties involved have access to the most recent versions of the documents and enabling real-time revisions.

Use Case 3: Enhancing Pharmacovigilance and Adverse Event Management

Pharmaceutical operations are not complete without pharmacovigilance and adverse event management, which guarantee the safety of pharmaceuticals on the market. Nevertheless, these procedures entail managing a substantial amount of safety alerts, adverse event reports, and associated paperwork. Pharmacovigilance procedures can be substantially improved by intelligent document automation, which will increase productivity and patient safety.

Adverse event reports and safety alerts can be automatically routed to certain queues using IDA's intelligent routing features, guaranteeing timely attention and cutting down on response times. IDA may extract vital information from these documents, such as patient data, medication details, and descriptions of adverse events, by integrating Intelligent Document Reader. Pharmacovigilance systems can easily incorporate this data, allowing for quicker analysis and potential safety issue identification.

The incorporation of Health Cloud and additional systems guarantees that pertinent parties obtain precise and current data, promoting cooperation and expediting the process of making decisions. (26)

4. Recent developments in document automation

A. Medical Document Automation

Every one of these approaches to automating healthcare documentation is essential for bringing healthcare procedures up to date, enhancing patient care, cutting down on errors, and guaranteeing regulatory compliance. The particular requirements and objectives of every healthcare organization determine the choice of automation tools and techniques:

i. **Electronic Health Record (EHR) Systems:**

Personalized EHR system development provides all-inclusive options that include billing data, medical history, and patient records on one platform. With the help of these systems, all patient-related data may be centrally stored for simple access and effective administration.

ii. **Document Management Software:**

Features like automated workflows, searchability, and document classification are available with specialized document management software. It makes it easy for healthcare organizations to arrange, safeguard, and access medical records.

iii. **Data Extraction Tools:**

Data extraction technologies take useful information out of medical records using machine learning techniques and optical character recognition (OCR). This technique reduces the amount of labour required for manual data input by automating the process of gathering data from paper-based documents.

iv. **Workflow Automation Platforms:**

Custom workflows for document management can be created by healthcare organizations using workflow automation technologies. These systems make it possible to automate time-consuming processes, including notifications, approvals, and document routing.

v. **Automated Coding and Billing:**

By using patient information as a basis for categorizing diagnoses and treatments, automated systems can minimize coding errors and guarantee accurate billing. Financial management and healthcare reimbursement depend on this. Do not hesitate to get in touch with our knowledgeable team if you need more advice on the integration and bespoke creation of healthcare billing systems.

vi. **Health Information Exchange (HIE):**

HIE systems provide secure patient data interchange across different healthcare organizations and providers. It ensures that vital patient data is available when needed.

vii. **Intelligent Document Processing (IDP):**

IDP processes and extracts data from medical papers using automation and artificial intelligence. It can classify documents, pull out pertinent data, and direct them to the right systems.

viii. **Secure Cloud Storage:**

Documentation and medical records can be securely stored with cloud-based medical automation technologies. Cloud platforms provide disaster recovery, scalability, and accessibility features.

A.1 Putting Medical Document Automation into Practice

Create the document templates and mobile/web forms:

- Design user-friendly web and mobile form interfaces to help healthcare personnel enter data more effectively.
- Optimise templates to minimize error and human labour while streamlining data entry and document generation.
- Make sure templates and forms are responsive on all devices to improve usability and accessibility.

Migrate from Excel to a Database Solution:

- Assess the linkages and data structure currently in place.
- Select a suitable database system.
- Create a plan for data migration and carry out a test migration.
- Carefully plan the data migration procedure to avoid mistakes.
- Before migrating, conduct an audit and purge the data from medical documents.
- Put in place backup and validation processes for operational and medical data.
- If moving medical data to the cloud is involved, take extra safety measures.
- Make sure data integrity is maintained and execute the migration during a time of low activity.

Staff Training:

- Offer training on data extraction tools, document management software, and electronic health record systems.
- Provide continuing instruction and update support.

Integration with Existing Systems:

- Assure smooth EMR integration, giving patient data synchronization top priority.

- Check that the new database solution and the current systems are compatible and that the data is consistent.
- To enable real-time data interchange, put data-sharing protocols and APIs into practice.
- Carry out extensive testing to verify accurate data synchronization and transmission throughout every integrated system.

Change Management:

- By implementing it into practice will significantly alter how healthcare organizations operate.
- To guarantee a seamless transition, take into account human factors in all changes and communicate the advantages while resolving concerns.

Compliance Assessment:

- Carry out a thorough evaluation in compliance with legal requirements, taking data retention and disposal rules into account. (27)

B. Fonto Integrated Authoring Platform

The Fonto Integrated Authoring Platform (IAP) has been released by RWS, a singular and globally recognized provider of technology-enabled language, content, and intellectual property solutions. This ground-breaking solution is intended to revolutionize the pharmaceutical industry's document creation and publishing process.

With Fonto, creating, revising, and evaluating important business documents—such as medication applications and regulatory submissions—becomes a simple, effective procedure instead of a difficult, time-consuming one. Because of its intuitive UI, which is akin to Microsoft Word, specialists may work together centrally to produce documents more quickly and with higher quality.

Working document creation is automatically created by Fonto IAP through its smooth integration with external data sources. By using templates and standardization, it also guarantees content uniformity and makes sure all documents adhere to legal standards. (28)

B.1 Steps in document creation

The platform offers a three-step procedure for creating documents: designing the template, creating the document, and creating the output. Content componentization is made possible by it, guaranteeing content integrity and regulatory compliance while permitting component reuse. It greatly minimizes the possibility of mistakes and inconsistencies by lowering the requirement for human editing.

- **Template Design**:

  Unlike conventional word processor templates, this procedure begins with a template. It is intended to add or remove information according to preset criteria automatically. This template, which includes logic for content instantiation, serves as the starting point for all documents.

- **Document Instantiation**:

  To make the document context-specific, this phase entails adding specific data and information. Variables and conditional material are automatically included, guaranteeing that the document is pre-structured with pertinent data for a certain product or market without the need for human interaction.

- **Output Creation**:

  Formatting and getting the document ready for distribution constitute the last step. The technology handles formatting features like table layout and page breaks automatically, saving the user from having to make adjustments manually. This automation guarantees that the document satisfies external authorities' submission requirements and is prepared for internal use as well.

  The purpose of these processes is to increase document creation efficiency, decrease manual errors, and streamline the authoring process. This eventually accelerates time-to-market. (29)

5. Conclusion

The integration of automation in documentation review processes offers significant benefits, including enhanced efficiency, accuracy, and consistency. By leveraging advanced technologies, organizations can streamline the review process, lowering the time and work involved in manual reviews. It accelerates the turnaround period for documentation and minimizes human errors, ensuring higher quality and compliance with standards.

As tedious and repetitive duties can be handled by automation systems, human reviewers can concentrate on the documentation's more complex and important features. Furthermore, by using data analytics, automated systems can offer insightful information that helps businesses spot trends and areas in need of improvement.

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