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Original Article

Sales of Medical Devices – SAP Supply Chain

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Abstract *- Medical devices sale are controlled by different authorities (FDA, EU-MDR, NMPA, CDSCO) worldwide, and every country has different rules to control it. These rules are very stringent. If not followed as stated, there are hefty fines and loss of business, which may damage the company's image in that country. Thus, the sales of medical devices must be managed using an automated solution. SAP is the best product for providing an integrated solution to control the medical device supply chain.*

Keywords *- Medical Devices, Supply Chain, IT, Product Registration, Business License, Sales Order, Delivery, SAP, ECC, GTS.*

1. Introduction

The sales of medical devices ought to be controlled using an automated solution combined with stringent process control to ensure medical devices are sold to approved countries. SAP is the best product for effectively providing an integrated business solution to run this complex supply chain process.

2. Business Process & System Design

Before building the SAP solution design, we must clearly define the business process for checking the medical device license and all systems involved in seamless integration.

2.1. Define Process

Plan a detailed discussion with all relevant business groups (Sales, Marketing, Supply Chain, Regulatory) to finalize the process and steps for the medical device check. Collaborate and decide on all processes before designing the system. Drive your decision based on strategy; business requirements aren't driven by system design. Document all the steps requested by the business for validating a medical device license. Is it going to be at the creation and approval of the quotation, sales order, or stock transfer order? Also, decide at the time of shipment validation what will happen during delivery, creation, picking, packing, and shipping.

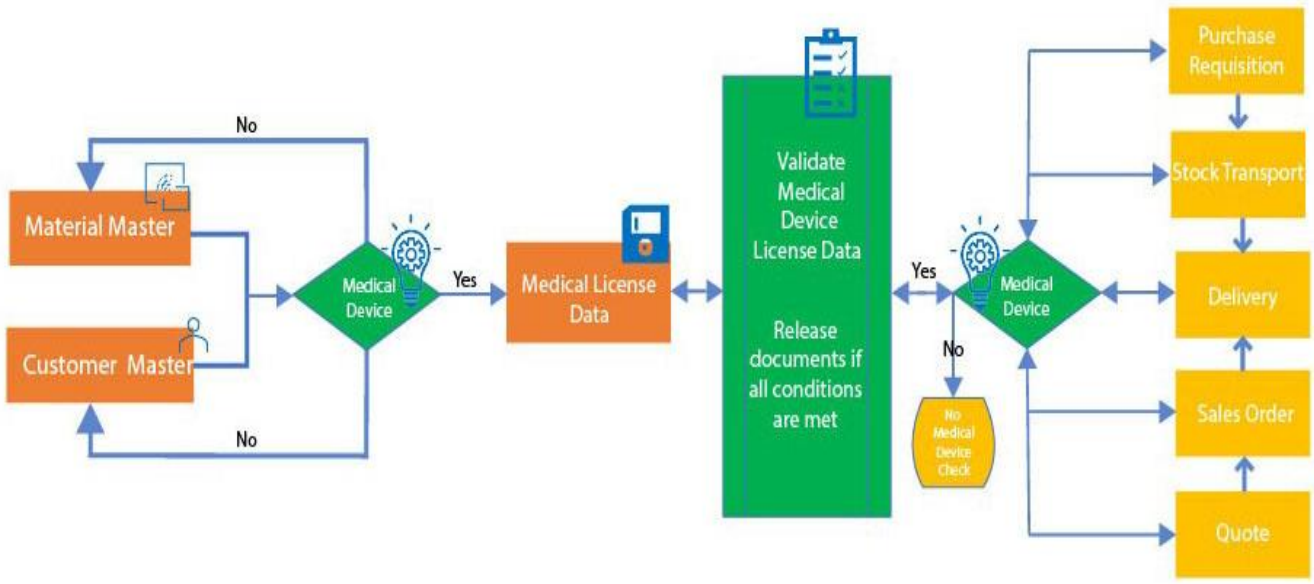
2.2. Define Systems

Identifying all the systems required for controlling the overall medical device supply chain is vital. Every organization differs and may use other systems for quotation, sales orders, STO, and delivery. Identifying all systems will help you design the overall architecture and process to control medical device sales. The following is one method to document it.

Process/Data	System
Material Master	SAP ECC SAP PLM
Customer Master	SAP ECC
Quotation	SAP-ECC, Webstore
Sales Order	SAP-ECC, Webstore
STO & Purchase Req	SAP-ECC
Delivery	SAP-ECC
Product Registration	SAP GTS
Business License	SAP GTS
Valida**tion** of all transactions	SAP GTS

2.3. Other Key Considerations

- Design high-level integration and trigger points for all systems.
- Implement a standard out-of-box function for the project's first phase.
- Understand the as-is process, and design a scalable and innovative to-be process. Don't just solve the current issue. Don't try to map existing operations in the new system. Design to ensure the new solution is future-ready.
- Implement standard controls and security models using risk-based prioritization.
- Create a process flow, and clearly define the point of control where you validate the medical device check. It helps explain the process clearly to the business and avoid gaps.



2.4. System Architecture

Ensure all integration points are designed in concert with the business process and systems. Develop this integration by considering different source systems (SAP-ECC, SAP-GTS, website, Salesforce, Oracle, etc.) for master data (material master, customer master, vendor master) and transactional data (quote, sales order, delivery). Define these systems' exact connection methods (EDI, IDOC, RFC, etc.). SAP-ECC is used as the material master, customer master, sales order, and delivery source in this example.

Medical device license data (product registration and business license) is maintained and managed in SAP-GTS and used for validating all transactional data.

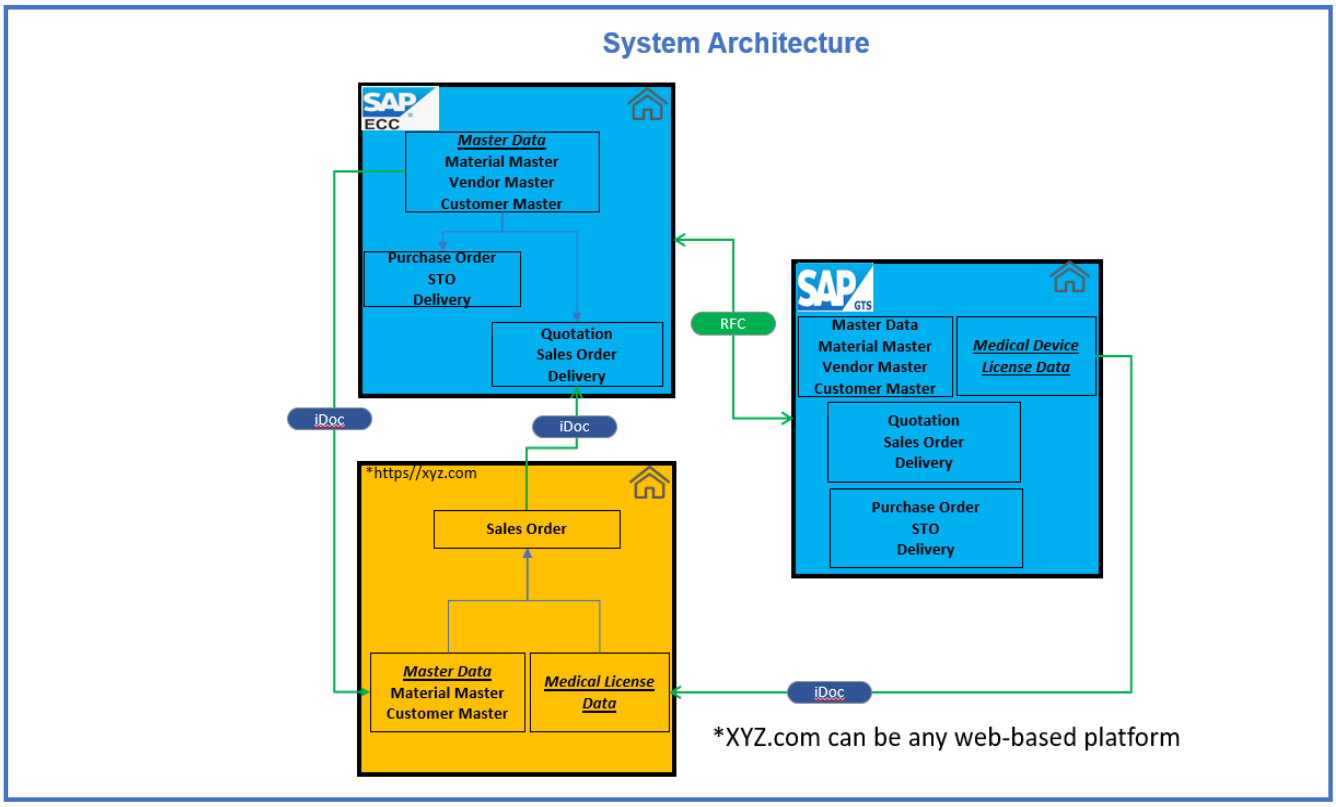
Seamless integration between SAP-ECC and SAP-GTS is designed by SAP. All data relevant to license checks are replicated from SAP-ECC to SAP-GTS using the default interface design. Using different configuration steps and ABAP coding, this interface can be further enhanced based on business requirements. Try to create one source of truth. If using other systems for creating the quote, sale order, and delivery, use data from the source system, so you will not create redundancy and always validate your transactional data using the latest and greatest information maintained in the source system. In this example, SAP-GTS will be the single source to maintain the medical device license data and validate from other systems like SAP-ECC and XYX.com. In the below system architecture, you can see SAP-ECC acts as the source for Material Master, Customer Master, and Vendor Master, as well as feeding this data to SAP-GTS and XYZ.com using RFC and IDOC, respectively; SAP-GTS is the source of the medical device license data.

3. Decide Migration Strategy and Scope

Data migration is the most prominent challenge organizations face because regulatory data is very tricky and may have different meanings for different authorities (the FDA, EU-MDR, NMPA, CDSCO, etc.). Considering the data's complexity, the data must be collected and reviewed by the regulatory team to avoid any gaps and incorrect interceptions of the data. Clearly defining the data collection methodology and review process is key. The following are a few steps that can be taken to define it.

- Data collection format
- Data load checklist
- Peer Review of Data
- Automate Rule to validate load files
- Data verification after loading in the system

Always initiate the data collection process immediately after the high-level design, which will help you gather the raw data. You can easily convert raw data into a system-consumable format. The following is a sample of the data collection format.



Product	External License Number	Valid from	Valid to	Lic. Type	Leg. Reg	Country	License status
ABC-001	REG_US_22	20220726	20290701	MDL	MDPR	US	Active
ABC-002	REG_US_23	20220726	20290701	MDL	MDPR	US	Active
ABC-003	REG_US_24	20220726	20290701	MDL	MDPR	US	Active
ABC-004	REG_US_25	20220726	20290701	MDL	MDPR	US	Active
ABC-004	REG_EU_26	20220726	20290701	MDL	MDPR	EU	Active
ABC-005	REG_EU_27	20220726	20290701	MDL	MDPR	EU	Active

Business Partner	External License Number	Valid from	Valid to	Lic. Type	Leg. Reg	Country	License status
BP001	REG_BP_US_20	20220726	20290701	MDL	MDBL	US	Active
BP002	REG_BP_US_21	20220726	20290701	MDL	MDBL	US	Active
BP003	REG_BP_US_22	20220726	20290701	MDL	MDBL	US	Active
BP004	REG_BP_US_23	20220726	20290701	MDL	MDBL	US	Active
BP005	REG_BP_US_24	20220726	20290701	MDL	MDBL	US	Active
BP006	REG_BP_US_25	20220726	20290701	MDL	MDBL	US	Active

Product: Medical Device Product Number

Business Partner: Business Partner relevant to medical devices

External License Number: This will be the number provided by different regulatory authorities

Valid From: Data when the validity of the license starts

Valid From: Date when the validity of license expires

Lic Type: What is the type of license you are creating

Country: This regulation you are creating is related to which country

Leg. Reg: Which regulation of that country

Country: Country for which regulation

License Status: Status of license active or inactive

4. Configuration Steps

4.1. Define Country Group

Use this step to define country groups to simplify the process of making license determination settings. Use this option if you have countries with similar or the same legal regulations.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide → SAP Global Trade Services →General Settings→Legal Regulation→Define Country Group

4.2. Assign Countries to Country Group

Use this configuration step only once the previous step of defining country grouping is completed.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→SAP Global Trade Services→General Settings →Legal Regulations→Assign Countries to Country Group

4.3. Define Legal Regulation

In this step, you will define legal regulation. The legal regulations are assigned to legal codes for categorization by the system. You use the attributes of the legal regulation to control the processes in the application.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide → SAP Global Trade Services →General Settings→Legal Regulation→Define Legal regulation

4.4. Activate Legal Regulations at the Country/ Group Level

In this step, activate all the Legal regulations you defined in the previous actions. Enter a country (or country group) of departure or destination for each legal regulation, depending on whether the process is inbound or outbound.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services→ General Settings → Legal Regulation → Activate Legal Regulations at Country/Country Group Level

4.5. Define Document Types for Application Areas

Create a document type and a description; enter the following details for the document type:

- Process (import or export)
- Number range number (number ranges for the document type)
- Service log (whether you want a log for analyzing and correcting errors)

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide → SAP Global Trade Services→ General Settings→Document structure→Define Document types for application areas

4.6. Activate Document Types for Application Areas

Define which document types you want to use for the individual application areas.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services→General Settings→Document Structure→Activate Document Types for Application Areas

4.7. Define Item Categories for Application Areas

Enter a name and a description for the document item; Using confluent system document type in the description for items from replicated documents is recommended.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services→General Settings→Document Structure→Define item categories for application areas

4.8. Activate Item Categories for Application Areas

Enter a name and a description for the document item; the recommendation is to refer to the document type from the confluent system

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→SAP Global Trade Services→General Settings → Document Structure→Activate Item Categories for Application Areas

4.9. Define Logical System

Use transaction /SAPSLL/MENU_LEGALR3 in the confluent system to define the name, recommendation is to use standard naming convention <system_name> <client_number>.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide → SAP Global Trade Services →System Communication→Define Logical System

4.10. Assign Logical System to a Group of Logical Systems

Assign the logical system of your SAP GTS and your confluent system to the respective clients.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→SAP Global Trade Services→ System Communication→Assign Logical System to a Group of Logical Systems

4.11. Assign Document Type at Feeder System Group Level

Perform the following functions:

4.11.1. Automatically Transfer Document Type

Use this function as an initial step to transfer all your document types from the feeder system to SAP GTS to ensure all your data is transferred. You can test the automatic transfer function by first performing the transfer in simulation mode.

You need to enter the feeder system and the legal unit to which you want to transfer the document types from the feeder system.

It is important that you check the automatic transfer afterward to ensure the assignments are what you want. You can do this in the manual assignment step described below.

You can completely retransfer all the document types from your feeder system by setting the Overwrite Existing Records indicator.

4.11.2. Manually Assign Document Type

We recommend using this function to check automatic document type transfers and assign new document types manually.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide → SAP Global Trade Services →General Settings → Numbering Scheme→Assign Document Type at Feeder System Group Level

4.12. Define Numbering Scheme of Export Lists

Define the numbering schema and description of it in this configuration step

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services →General Settings →Numbering Scheme→Define Numbering Scheme of Export Lists

4.13. Assign Numbering Schemes to Legal Regulations of the Application Areas

In this configuration, choose the numbering scheme for medical regulation and specify any additional validity characteristics for the schemes of a numbering system.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services→General Settings→Numbering scheme→Assign numbering scheme to legal regulation of application areas

4.14. Activate Legal Regulations

Select the Medical Device legal regulation and activate it per the agreed setup for the selected Country or Country Group.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide →SAP Global Trade Services→ Compliance management→ Legal control→Activate Legal Regulations

4.15. Define Determination Procedure to Automatically Determine License Types

Enter a name and a description for the determination procedure. Then assign a determination strategy to the determination procedure. Enter sequential numbers, starting with 10, 20, and so on, and then choose which level you want the system to determine the license type under Determination Strategy, for example, At the Country/Control Group Level. The system then searches for a suitable license type based on the sequence and the conditions you have defined for a specific determination procedure.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide →SAP Global Trade Services→Compliance management→ Legal control→Define and Determine the procedure to determine license types automatically

4.16. Control Settings for Legal Control

Configure the control parameters for the Legal Control application area in this Customizing activity. It defines the determination of licenses and the methods used within legal control. You have to configure the individual settings for each legal regulation. When you are finished configuring the control parameters, you have to define the allowed statuses of a license for the legal regulation and enter potential dependencies on time zones

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services→Compliance management→ Legal control→Control settings for legal control

4.17. Define License Types

In this Customizing activity, define the types of import and export licenses. When you represent the license types, you can also select which objects the system checks when determining the license types.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide →SAP Global Trade Services→ Compliance management→ Legal control→Define License types

4.18. Define Number Ranges for Licenses

In this Customizing activity, define the number ranges for the business objects that SAP Global Trade Services maps with the technical object of the license.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→SAP Global Trade Services→ General settings→Number ranges→ Define number ranges for license

4.19. Define Groups of Partner Functions

In this Customizing activity, combine partner functions in groups that you. It is advisable to group the partner functions in the same way as the business processes. It will enable unique and easy assignment of partner functions or partner function groups.

Transaction Code	SPRO
IMG Menu	SAP Customizing Implementation Guide→ SAP Global Trade Services→General settings→ Partner Structure→Define Groups of Partner Functions

5. Training

As a regulatory project, deciding on a training strategy is crucial. When deciding on training, analyzing the audience and timeline for the training is crucial. The following parameters can be used to design effective training.

- Audience analysis
- Basic system training
- Train the trainer
- Report training

6. Communication

When communicating with different stakeholders and partners, be sure to communicate to the point and try not to use complex IT or business words. Make sure the following point are considered in your communication

- What is happening and why?
- What's changing?
- When is it happening?
- What do I need to do?
- How do I get help?

7. Conclusion

Understanding the end-to-end business process before designing a solution to implement the SAP supply chain process for medical devices is critical. Creating a control of medical devices license is one of the significant components of this configuration. It must be carefully discussed with business teams to include all the required master data and business transactions. SAP-GTS license configurations are very robust to create an automated control for medical device sales and provide excellent integration.

References

[1] https://Help.Sap.Com/Docs/SAP_GLOBAL_TRADE_SERVICES_EDITION_HANA

[2] "Configuration Guide for SAP Global Trade Services," *Edition for SAP HANA* | SAP Help Portal .

[3] V.Ramana Reddy and E.Sakshal Sreeman, "Sustainable Aspects of Green Supply Chain Management in Manufacturing Environment," *SSRG International Journal of Industrial Engineering*, vol. 3, no. 3, pp. 17-22, 2016. Crossref, https://doi.org/10.14445/23499362/IJIE-V3I5P104.

[4] https://Help.Sap.Com/Saphelp_Tm80/Helpdata/En/74/Cfdfcc866b409a8257e43839547bd2/Frameset.Htm.

[5] "Redefining B2B Customer Experiences for Clinically Complex Medical Devices", *SAP Blogs*

[6] "Is Digitalization Causing or Enabling the Blurring of Industry Boundaries Across Health Sciences?," *SAP Blogs*

[7] "Krypt Blog Know How SAP GTS Helps Keep Companies Compliant During Crisis," Owler Reports

[8] Saikat Mazumder, Amiya Bhaumik, "Blockchain: Transforming Supply Chain Management Amidst Covid-19," *International Journal of Engineering Trends and Technology*, vol. 70, no. 6, pp. 100-105, 2022. Crossref, https://doi.org/10.14445/22315381/IJETT-V70I6P212.

[9] "The Business and Social Imperative for Digital Transformation in Health Sciences," *SAP Blogs*.

[10] "Reducing the Cost of Selling in Medical Devices to Drive Profitability," *SAP Blogs*.

[11] Vishwanathkumbar, Dr. G. Srinivasa, Mrs. Anuradhabhushan, " 3pls (Third Party Logistics Providers) as a Supply Chain Strategy in Integrating the Distribution Network for Reaching the Unreachable Rural Consumer," *SSRG International Journal of Economics and Management Studies*, vol. 3, no. 9, pp. 13-18, 2016. *Crossref*, https://doi.org/10.14445/23939125/IJEMS-V3I5P115.

[12] "SAP and Mercy Harness RWE to Improve Implantable Devices and Patient Outcomes," *SAP Blogs*.

[13] "Product Classification in GTS," *SAP Community*.

[14] Hulas Raj Tonday, Poonam D. Katore, Dipali S. Raut, Akash D. Rathod, Anuja I. Morwal, "Study of Implementation of Agile Supply Chain for Efficient Delivery of Essentials During Covid-19," *SSRG International Journal of Mechanical Engineering*, vol. 8, no. 8, pp. 1-5, 2021. *Crossref*, https://doi.org/10.14445/23488360/IJME-V8I8P101.

[15] SAP Global Trade Services, *SAP Help Portal*.

[16] Export License Determination-Sap Gts, *SAP Blogs*.

[17] Rashmi V Bhat, Shruti H Hegde, "A Survey on Applications of Blockchain in Healthcare Sector," *International Journal of Recent Engineering Science*, vol. 7, no. 3, pp. 36-39, 2020.

[18] "Legal Regulation Configuration Setup in SAP GTS" *SAP Blogs*.

[19] "Business Partner Based License in SAP GTS" *SAP Community*.

[20] Abhijith Manoj, Jatin Yadav, Arfat, Mayar Mui, Nandini K, "A Secure Based Land Registry Decentralized Framework Using Blockchain on Cloud," *International Journal of Computer and Organization Trends*, vol. 11, no. 3, pp. 5-10, 2021.

[21] "GTS FM to Get License Data on Customs Declaration Output," *SAP Community*.

[22] "SAP License Management," *SAP Blogs*.

[23] Healthcare | Industry Software | *SAP*.

[24] Sweetline Priya, R. Priya, R. Surendiran, "Implementation of Trust-Based Blood Donation and Transfusion System using Blockchain Technology," *International Journal of Engineering Trends and Technology*, vol. 70, no. 8, pp. 104-117, 2022. Crossref, https://doi.org/10.14445/22315381/IJETT-V70I8P210.

[25] SAP Logistics Info Days 2022, *Krypt Inc*.

[26] "Krypt Partners with SCT Software to Provide Customers with an Extended Adaptable Supply Chain Experience Within SAP," *Krypt Inc*.

[27] "Medical Device Downtime – Challenge and Opportunity for Medical Device Manufacturers," *SAP Blogs*.

[28] Doaa Hegazy, Dr. Shimaa Ouf , Dr. Tarek S. Elhabian, Pr. Ibrahim El Henawy, "Intelligent Logistics Industry (ILI) Based on Blockchain," *International Journal of Computer and Organization Trends*, vol. 10, no. 2, pp. 4-12, 2020.

[29] "3 Ways Medical Device Brands Can Beat Unauthorized Sellers," *SAP Blogs*.

[30] "Transforming Life Sciences to Reduce Costs, Increase Value and Improve Outcomes," *SAP Blogs*.

[31] Ayesha Saleem, Somia Ali, Iraj Anjum, Fatima Anwar, "Challenges and Strategies for Sales Prediction in Apparel Industry," *SSRG International Journal of Computer Science and Engineering*, vol. 6, no. 8, pp. 7-11, 2019. Crossref, https://doi.org/10.14445/23488387/IJCSE-V6I8P102.

[32] "Managing Contract Manufacturers in Life Sciences: Complex But Critical Strategy," *SAP Blogs*.

[33] "IT Technologies Disrupting R&D, Operations, and Customer Interactions in Life Sciences," *SAP Blogs*

[34] SAP GTS on SAP HANA | Beginner's Guide - By SAP PRESS. (Sap-Press.Com).