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Relevance of Master Data Management in Pharmaceutical Industries

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Abstract: ***This paper aims to provide the view for a single data management in pharmaceutical industry with cross application consistency. There are varied sources that contribute to data in any industry. The proper organization, easy flow and better connectivity of this data is essential for functioning in a suitable manner. Master data management is the basis on which the business processes can be developed and handled. Like any other industry, pharmaceutical as well incorporates several areas from which data can be gathered or manipulated. Also, there are diverse challenges that can act as a roadblock to smooth distribution of data. The article presents a detailed study of hierarchies in a pharma-based industry and the nature of problems faced by them at different levels. There are companies that face resistance while implementing Master Data Management. The manifold cause for this, when considering a pharmaceutical industry, have been outlined. This further encompasses the requirement of data governance and use of technology to strengthen the data management procedure. Finally, the article brings out possible approaches and vendor systems that can potentially create singularity in a pharmaceutical company, where data ranges from being ambiguous to highly specific.***

Keywords: ***Master Data Management, pharmaceutical, data governance, implementation, ETL, MDM vendor, customer data***

I. INTRODUCTION

Master Data Management (MDM) organizations intend first to develop and then ensure the efficiency, integrity and accuracy of master data. It includes both operational structures and the monitoring of internal procedures. Both are challenging, but in the last mentioned, there are more difficulties. It seems that, in many organizations, no one is responsible for master data or lacks the resources to carry out such a task. Technical structures and operational processes are assisted by MDM initiatives, such as master data creation, master data quality improvement and knowledge architecture. Weak master data management results in a lack of market and efficiency goals, insufficiently concurred data control, fragmented data collection systems and a lack of effective data quality assurance. Master data is an organization's data center that is closely related to its operations and capabilities. In addition to the technical methods of dealing with MDM, it is often used as a set of strategies for dealing with each of the master data angles. It shows the support for company needs. Master Data Management (MDM) can be characterized as something that includes procedures, regulations, policies, standards and resources that reliably identify and maintain the organization's essential data to include a single point of reference, and that single point of reference is often referred to as golden record. MDM is also a rather far-reaching term, one that has the ability to be underestimated and misinterpreted, whether it is viewed as something too broad and complex to be applied successfully, or as something that can address virtually any data management challenge it poses.
Review of each aspect of MDM will make a major difference to understanding what MDM should and should do and what it does not do.

II. NEED TO MANAGE DATA IN PHARMACEUTICAL INDUSTRY

The reason for which MDM operates is to handle the important data of an enterprise. All kinds of businesses may have various forms of sensitive business data by their very existence. In pharmaceutical firms, some major fields of critical data include:

1) *Drugs*- Medicinal Drugs, Distribution Systems
2) *Components for Goods*- Ingredient Compounds, Packaging
3) *Report*- All health practices and research results
4) *Processes*- Submissions, Authorizations and Project Administration
5) *People*- In diverse capacities, such as personnel, inspectors and test subjects
6) Other organizations, such as enforcement authorities and vendors
7) Resources and services, like buildings and equipment

Companies can start with one or more key areas and expand into other areas as experience and business need requires, leveraging opportunities from business drivers to manage the scope.

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A pharmaceutical organization has a vast customer landscape with different types of entities and hierarchies:

a) *Network:* An entity that holds more than one system, institution and/or unit together with non-ownership relationships such as 'affiliation,' 'association,' 'group purchasing'.
b) *System:* An entity that holds together more than one institution or unit with legal ownership relationship
c) *Institution:* An entity that exists as a physical structure with a unique public street address and provides health care services to patients
d) *Unit:* An entity that is physically within a structure or building and is characterized by a distinct medical functionality. It may or may not be owned by the institution in that building (if one exists)

As an organization expands its product portfolio and source of customer information, additional entity types and hierarchies need to be integrated to achieve a unified view.

The benefit of a golden record for an organization is that it improves both data accuracy (by minimizing or removing inaccurate data, redundant data and defective data) and performance (by reducing or eliminating time expended on data correction or maintenance, and also by reducing or eliminating data incomprehension) [1].

The increase in data quality and efficiency will manifest itself in different ways for the different process that occur within the various parts of an enterprise.

For example, a single global description of a medicinal drug would ensure that the regulatory agency can more accurately monitor what is approved for that drug in every jurisdiction and in all jurisdictions, handling foreign birth dates and updating the requisite daily submission documentation more efficiently.

Similarly, the same concept helps the supply / logistics divisions, allowing them to better monitor how their goods are being sold; foresee and, thus, fix drug problems when they are critical; and to provide a clearer picture of potential counterfeit issues. Getting a consistent overview of the processes and practices that are performed to perform the enterprise is especially useful for monitoring and benchmarking across various areas of the global organization.

It should be remembered that, historically, MDM was originally introduced to support wide-scale analytics ('big data' and its forerunners), often positioned on top or alongside a massive data warehouse, providing data visualization between the same data objects and attempting to address anomalies (e.g. whether a source has a somewhat different hue for a data item) as data poured into the warehouse from various places [2]. Current thought, especially with regard to data on medicinal goods, is that, rather than attempting to overcome these complexities, it is both necessary and beneficial to eradicate them using a simple knowledge model.

As the number of data sources and complexity of sources increases, pharmaceutical organizations face unique challenges:

A. Business Needs

1) A single trusted source for customer affiliation or hierarchy to provide reliable professionals-to-organization and organization-to-organization relationships
2) Risk in meeting regulatory/contractual requirements

B. Unique Customer Relationship

1) Each type of account data requires in-depth understanding of complex entities, their relationships and significance to the end users, i.e., managed care ecosystem requires understanding of different plan hierarchies, while HCP ecosystem requires understanding of B2B affiliations, influences and relationships

C. Data Stewardship

1) Unique issues including data capture, sample size, data masking and de-identified patient information make it difficult to get a comprehensive picture of customer situation
2) Lack of automated standard QA/QC and match statistics to analyze the matching results with business user-friendly interface and process

D. New Sources Integration

1) Organizations need to incorporate new data sources to support additional as well as evolving business needs
2) Data mismatches due to issues like quality, disparity in format, timing, etc.

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Well-integrated and unified view of customer data is critical in supporting a range of commercial business processes. These processes for the basis of any pharmaceutical industry. Below are the descriptive points for these:

a) Targeting
- Identify actual customers who treat patients, regardless of whether sales are captured for them or not
- Prescribers are rarely silos, need to understand their groups and institutional affiliations
- Integrate retail sales, non-retail sales, segmentation, rep feedback and affiliations

b) Incentive Compensation
- Correctly link sales activity with sales performance of customers to motivate and reward fairly
- Need to account for environmental factors by integrating managed care and network (IDN) data

c) Growth Opportunity
- How can the brand grow, which customer segments, against which competitors, what messages
- Integrate patient, sales, payer, activity and segmentation data

d) Resource Allocation
- Which marketing tactic has highest impact for which customers? What is the best allocation for future?
- Integrate sales, segmentation and marketing programs data

e) Performance Monitoring
- What is the performance trend? What are the drivers of performance?
- Integrate sales, segmentation, marketing activity and payer data

f) Contracting and Tracking
- Which payers are advisable for contracting and how has historical contract performance been
- Integrate sales, plan-payer hierarchy and chargebacks data

g) Pull-through
- Given the formulary status, which plans and payers are lagging in performance?
- Integrate alignment, sales, formulary, claims and plan-payer hierarchy information.

III. KEY CONSIDERATIONS WHILE IMPLEMENTING MDM:

Healthcare ecosystem is complex and ever changing with the introduction of new entities, roles, and affiliations and many to many relationships. These can be discussed in further details:

A. Commercial affiliations with data sources are not comprehensive and up to date, hence there is a need to capture field/headquarter intelligence
B. Defining clear short term as well as long lasting capabilities like influence mapping, referral networks etc. and building affiliations in that specific context is key
C. Effectively meeting the varying business process needs of different teams like sales and contracting is important.

There are certain aspects that should be kept in mind while implantation of the master data management. These are mentioned below:

1) Identify business case and an executive sponsor who is involved throughout the project and can champion the MDM within the organization.
2) Think of MDM as a data governance program facilitated by technology, rather than the other way around.
3) Plan the implementation well by clearly prioritizing different data sources, having a phased approach and offering a flexible, service-based model (Enterprise objects).
4) Perform experimentation and data analysis outside of the matching engine. Perform one-time data matching differently than ongoing cleansing.
5) Develop processes and user-centric tools that align with the needs of data stewards, data governors and business process need.
6) Incorporate communication, training and change management throughout the implementation.

Data Governance (DG) is a framework for aligning strategy, defining objectives and establishing policies for enterprise information. Following are the considerations that encompass the vision of data governance towards building MDM:

a) Data Vendor Management: Ensure adherence to current vendor contracts and facilitate evaluation of new data sources
b) Data Management: Ensure high-quality, relevant and consistent information utilized in business decision-making
c) Business Rules & Policies: Facilitate cross-organization communication and consensus on business rules, data usage protocol, etc.
d) Data Availability & Delivery: Represent and support end-users' information needs in a consultative and timely manner
e) Compliance & Adherence: Establish processes to ensure compliance with regulatory requirements (e.g., state-level expense reporting, etc.)

IV.METHODOLOGY OF MASTER DATA MANAGEMENT

MDM is accomplished by a mixture of systems, legislation, regulation, norms and tools. The criteria are more specifically seen to be used in MDM devices. All items that can be categorized as "master details" have different characteristics ("attributes") that define them: for example, a pharmaceutical substance has a dosage type, and if that dosage type is a tablet, the tablet would have a scale, shape, and color. They will have ties between them: for example, a pharmaceutical drug must have an authorization to sell it in one or more jurisdictional markets.

Unfortunately, each item defined as master data and its properties and relationships can be represented in various ways in various frameworks, which also means that it is difficult to locate a consistent source of reality. For example, whether the tablet 6 mm in diameter, or is it 6.2 mm in diameter? Was the 6 mm a rounded number so only an integer value can be taken from the system? Often the definition is only accessible in a text, which means that it becomes much more difficult to locate a vital piece of knowledge quickly. Using keyword search and browsing through in large databases is very time-consuming.

MDM uses a common template (model) to define the essential business data of an organization – the items that may be categorized as master data, their characteristics, and the relationships between them, to eliminate confusion, and to facilitate the production and preservation of a living golden record for all in the organization to use.

This is where the analytical knowledge model of the IDMP (Identification of Medicinal Products) plays such a crucial role; as international guidelines, it builds on a broad variety of experience to identify crucial persons, characteristics and their interactions in order to better explain medicinal products in life sciences [4]. The Standardized Product Label Design complies with the IDMP Knowledge Model and is an implementation of it.

The IDMP model is also consistent with other models in the field of clinical research, in particular the BRIDG (Biomedical Research Integrated Domain Group) model, which is an ISO standard that can be broadly used (e.g. for clinical trial management and application management). It also offers essential guidance for pharma-co-vigilance and the Individual Case Safety Report (ICSR). Regulatory information requirements continue to be developed and refined: for example, the Regulated Product Submission (RSP) standard (which will finally also integrate version 4 of the Electronic Common Technical Manual (ECTD)) and the Clinical Trial Registry Guidelines (CTR).

Note that specifications that identify and explain all essential artifacts and their relationships are more useful, which is why some of the CDISC specifications, where relationships between data items are not well described, may have limited applicability. There are also guidelines for the management and usage of standardized terms used in the MDM. Standards themselves typically come with guidelines (policies and processes) for their application and legislation, either specifically (e.g. ISO TR 20443 for the introduction of IDMP) or indirectly (e.g. any regulated terminology requirement should be based on the concepts of terminology management standards).

Through implementing specifications, using an IDMP model in MDM — individual organizations may not need to create an MDM system by themselves, which would be costly and wasteful [7].

Standards also ensure that the reach of the MDM can be increased consistently over time, as knowledge increases and rewards are recognized, without expensive reworking of the foundations.

Any organization adopting MDM will follow these guidelines and incorporate them into a series of processes to ensure that the applicable governance criteria for their master data are adhered to. These systems, typically outlined in Standard Operating Procedures (SOPs) and Obligation Matrixes, explain how changes can be handled (new items created, existing items modified, expired items removed) and how change itself can be requested.

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MDM solution follows a well-defined methodology for pharma data and processes:

A. Discover

The first phase of any master data management structure constitutes of discovering the background and needs of the system. This includes executive sponsor identification, stakeholder identification, MDM business case development, process-specific use case development and review of current processes and issues. The inventory of current source systems and technology platforms, along with setting up of data governance team is an extension to this phase.

B. Analyze

The next step to formulating MDM is analysis of the environment within, as well as consideration of external factors. There are various prospects of this analysis, some of which are, customer classification and definition, canonical party data model, defining standard account and individual profiles, defining customer master consolidation rules, customer hierarchy management, defining data quality metrics and policies for derived attributes along with the data steward workflow.

C. Design

Designing a system with data perspective is the next important stage. There are levels defined for data in a management system. Adhering to these the models or designs can be categorized as stated below:

1) Core Services Design
2) MDM Hub Data Model
3) Design Source System ETL
4) Design MDM to Publishing ETL

D. Build

According to the design developed in the previous phase, the system needs to be built. In sequence, this procedure starts with Data Profiling, moves towards developing Baseline Configuration for account and individual and performing threshold analysis. As we go into details of the system, there are configuration of relationships and web reports are generated. Data steward tool and master data publish layer is the outcome of this phase that we can see as the basis on which work survives. There are Bulk and Ongoing Publish that run the system daily. The data steward workflow helps in developing Source System Integration ETL and MDM to the Publishing ETL.

E. Test

The next two steps are performed in order to check for the robustness of the developed MDM. There are number of testing which a built master data management must go through. These checks are to find whether source system integration ETL, MDM to publishing ETL and integration of MDM Hub has occurred accurately. Further, performance/stress testing, configuration and ETL testing and user-acceptance testing is done.

F. Deploy and Operate

For deploying and operating a well built and tested MDM, it should be must that all production, stand-by database and fix environments are ready. There should be a proper layout developed in order to execute the deployment plan. Also, a smooth transition to support has to be made sure of, accompanied with a complete support documentation for the same.
The MDM will operate in full functional capability only if the SLAs (Service Level Agreements), MDM success metrics and sage of master data is monitored properly. There should be regular follow ups to the operation procedure, as well.

V. MASTER DATA IMPLEMENTATION FOR A PHARMACEUTICAL COMPANY

A. Challenge

1) The company wanted to improve efficiency and effectiveness of its MDM solution in response to new product launches and increased regulation
2) The current systems offered limited flexibility to easily add additional data sources
3) Inconsistencies in master data across systems results in confusion and resolution required significant resources

B. Approach

1) Develop a process to standardize the customer profiles information across different sources
2) Develop a configurable matching solution where new matching rules can be added with minor modification
3) Provide customer matching capability outside of customer master to address ad hoc matching needs
4) Enable mechanism to avoid duplicates, creating a single version of truth for each customer in customer master

C. Solution

1) ETL – Informatica IDQ mappings and processes to integrate customer profiles, attribute and relationship data across existing sources
2) A Web-based data stewardship tool
3) It reviewed the results of exact/fuzzy match, set matching parameters and export results
4) Impact:
5) A single Version of the Truth was obtained, hence establishing and maintaining master lists of physicians and accounts across a variety of data sources
6) It assessed the quality of the data source before integrating it in the enterprise database for further flow in downstream channels.
7) It provided the ability to support product launches and call plans by quickly identifying new customers that were added in the system.

VI.SUPPORTING MASTER DATA MANAGEMENT- MDM VENDORS

A. The MDM program has two key objectives:

1) To create and preserve master data (gold record) for each item labeled as master data using the correct template as well as the necessary regulated terminology
2) To make master data accessible for use throughout the enterprise. MDM systems have a range of functions (capacity) to accomplish this. Certain systems have all the functionality themselves, while others use the functionality of subsystems to accomplish the target. For example, the MDM program can be used to create and manage master data, by doing any of the following:

a) It may undertake to maintain its own information model, or it may provide facilities to import an information model from a library
b) Maintain and version its own managed terminology, or it may merge with a proprietary terminology processing network
c) Manage and version its own registries, or it may provide facilities to import registry data from an external source—or it may do both, providing the necessary matching and ranking services for that.
d) However, all MDM programs must provide life-cycle maintenance for master data to help the business process for that life-cycle (including duties and obligations and governance) and promote impact analysis as improvements to key knowledge arise. In addition, when data is inserted into the MDM, the program can preserve traceability to the source(s) and provide reconciliation and remediation facilities for data purification [11]. To allow the use of master data, all MDM programs will have
e) Search and display facilities (including comparison) for specific views of data
f) Data-sharing facilities:

3) Integration with other systems in the enterprise as a core data source
4) Data extraction

B. Master Data Management Vendors

1) Informatica provides a modular set of mdm products powered with ai.

Informatica has become a long-standing MDM space leader with multi-domain cloud and on-site offers. It also offers Consumer 360, Manufacturer 360 and Commodity 360 (PIM) as pre-built MDM solutions as well as business accelerators such as GDSN / GS1 syndication services for CPG and product information exchanges for retailers. Informatica's future software plan is to use its AI system, CLAIRE, to ease MDM integration, to provide matching, to discover relationships, or to optimize data quality based on guidelines. Forrester expects Informatica to adapt its MDM package to the growing midsize market and to ready its IoT portfolio with stronger support for asset data domains. In February 2019, Informatica bought Allsight, offering out-of-the-box consumer visibility into company master information. This will allow a third-generation MDM product to be shipped.

2) Reltio Renews The Mdm Category With Modern Architecture And Advanced Features

Reltio only provides a multi-domain MDM application in the cloud using a multi-tenant architecture. This helps consumers to continually benefit from the new upgrade and eliminates the need to include the interface. The software is also available on Amazon Web Services (AWS) and Google Cloud Software (GCP) with Microsoft Azure on the road map [6]. Reltio uses deep learning, information network, network database, self-optimization of resources, and embedded analytics to provide one of the most flexible MDM devices on the market and one of the few able to develop into a third generation Master Data Management.

Reltio's plan is to grow its platform for MDM software and platforms to help third parties drive broader industry acceptance. Reltio also focuses on providing more users with a configurable user interface as well as improved efficiency, reference data collection and data cataloging. Its consumer references praise the ease of use of Reltio and the fact that the software adapts very well to the way a organization works, without needing any change management. They lament the difficulties of deployment and the lack of responsiveness for the service-support.

3) Enterworks Provides MDM for Ecosystems in a b2b2c Model.

EnterWorks offers a range of products, including product knowledge management and digital asset management. Its MDM is a completely multi-domain, online, on-site, and hybrid platform that offers data processing, mastering, and delivery. The EnterWorks deal is especially successful in harmonizing the delivery of commodity details across communities owing to its syndication capabilities. The ever-increasing need for consumers to gain more information before purchasing makes the exchange of information in B2B2C scenarios highly important in sectors such as food, CPG and retail.

EnterWorks is planning ecosystem assistance for the third generation of MDM. Its marketing approach relies on app experience, AI and machine learning. Customer comparisons such as ease of use, quick time-to-value, and reliability. They would welcome a great user interface, an ERP integration, and an API operation.

4) Semarchy Revolutionizes MDM using Modern Cloud Architecture and Agile Methods.

Semarchy offers a server, on-site, hybrid, and multi-platform approach to ease MDM adoption. Semantic technologies around the SemQL language are used to interrogate and test some data, including graph data. This also offers technology such as auto-form production for the accelerated creation of applications. All of these developments allow for a new, agile approach to the implementation of MDM. As an accelerator, Semarchy provides an application supporting the EU's General Data Protection Regulation (GDPR), which includes the right for portability — which is rare on the market [10].

Semarchy's product strategy is to continue to simplify the user interface, add collaboration capabilities, involve more stewards, and produce meaningful dashboards. Its client references value the simplicity of installation, delivery, and use of the software; the flexibility to conform to the organization; and the time to produce the product. They also admire Semarky's high degree of direct assistance to reach the highest possible degree of results. They would like to see even more productivity through data governance implementation using machine learning.

5) Comparison Between Two of the Leading Software Available

RELTIO	INFORMATICA
Reltio's platform provides a multidomain MDM product in the cloud only, using a multitenant architecture	Informatica's MDM products are powered by AI with multidomain cloud and on-premises offerings
The Reltio platform is available today on Amazon Web Services (AWS) and Google Cloud Platform (GCP), with Microsoft Azure on the road map	Informatica provides Customer 360, Supplier 360, and Product 360 (PIM) as prebuilt MDM solutions
Reltio adopts machine learning, knowledge graph, graph database and embedded analytics to provide a versatile MDM product	Informatica's AI engine, CLAIRE will simplify MDM integration with matching, discover relationships and automate rules-based data quality
Reltio is developing a strategy for MDM applications and frameworks to get help from third parties to accelerate broader market adoption	According to Forrester, Informatica will tailor its MDM product to the growing midsize market and to prepare its offering for the IoT with better support for asset data domains
Reltio is focused on developing a configurable user interface with better performance, reference data management and data cataloguing	Informatica purchased AllSight In February 2019, providing out-of-the-box customer insights for customer master intelligence
Reltio' s ease of use and adaptability to diverse businesses was highly appreciated in customer references	Informatica is equipped to provide a third-generation MDM product

VII. CONCLUSION

When applied efficiently, based on well-accepted knowledge principles, with consistent reach and realistic governance processes, MDM is a powerful enterprise-wide platform that improves data consistency and performance in data processing and market analytics.

Key deliverables of a typical MDM strategy and implementation project:

A. Discussions with all stakeholders to understand the different requirements and also the underlying business logic and processes behind the requirements is vital for a successful implementation. The first deliverable in any such project is a Detailed Requirements Document

B. Identifying key requirements and clearly defining the functionalities of existing systems in an Implementation and Mitigation Strategy document

C. Defining the future state of the MDM system and defining the eventual functionalities of all systems involved. The strategy document serves as a guideline for implementation following the requirements document

D. Closely tied to the implementation strategy is a detailed Project Plan

E. Post the requirements phase, typically all information is followed up with both a high-level and Detailed Design Documents

F. One of the most important aspects of an MDM implementation project is to identify external dependencies and key change management processes involved. These important aspects are captured in a Cutover Plan and Change Management document.

Overall, we draw from this that a Master Data Management strategy in the spectrum of pharmaceutical industries is highly essential. This is because it improves the customer service and deliver products efficiently through their preferred channels. Also, this ensures that complete and accurate organizational hierarchies are available to sales and marketing teams. It further reduces the financial or legal risk of doing business with a subsidiary of the current customer or prospect. Finally, it provides insight into the industry's future owing to the historical database formulated in a compact and useable manner, which can be referenced to, later.

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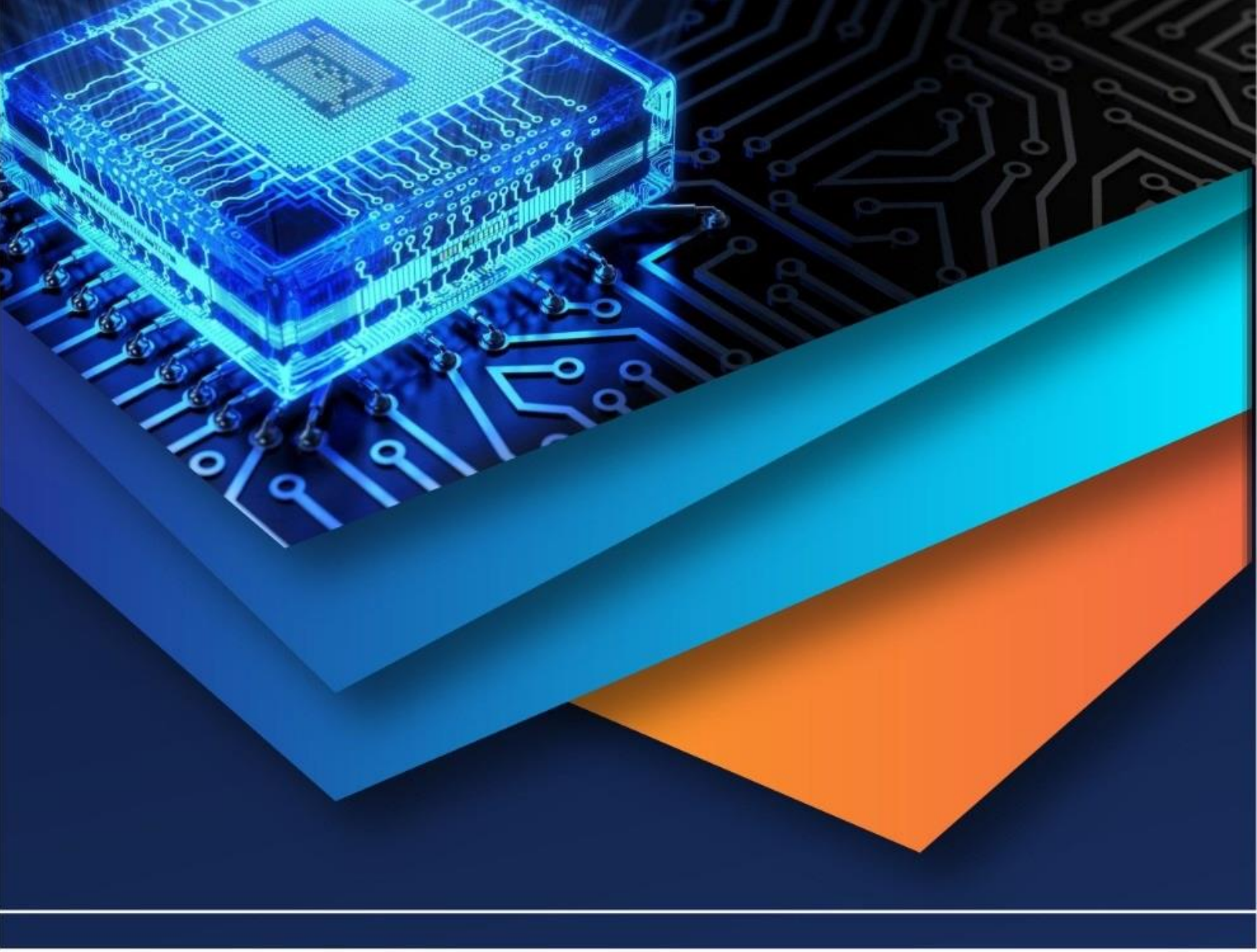

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