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Detection of Counter Feit Medicines in Pharmaceutical Field Using Blockchain

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Abstract: ***This study aims to develop a pharmaceutical blockchain system and test its functions in a simulated network. It includes developing a Distributed Application (DApp) that will run on smart contracts using Ethereum. This system will be used to test the validity of the medicines used in the market and make sure that it is fit for consumption. The following 5 nodes namely Admin, manufacturer, wholesaler, retailer, and the consumer will play important roles in the system.***
Keywords: supply and distribution, counterfeit medicines, blockchain, token, cryptography, encryption, hash, nodes

I. INTRODUCTION

In today's world, the counterfeiting of medicines has become a major problem, reports the World Health Organization. It has been recently classified to be a world-wide issue. In countries where the financial status is not that high, it is estimated that 1 out of 10 medicines are fake or of extremely low quality. People on consuming these medicines are prone to severe health issues and will be facing side effects caused due to these faulty medicines. These cases happens where there is no proper moderation or regulation in the supply and distribution of medicine. Even if proper medicines are available, they will be in high demand which naturally leads to high cost making it unaffordable for the poor which in turn will lead to massive uncontrolled diseases and demise of people.

If medicines of substandard quality are given to patients, the results would be hazardous. The innocent patients consuming these false medicines would not be aware of the ingredients and composition of medicines he/she consumes which may result in dangerous after effects. For instance, multiple reports have arisen from various sources regarding the existence of these kind of fake medicines being the cause of unwanted casualties. The immunity of the patient will be at stake if medicines are consumed in a quantity more than the desired quantity. The mortality rate is increasing rapidly day by day in the world we live in due to this careless error. As a result, people might actually lose hope in legit medicines which are sold in an authentic protocol.

The Food and Drug Administration (FDA) are taking steps in order to regulate the safety and authenticity in the fields of food, healthcare and medicines. The problem is bridging the gap between the willingness to stop the issues and being able to monitor and take control of the situation. They have started to send out warnings in order to spread awareness among the general public to be aware of such retailers who sell counterfeit medicines.

When these regulatory bodies actually take a step in the right direction by conducting laboratory tests for checking the authenticity of medicines, there exists the need for a secure platform where they can add the list of valid medicines. Blockchain technology can help in this scenario by providing secure means to share and add data. A decentralized database can be used which is constantly updated by regulatory bodies. Simultaneous access to publicly available information can be made easy by implementing blockchain technology to the core. The entire treatment process will be simplified up on implementing the blockchain in this field as doctors will get a clear idea of what to prescribe to the patients suffering to a particular symptom based on the approved medical history. All the parties involved in the systems like general practitioners, doctors, hospitals, therapists can be benefitted from this for effective treatment of the patients.

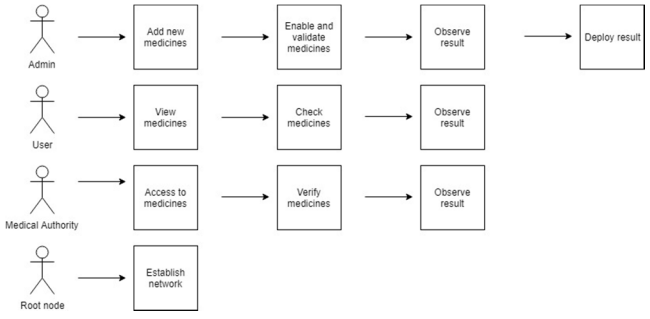

Figure 1: Roles and processes

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Blockchain technology that shines like a star after the entrance and widespread acceptance of Bitcoin, the very first cryptocurrency in people's' everyday life, has become a trending topic in today's software world. At the beginning, Blockchain was only used for monetary transactions and trade, but studies but in further studies it has suggested that it can be used in various fields, because the degree of transparency is high in the field of Blockchain. A consensus algorithm is deployed in order to avoid the duplication of transactions in the network which allows the nodes to verify the information. As the nodes verify the information, it can be added to a new hash value which is derived from the previous block thereby generating a sequence of data comprising of newer data and hash of the previous node. This will lead to the formation of a new block by making use of a cryptographic one-way hash function. The hash value implies to a continuous arrangement of letters and numbers which might seem irrelevant upon reading. This hash value can be generated with the help of an encryption algorithm. The algorithm used here is SHA-256. The value of each hash is distinct. These properties of the blockchain makes it resistant for intruders to interfere. network can persist amidst node failure. The efficiency of the chain is dependent on the number of nodes existing in the network. If the number of nodes in the network is high, the chances of the network to be efficient and fail proof is higher than chains with less number of nodes.

Recent studies have proven that blockchain technology is viable to be applied for solving the current problems existing in the world.When integrated with smart devices powered by internet of things, the ability of these techniques can scale up to an extent that it would reduce the number of fake medicines. Through its decentralized nature, the details are available for everyone in the system to get a better understanding of what is happening in the setup.

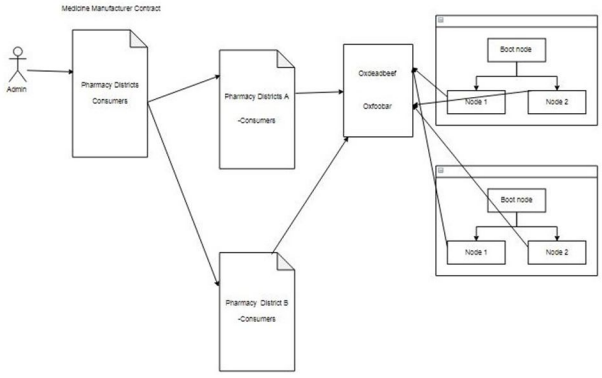

Figure 2: Pharmacy as a smart contract

More and more firms are gaining interest in the application of blockchain technology in medical field. This will result in the advancement and improving the use cases of the technology so that more developments can be done for the common welfare.

II. SURVEY

A. Pharmaco surveillance Blockchain System

1) System Design and Development: The prototype of a system will be a distributed application (DApp) along with back-end distributed file system (DFS) which will be a supporting private blockchain network. The concept used is smart contracts.

In Ethereum blockchain platform, an instance will be created, which will be an open-source and it is the largest public platform network, boasting an active community and a sizeable public repository of DApps. The current platform which is currently being used is proof-of-work (PoW) consensus algorithm called Ethash; however, The current generation developers are planning to change it to a proof-of-stake (PoS) algorithm for scalability. Ideally, a delegated proof-of-stake (DPoS) or a practical Byzantine fault tolerance (PBFT) consensus algorithm which will ideally fit into the environment of pharmaceutical supply chain, so it is necessary for the further modifications. Furthermore, Ethereum does not support encryption in default, which will additional development.

In hyperledger fabric blockchain platform, a second instance will be created. Unlike Ethereum, this platform is also created for private consortium networks. It is modularized, open-source, and by default it also uses data encryption and a DpoS or PBFT consensus algorithm.

Swarm, a native base layer service in Ethereum is included which id DFS, which is a good candidate for inclusion because of its default integration with the platform. The DFS component will store the DApp, smart contracts, and the blockchain. An element which is included in the system is called swarm.

A prototype for the system will be created with 5 starting nodes, one node will be created for each and every participant in the traditional drug distribution model: Additional nodes are created which are the manufacturer, the wholesaler, the retailer, and the FDA, as well as a bonus node that will be created and will house a consumer portal website through which consumers can purchase and view the available drugs using the interface which is being created. To define contract-based relationships between participants, Smart contracts will be used and the supply chains will be reflected in the in which the logged account is involved. The datas which is present in the system will be distributed across the DFS, accounts will only be able to visualize and decrypt files intended for them—in other words, sub chains will exist within the network.

In a system, Taking into consideration the orientation of the internode connections, the movements of the drug will be distributed to all the nodes in and across the network. The DApp has a special feature to detect the anomalies, unauthorized data insertions, and missing drug will compare the DFS content with the ledger record. Each step will have a timestamp which will be useful for auditing.

All the nodes will have DApp front end and all the additional nodes will also have the extension. The interface will have the feature which will display all the transactions performed within the chain as well as it has an additional feature to detect the anomalies and information discrepancies in a dashboard. The drug products will be traced as it moves along the chain and it generates a timeline for supply chain. An important feature is to provide notifications for shipment and problems detected in the chain. FDA account will define the authorized manufacturers and dealers and will store all the information's in the form of encrypted file or in a smart contract.

In Drug Supply Chain Security Act, The system will adopt the recommended GS1 pedigree standard. The participants will have the right to create product manufacture pedigrees, receipt pedigrees (where and when applicable) where each and every pedigree will be electronically signed and appended to all the nodes down the supply chain by the authors. The pedigree content will exactly satisfy the standardization of the data and documentation Practices for Product Tracing Guidance for Industry document published by the FDA. To identify the identifiers, GTN can be used.

2) *Food and Drug Administration Account:* The FDA account will have access to functions that allow the user to add information to reference smart contracts that define authentic drug products, supply chain participants, and contract relationships. Information uploaded by this account to the network will be considered authentic and will be used as the reference against which documents in the DFS will be checked. All sections and functions of the client application will be accessible to this account. Furthermore, this account verifies all transactions—all other accounts will automatically publish a session key encrypted with the FDA public key when they attempt to upload a file into the DFS.

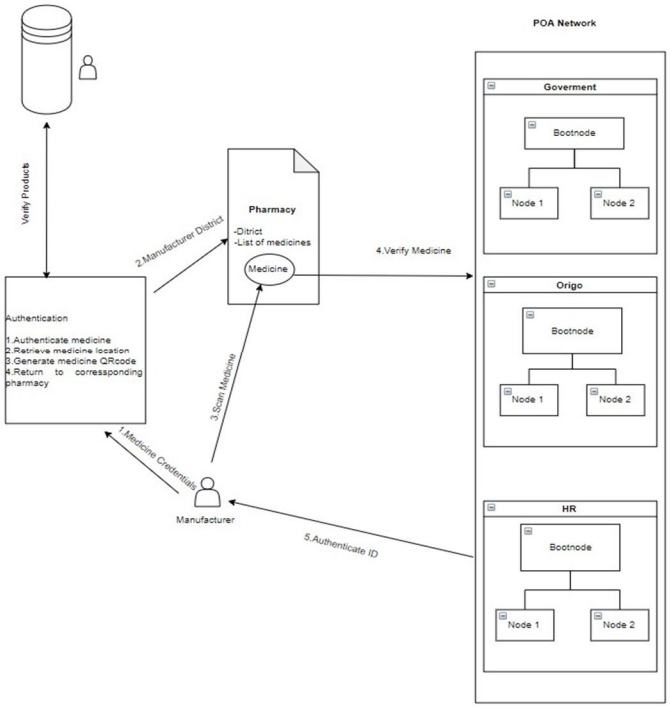

Figure 3: Manufacturer authentication of medicines

3) *Manufacturer Account:* Information uploaded by this account to the network will have credentials and certificates linked and will initiate supply chains, which the system will subsequently track using the pedigree files in the DFS. Upon verification of identity and registered distribution contracts linked to the specific brand of drug product, the system will determine whether the merchandise moves along a registered chain and will verify consistency of information through each node. Distribution chains may branch out or merge at certain nodes, and the system should detect such patterns when it visualizes them into timelines. For improved auditing, the system will also track the amount or stock number of each brand of drug product that moves across each node, using the various pedigrees submitted by the supply chain participants.

III. PROPOSED WORK

The system will have a DApp with a front end that provides a user interface. The DApp will have permission access to documents and records despite the said files existing in all nodes. The working application will be locked behind a login interface with two-step verification process authentication. The interface will ask for the user credentials such as username and password, The system will also send a verification notification through an authenticator application. All the credentials given in the interface including the authenticator application will be processed by FDA through the user management module which is being included in the system. In each supply chain participant account, where each and every account is issued with a pair of keys and the pedigrees will contain all the information's of currently logged-in user. The system also includes transaction history which is a simple data visualization widget where the virtualization process is accessible to all the user accounts. The system involves the distribution of the pedigree files across all the nodes present in the network, every file in the system will have defined permissioned recipients. the above parameters are encrypted with session keys which will be again encrypted for the recipients. The pedigree button can be created using the '+' button at the lower right portion of the screen, and the pedigree is appended to overall document, and finally it is submitted to the network for verification. The timeline dashboard is included in the system which generates graphs that will produce the progress of the drugs that is processed in the supply chain. All the discrepancies information involved by the nodes will be marked with red badge. This badge can be used to retrieve all the currently stored information submitted by that particular node. The DApp will automate the verification of pedigree documents within the blockchain ledger, the pedigree manufacturing process, and the defined supply chain smart contracts. If a malicious document is inserted into the system, it will automatically detect that particular file which is stored in the repository, bypassing an intended recipient, the system is programmed to detect the anomaly in an automated process. The next screen after the contract button (Pen and Paper) on the left side panel is clicked to create a new contract form. The contract form will collect all the information's from the participants. The details of the particular contract will be displayed by hovering over the contract icons to the right and the information will be displayed in a small window. The repository of smart contract will contain a canonical definitions through which the system can detect all the problems and break the supply chain events. The anomalies in the system is given by the participants of the network. The interface will contain the set of definitions which will be stored in the repository as registries. The contracts can be added and edited Only by the FDA account. In this blockchain process, if a contract is committed once, once a contract is committed, the record cannot be modified prior its creation, tampered with, or deleted. A contract which is created will contain the name of the drug product and the history of the drug is stored in the contracts, a source and recipient (both should be FDA-certified and registered to the system before the creation of the contract), and other metadata such as unique identifiers, certificates, and start and end dates. By design, each and every drug product will be assigned with a contract and the transaction occurs between 2 supply chain participants. At any situation, a particular participant can have many number of contracts with other participants. The definition will be handy to the participants and the verification of the transaction will include two step verification in the supply chain. first, the sender must be authenticated and certified by FDA, and second, the hash values of the data present in DFS should match with the blockchain ledger, the drug definition information in the DFS must match all the definitions respectively

IV. IMPLEMENTATION

The pharmacosurveillance blockchain was proposed for highly disruptive and for perfect execution of the user queries, particularly in low supply chains country like philliphines. It was carried out to affect not just the pharmaceutical industry but the entire distributed chain is being affected. Two elements such as Adoption and sustainability is achieved only by consumer awareness and customer empowerment with sound policy backing and good governance. The main assessment for adoption potential at a particular level named feature level using the unified theory of acceptance and use of technology (UTAUT) and for each affected sector, the respective extensions are performed once the technology has been developed and tested. In UTAUT, prevailing conditions, social influences, effort expected and system performance, effort expected and social influences and other important factors will determine whether the introduction of new technology will be successful or not. In a developing country such as the Philippines, the last 3 components are very hard to determine in order to determine the success of the system.

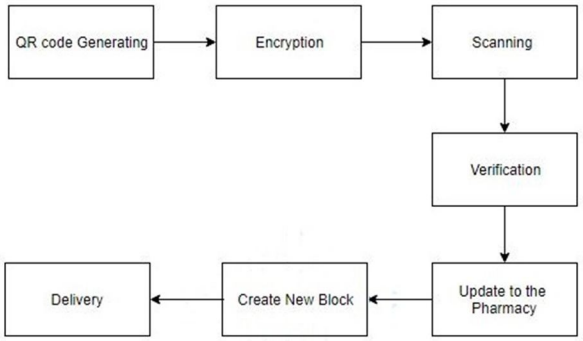

Figure 4: Overall process in the system

As SSFFCs of different modules travel outside for the official drug supply chains, the system which is created cannot detect the result until the SSFFCs reach the consumer. At this point, the consumer awareness and empowerment will play an important role in the implementation: first, the consumers will have to be aware that each and every purchases must come with receipt which contains distribution history code that is usd to scan and verify the authenticity of the drug, and second, if there is discrepancies, the should be empowered to report the problem to FDA.. In turn, the FDA will have to quickly accommodate, process and respond to reports from the system and consumers.

In terms of policy, two important and very important issues have been identified for adoption: first, Both the local and national laws have to recognize the ledger records for truth verification, which is provided as evidence in the court. Second, the policy will have to reduce the sensitivity on investments in infrastructure and human resource who are the participants in the drug supply chains. The government and other FDA agencies will take over the capacity building role from participants in the drug supply chain, The practises of the above two points will mitigate the drug supply chain so that the consumers can afford non-falsified drugs with accurate drug history .

A DpoS or PBFT consensus algorithm are the perfect algorithm for several reasons: first, these algorithms will directly affect or delete the third party miners, who will compete with other miners for computing power under PoW and currency under PoS, in a scenario where all the resources are low and in a industry where the participants are high have equal part in their own success of their supply chains. Second, in terms of power consumption, the resources provided are economical. Third, for private consortium networks, the system is specially designed, which can be directly compared with the current example. Various verification process will be identified and FDA will be the head to the verification process, each and every participants will be paired with other participants and will have the authority to verify contract-specific information, for instance, a wholesaler must verify that the medicines currently received packages and shipping and manufacturing pedigrees match.

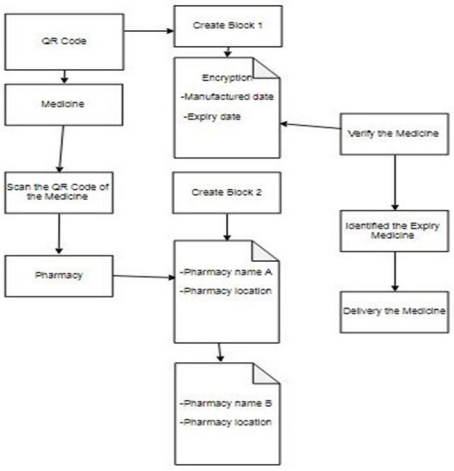

Figure 5: Block added to the blockchain

A. Algorithm

1) Initialisation Phase 1

a) Proceduremedicine(manufacturer, pubk length Phase One, length Phase Two, returnmedicine)
b) Pharmacy sellers
c) Pubk ← pubk
d) Expirydate dateNow() + length Phase One
e) Manufacturing end time ← productexpiry date + length Phase Two
f) Returnmedicine ← returnmeicine During the manufacturing of an medicine, a genesis contract must be placed on the blockchain. This genesis contract contains all of the information that will be necessary to validate the medicine expiry date and manufactured date, ensuring that none are placed after time, that none are placed without the appropriate signed token, if the medicine is expired it will not sold by the consumers.medicine expiry date and manufactured date will be encrypted by using blockchain.

2) Medicine Entry Phase

a) Procedure CHECKMEDICINE(MEDICINE,vote,msghashed m,r,s)
b) Require((dateofproduct() < medicineexpirydate) And (verifyMedicine(msghashed,v,r,s))
c) New pharmacy(mid, medicine)
d) Procedure Pharmacy(mid, medicine)
e) Mid ← mid
f) Medicine ← medicine
g) Sealed ← true
h) Unsealed Time Stamp ← null In order to place a expiry date and manufacturer date on the blockchain, (Algorithm 2) the seller must have first communicated with the CA to receive a signed token authorising the pharmacy. When they make their submission, the manufacturer must include the component parts of this signed token (separation of the token into its component parts costs too much gas on the blockchain to be considered feasible).

3) Medicine Validation Phase

a) Procedure RETURNMEDICINE
b) Require (expiry date < date now())
c) If is Sealed then
d) Is Sealed false
e) Unsealed Time Stamp date Now()
f) Return(sell)

The MID of the sell is publicly available. If this is an changing pharmacy, the replaced Pid MID is also available. It is at this point that the changing the pids can be checked for their validity before the medicine is sell. Security is ensured by the fact that every node on the private blockchain has access to this information also and so can independently verify the medicine manufacturing date and expiry date.

V. CONCLUSION

Development is the desired process in this system. FDA is the important element in this system which will placed in the supervisory data verification role, where each and every data will be supporting the primary data to validate the existing data. The manufacturer will initiate the supply chain process and for every transaction, recursive verification is done. It will allow the consumers to verify the history of the drug which is being purchased by the consumer.. In stimulated network, development and testing will be conducted and thus, the result which is produced will differ from the original results.The project which is being proposed will be disruptive. once tested, the team intends to engage the Philippine FDA to discuss implementation plans and the standard rules are passed to facilitate adoption and sustainability.

A. Abbreviations

DApp - Distributed application
DFS - Distributed file system
DPoS - Delegated proof-of-stake
D-PUNCH - Destroying Products Unfit for Human Consumption

FDA - Food and Drug Administration
GTIN - Global identifier number
PBFT - Practical Byzantine fault tolerance
PoS - Proof-of-stake
PoW - Proof-of-work
RFID - Radio-frequency identification
SSFFC - Substandard/falsely-labeled/falsified/counterfeit
UTAUT - Unified theory of acceptance and use of technology

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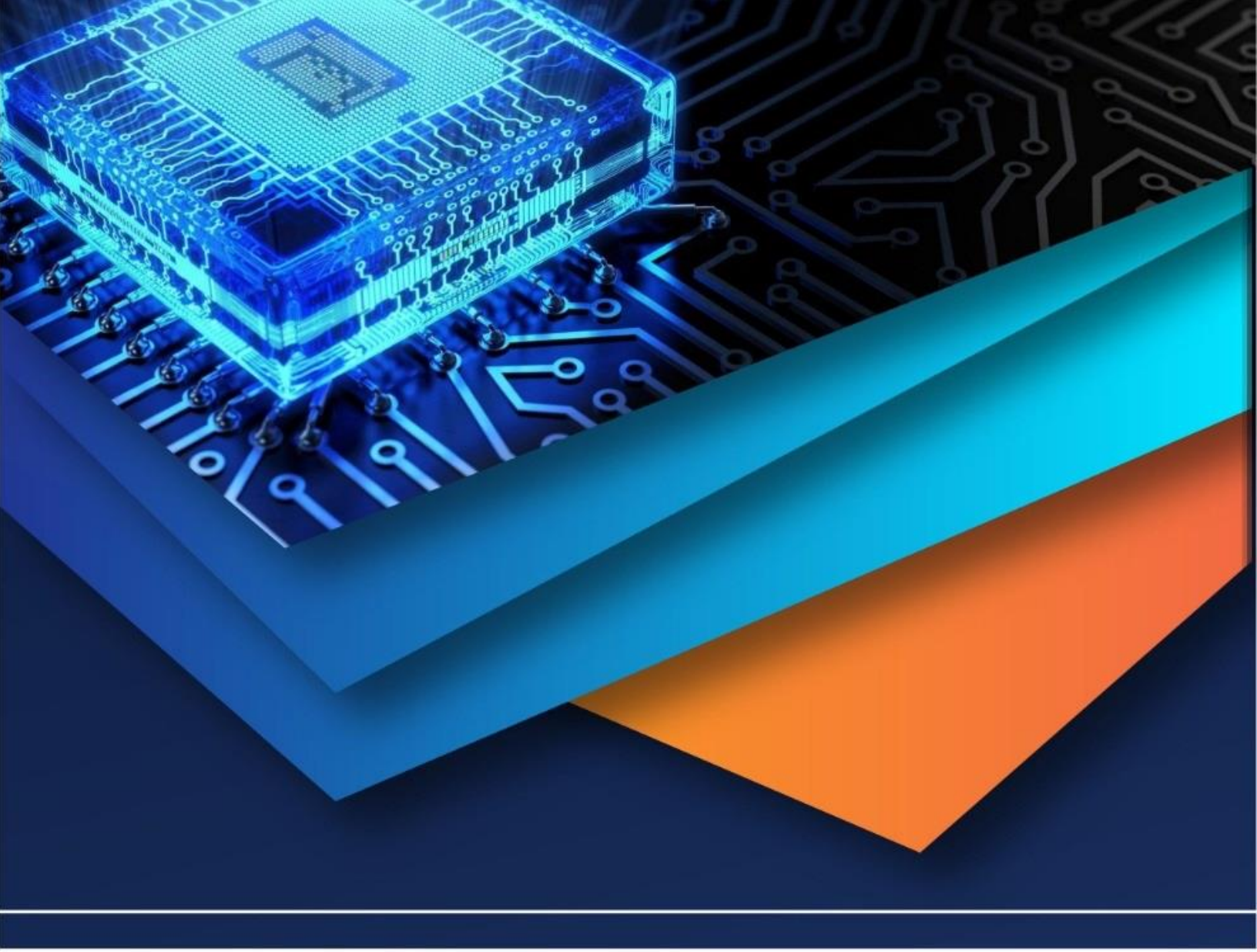

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