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# Regulatory Authority in Pharmacovigilance

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***Abstract:*** ***Based on their Gross National Income (GNI) per capita, the World Bank has categorized 80 economies as High-Income. Global pharmacovigilance rules are primarily driven by three major regulatory stakeholders: the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Pharmaceuticals and Medical Devices Agency (PMDA). This article's goal is to provide an overview of pharmacovigilance systems and procedures in high-income nations, especially those that are also International Conference on Harmonization (ICH) members. Every high-income nation is a part of the WHO PIDM. Medication safety precautions are directly correlated with a nation's income level. The 10 intrepid members of the Uppsala Monitoring Center are from affluent nations and were among the first to act following the thalidomide catastrophe, establishing drug appraisal committees, launching ADR reporting forms, and implementing safety protocols. Although VigiBase is accessible, several nations have their own databases for data management and analysis, such as the FDA Adverse Event Reporting System, the French pharmacovigilance database, the EU's Eudravigilance system, and Canada's Vigilance online database. Strong pharmacovigilance systems are present in all high-income nations. The two international leaders in pharmacovigilance are the USFDA and EMA. The majority of wealthy nations adhere to EMA regulations. The degree of affluence in a nation directly affects the safety of medicines.***

## I. INTRODUCTION

### *A. Pharmacovigilance*

Pharmacovigilance (PV) commonly referred to as drug safety, is the branch of pharmacology that deals with gathering, identifying, evaluating, keeping track of, and preventing harmful effects from pharmaceutical goods. Pharmakon (Greek for drug) and vigilare are the etymological sources of the phrase "pharmacovigilance" (Latin for to keep watch).

Pharmacovigilance therefore places a lot of emphasis on adverse drug reactions (ADR), which are defined as any noxious and unexpected response to a drug, including lack of efficacy with the caveat that this definition. Pharmacovigilance therefore places a lot of emphasis on adverse drug reactions (ADR), which are defined as any noxious and unexpected response to a drug, including lack of efficacy with the caveat that this definition only applies with the doses typically used for.[2,4]


Fig : 1 Key goals of pharmacovigilance

An important part of supplying the data required for pharmacovigilance is information obtained from patients and healthcare providers via pharmacovigilance agreements, as well as from other sources including the medical literature.

Most nations require the licence holder (often a pharmaceutical corporation) to provide adverse event data to the local drug regulatory authority in order to market or test a pharmaceutical product.{20,4}

## II. REGULATORY AUTHORITY

1) Medication errors including overdose, drug addiction, misuse, and exposure to medications when pregnant or breastfeeding are of interest even when there are no adverse events since they may trigger a bad pharmacological reaction.{1}
2) Information received from patients and healthcare providers via pharmacovigilance agreements, as well as from other sources including the medical literature, is crucial for providing the data needed for pharmacovigilance. To advertise or test a pharmaceutical medication, most countries need that the licence holder—often a pharmaceutical company—provide adverse event data to the regional drug regulatory authority.
3) Pharmacovigilance's primary goals are to identify the risks associated with pharmaceutical goods and to decrease the possibility. {1,8}

### A. *Functions of Regulatory Authority*

1) Product registration, including drug evaluation, authorization, and efficacy and safety monitoring.
2) Controls on the production, importation, and distribution of drugs.
3) Information and advertising about drugs are regulated and controlled.
4) Monitoring of adverse drug reactions (ADR).
5) Possession, use, and practise of licences.
6) The main objective of drug regulation is to ensure the efficacy, safety, and quality of medicines.{2}

### B. *Various Regulatory Authority*

1) CDSCO
2) FDA
3) EMA
4) TGA
5) MHLW

## III. LITERATURE SURVEY

### A. *WHO. The Importance of Pharmacovigilance, 2002* {2}

1) Staff and consultants in national drug regulatory authorities
2) Healthcare practitioners including doctors, nurses and pharmacists
3) Pharmaceutical industry executives and scientists
4) Professional staff in national pharmacovigilance centre
5) Editors of medical and scientific journal
6) Health epidemiologists
7) Health economists
8) Professional staff of poison and drug information centres
9) Health administrators
10) Consumer groups and patient support groups
11) Legal advisors in health care
12) Schools of health sciences.

### B. *Greene W. The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market. U.S. International Trade Commission 2007.* {10}

This paper presents an overview of India's pharmaceutical industry and its evolution for almost non-existent to one of the world's leading suppliers of generic drugs. The Indian pharmaceutical industry was allowed to take off when India met its WTO TRIPs obligations and amended its patent laws with the passage and implementation of the Patents (Amendments) Act 2005.

### C. *Wiktorowicz ME, Lexchin J,2008.* {19}

Although pharmaceuticals are assessed for pre-market safety and efficacy, their evaluation involves a risk-benefit analysis recognized as incomplete given the much larger postmarketing experience to follow.

1-4 The market for a product once it has been approved most often includes patient and disease groups never assessed in pre-market clinical trials.
5 Canada's lack of systematic prospective monitoring of drugs once they are marketed means that adverse drug reactions (ADRs) are often not uncovered until years after a drug is on the market.

## IV. SCOPE OF PRESENT WORK

### A. *Important of Regulatory Authority*

In a regulatory or supervisory role, a Regulatory Authority of India is a public entity or governmental body accountable for exercising independent control over specific areas of human activity. {2,4}
They are in place to ensure that safety and norms are adhered to.Regulatory Authorities are government-created institutions that regulate, supervise, and govern diverse industries like insurance, finance, education, and healthcare. Each sector in India has its Regulatory Authority.
They may be independent or act under executive supervision. For example, food safety is the responsibility of the FSSAI, just as financing of rural development is the responsibility of the NABARD. Telecom Regulatory Authority of India (TRAI), National Housing Bank (NBH), National Green Tribunal (NGT), and others are instances of regulatory entities.{20"}

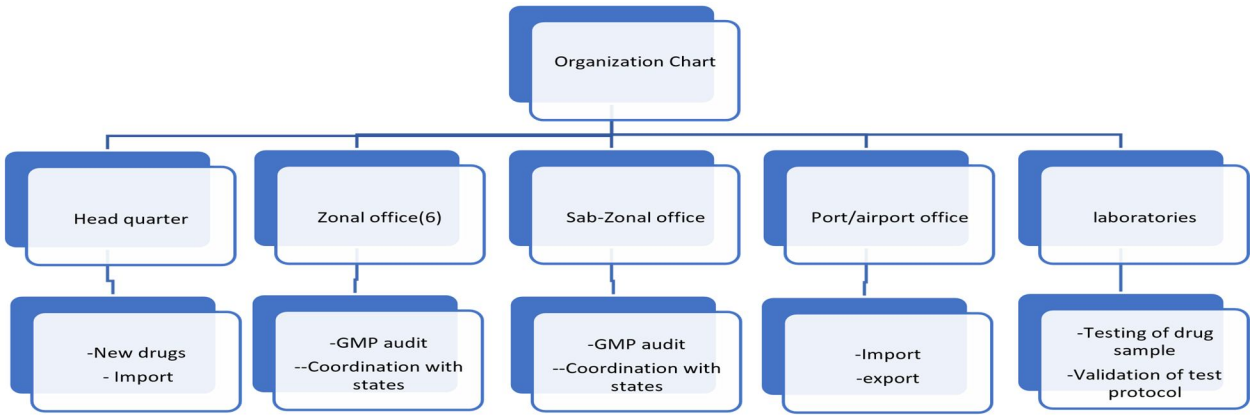
## V. CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

*1)* The National Regulatory Authority is the Central Drugs Standard Control Organization (CDSCO), which is a part of the Directorate General of Health Services, Ministry of Health & Family Welfare, and Government of India
*2)* India's (NRA). Its headquarters are located at FDA Bhawan, Kotla Road, New Delhi 110002, and the organisation also has offices dispersed around the nation in the form of six zones, four subzones, thirteen ports, and seven laboratories.
*3)* The Drugs & Cosmetics Act, 1940 and guidelines, 1945 have given federal & state regulators specific duties for the control of drugs & cosmetics. It plans on implementing the Act's and its Rules' provisions consistently in order to protect patients' safety, rights, and wellbeing by controlling the use of pharmaceuticals and cosmetics. The mission of CDSCO is to promote transparency, accountability.{20}

### A. *Function of CDSCO*

*1)* Directorate General of Health Services.
*2)* Ministry of Health & Family Welfare.
*3)* Government of India is the National Regulatory Authority (NRA) of India.
*4)* Drugs Controller General of India (DCGI).
*5)* Government of India. {4}
*a)* *Vision:* To Protect & Promote Health in India .
*b)* *Mission:* To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

### B. *Organization of CDSCO: {1}*



*1) Head Quarter*

It is in New Delhi. □

*2) Zonal Office*

*a)* Mumbai
*b)* Kolkata
*c)* Chennai
*d)* Ghaziabad
*e)* Ahemdabad
*f)* Hyderabad

The zonal offices support the State Drug Control Administration in ensuring uniform enforcement of the drug act and other related laws across all of India by working closely with them. These are tasked with performing GMP audits and inspecting the production facilities for significant quantities of parental, sera, vaccine, and blood products.{1}

*3) Sub-zonal Office*

*a)* Chandigarh
*b)* Jammu
*c)* Bangalore

These centre co-ordinate with state drug control authorities under their jurisdiction for uniform standard of inspection and enforcement.

*4) Port Offices of CDSCO*

*a)* Examining entrance documents carefully to make sure that imported pharmaceuticals adhere to the law.
*b)* To maintain compliance with the rules by checking the shipping invoices for export for statistical information.
*c)* To make sure that no new drug is introduced into the nation unless the Drugs Licensing Authority approves it in accordance with Rules 122 A & 30AA.
*d)* To confirm that the appropriate Test License (11 or 11-A) or Permit License (12 B), as applicable, has been obtained for any minor amounts of pharmaceuticals imported for use in clinical trials or for personal use.
*e)* Updating statistics on the import and export of medicines and cosmetics.

Collaboration with Customs officials. coordination with Zonal Offices and State Drug Controllers for post-import inspections. creation of monthly, quarterly, and yearly reports.{1,4}

*C. Central Drugs Testing Laboratories (CDTL)*

*1)* Central Drug Laboratory, Kolkata.
*2)* Central Drug Testing Laboratory, Mumbai.
*3)* Central Drug Testing Laboratory, Chennai.
*4)* Central Drug Laboratory, Kasauli.
*5)* Regional Drug Testing Laboratory, Guwahati.
*6)* Regional Drug Testing Laboratory, Chandigarh.
*7)* These laboratories are established under the Indian Drug and Cosmetic Act, 1940 and responsible for quality control of drugs and cosmetics in the country.{7}

The functions of this laboratories include:

*a)* Analytical quality inspection of the vast majority of imported medications sold in the Indian market.
*b)* Serving as an appellate authority in cases of drug quality complaints.
*c)* Establishing standards for medications, cosmetics, diagnostics, and equipment.
*d)* Establishing regulatory measures and amending laws and rules.
*e)* To control the approval of new medications for sale.
*f)* To control Indian clinical research.{15}

*D. Components*

*1)* BA/BE.
*2)* Biologics
*3)* Clinical Trials.
*4)* Cosmetics
*5)* DTAB-DCC
*6)* Drugs
*7)* International Cell Medical Devices & Diagnostics.[16]

*E. Members*

*1)* Director General of Health Services (Chairman).
*2)* Drugs Controller, India.
*3)* Director of the Central Drugs Laboratory, Calcutta.
*4)* Director of the Central Research Institute, Kasauli.
*5)* President of Medical Council of India.
*6)* President of the Pharmacy Council of India.Director of Central Drug Research Institute, Lucknow.[20]

*F. Online Portal*

SUGAM is an online portal for licensing,online submission of applications requesting for permissions related to drugs, clinical trials, ethics committee, medical devices, vaccines and cosmetics.
https://cdscoonline. gov.in/CDSCO/homepage.


Figure No-2 Central Drugs Standard Control Organization

*G. ADR Reporting Form*

Suspected adverse drug reaction reporting form is a form which is used for adverse reaction reporting.[21]

## VI. FOOD AND DRUG ADMINISTRATION (FDA)

The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services.
Headquarters: Silver Spring, Maryland, United States
Commissioner: Janet Woodcock
Jurisdiction: United States
Founded: 30 June 1906
Subsidiaries: Center for Drug Evaluation and Research, more
Founders: Theodore Roosevelt, Harvey Washington Wiley
Parent organization: United States Department of Health and Human Services.

The 1906 Pure Food and Medications Act, a law that took 25 years to pass and outlawed interstate commerce in contaminated and misbranded food and drugs, marked the beginning of FDA's contemporary regulatory activities, even though it did not take on its current name until 1930. The law's primary proponent and early enforcer was Harvey Washington Wiley, Chief Chemist of the USDA Bureau of Chemistry, who provided the fundamental[8]

*A. Function of FDA*

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiat.[4]

*B. Components*

*1)* Food
*2)* Drugs
*3)* Medical Devices
*4)* Vaccines, Blood, and Biologics
*5)* Animal and Veterinary
*6)* Cosmetics
*7)* Tobacco Products

*C. Members*

*1)* Scientific experts including physician- researchers, statistician, engineers medical faculty, chemist biologist and other science orated professionals.
*2)* Consumer representative.
*3)* Industry representative. [4]

*D. Online Portal*

FDA eServices Portal is used for the application for license to operate for health-related devices.


Figure No-3 eServices portal FDA

*E. Form*

Medwatch 3500 – adverse event reporting for consumer
Medwatch 3500 A – adverse event reporting form for health care professionals.[8]

## VII. EUROPEAN MEDICAL AGENCY (EMA)

1) The European Medicines Agency (EMA) is an organisation within the European Union (EU) in responsibility of monitoring and evaluating pharmaceuticals. The name of the organisation was the European Agency for the
2) Medicinal Product Evaluation or European Medicine Evaluation
3) Agency (EMEA) (EMEA)
4) Founded on January 1, 1995, or 27 years ago
5) Headquarters: Netherlands, Amsterda
6) Since its founding in 1995, the European Medicines Agency (EMA) has worked to safeguard human and animal health throughout the European Union (EU) and around the world by evaluating medications in accordance with strict scientific standards and by giving partners and stakeholders unbiased, factual information on medications.[14]

*A. Fuctions of European Medical Agency (EMA)*

The European Medicines Agency (EMA) protects and promotes human and animal health by evaluating and monitoring medicines within the European Union (EU) and the European Economic Area (EEA).
For 25 years, EMA has been fostering research and innovation in the creation of medicines while assuring the efficacy and safety of human and veterinary medicines throughout Europe.[14]

*B. EMA Scientific Committee :*[14]

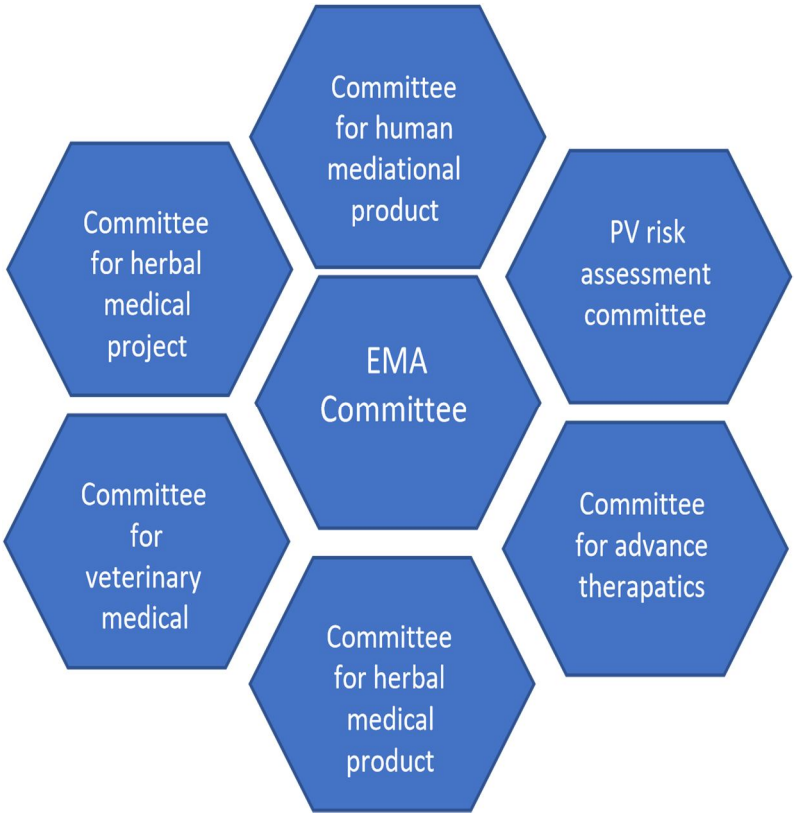



Figure No-4 EMA Committee

*C. Online Portal*


Figure No- 5 Europian Medicine Agency

The Organization Management Service (OMS) was established by the European Medicines Agency (EMA) to support regulatory activities across the European Union (EU). To support EU regulatory actions and corporate processes, the OMS offers a solitary source of organisation data that has been verified. Organized by: https://www.ema.europa.eu.{1}

*D. Forms*

CIOMS- I- Adverse event reporting form

It is form used for reporting adverse reaction of occure due to the drug medicinal product.

## VIII. THERAPEUTIC GOODS ADMINISTRATION (TGA)

The Therapeutic Goods Administration (TGA) is the Australian government's regulatory body for drugs and treatments. [4] The TGA oversees the quality, supply, and marketing of drugs, pathology equipment, medical devices, blood products, and the majority of other therapies as a division of the Department of Health. The Therapeutic Goods Act of 1989, the Therapeutic Goods Regulations of 1990, or a ministerial order all require the TGA to approve and register in the Australian Register of Therapeutic Goods any products that make a therapeutic effect claim, are used in the administration of medication, or fall under any other of those categories.{17} In Australia, the TGA and Office of Drug Control are responsible for overseeing the regulation of medicinal items (ODC). The Health Products Regulation is made up of the TGA and ODC together.{17,4}

## IX. MINISTRY OF HEALTH LABOUR AND WELFARE (MHLW)

Japan's Ministry of Health, Labor, and Welfare (MHLW) is the regulatory authority responsible for establishing and enforcing safety standards for pharmaceuticals and medical equipment. The Pharmaceutical and Medical Device Agency (PMDA), a separate organisation that works with the MHLW, is in charge of examining applications for drugs and medical devices. In order to evaluate the safety of new products, create thorough rules, and keep track of post-market safety, the PMDA collaborates with the MHLW. The Pharmaceuticals and Medical Devices Act (PMD Act) .

The Pharmaceuticals and Medical Devices Act (PMD Act) outlines the current Japan PMDA rules.

The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics is commonly referred to as the Medical Devices Act (PMD Act). {19}

### *A. Forms*

Pharmaceutical and medical device agency [PMLW] –Adverse event reporting agency.

Functions of Regulatory Authority

*1)* Product registration (drug evaluation and authorization, and monitoring of drug efficacy and safety.
*2)* Regulation of drug manufacturing, importation, and distribution.
*3)* Regulation & Control of drug promotion and information.
*4)* Adverse drug reaction (ADR) monitoring.
*5)* Licensing of premises, persons and practices.
*6)* Main goal of drug regulation is to guarantee the safety, efficacy and quality of drugs.[{2,4}]

Timelines for Report Submission:
7 day for Fatal and life threating.
15 days for other serious cases.
90 days for non-serious cases.

## X. CONCLUSION

*1)* Regulatory authority act as guardian that ensure the safety, efficacy and quality of drug available to the public health.
*2)* It has main role in giving permission to any medicinal product for marketing.
*3)* It has main role in etiological study of drug throughout its life in market.
*4)* The guidelines they provide for Development, manufacturing, marketing and post authorization study of drug is mandatory to follow.

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## REFERENCES

[1] Bégaud B, Chaslerie A, Haramburu F. 1994. Organization and results of drug vigilance in France. Rev Epidemiol Sante Publique. 42, 416-23. [
[2] WHO. The Importance of Pharmacovigilance, Safety Monitoring of medicinal products. World Health Organization 2002.
[3] Report E. Effective communications in Pharmacovigilance. International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily 1997; 24-27.
[4] Shuka SS, Gidwani B, Pandey R, Rao SP, Singh V, et al. 2012. Importance of Pharmacovigilance in Indian Pharmaceutical Industry. Asian J. Res. Pharm. Sci. 2, 4-8.
[5] Strom BL. Overview of automated databases in pharmacoepidemiology (ed). Pharmacoepidemiology Chichester. UK, John Wiley & Sons. 2005;p.219–22.
[6] Butlen S, Ducuing F. 2010. European medicines agency support mechanisms fostering orphan drug development. Drug News Perspect. 23, 71-81. 10.1358/dnp.2010.23.1.1437303
[7] Herret E. 2010. Validation and validity of diagnoses in the general practice research database. J Clin Pharmacol.
[8] Abenhaim L. 1996. Appetite-suppressant drugs and the risk of primary pulmonary hypertension. N Engl J Med.
[9] Kaufman DW. 2001. Signal generation and clarification: Use of case-control data. Pharmacoepidemiol Drug Saf.
[10] Greene W. The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market. U.S. International Trade Commission 2007.
[11] "ICH Electronic Common Technical Document (eCTD) v4.0 Implementation Guide in Japan v1.2.0" (PDF). PhMDA. December 2017.
[12] Dr. V. G. Somani, Drugs Controller General of India.
[13] Tulasi Raman Senior pharmacovigilance physician at Quintiles, bangalore.
[14] Committee for Medicinal Products Human Use (CHMP)". European Medicines Agency (EMA). Retrieved 26 July 2020.
[15] Emer Cooke is an Irish pharmacist and Executive Director of the European Medicines Agency (EMA) since November 2020. Regulation (EC) No. 726/2004
[16] Linger M, Martin J. Pharmacovigilance and expedited drug approvals. Aust Prescr 2018.
[17] Therapeutic Goods Administration. Half yearly performance snapshot: July to December 2019. Canberra: Commonwealth of Australia; 2020. [cited 2021 Jan.
[18] Mackay K. Showing the blue card: reporting adverse reactions. Aust Prescr 2005.

[19] Wiktorowicz ME, Lexchin J, Paterson M, Mintzes B, Metge C, Light D, et al. Research networks involved in post-market pharmacosurveillance in the United States, United Kingdom, France, New Zealand, Australia, Norway and
[20] Mann RD, Andrews EB,eds. John Wiley & Sons Ltd, Pharmacovigilance, Chichester. 2002.
[21] Lazarou J, Pomeranz BH, Corey PN, Incidence of adverse drug reactions in hospitalized patients, JAMA, 1998;q
[22] Bord CA, Rachl CL, Adverse drug reactions in United States hospitals. Pharmacotherapy, 2006.
[23] Danan G, Benichou C, Causality assessment of adverse reactions to drugs- a novel method based on the conclusions of international consensus meetings: application to druginduced liver injuries, J ClinEpidemiol, 1993

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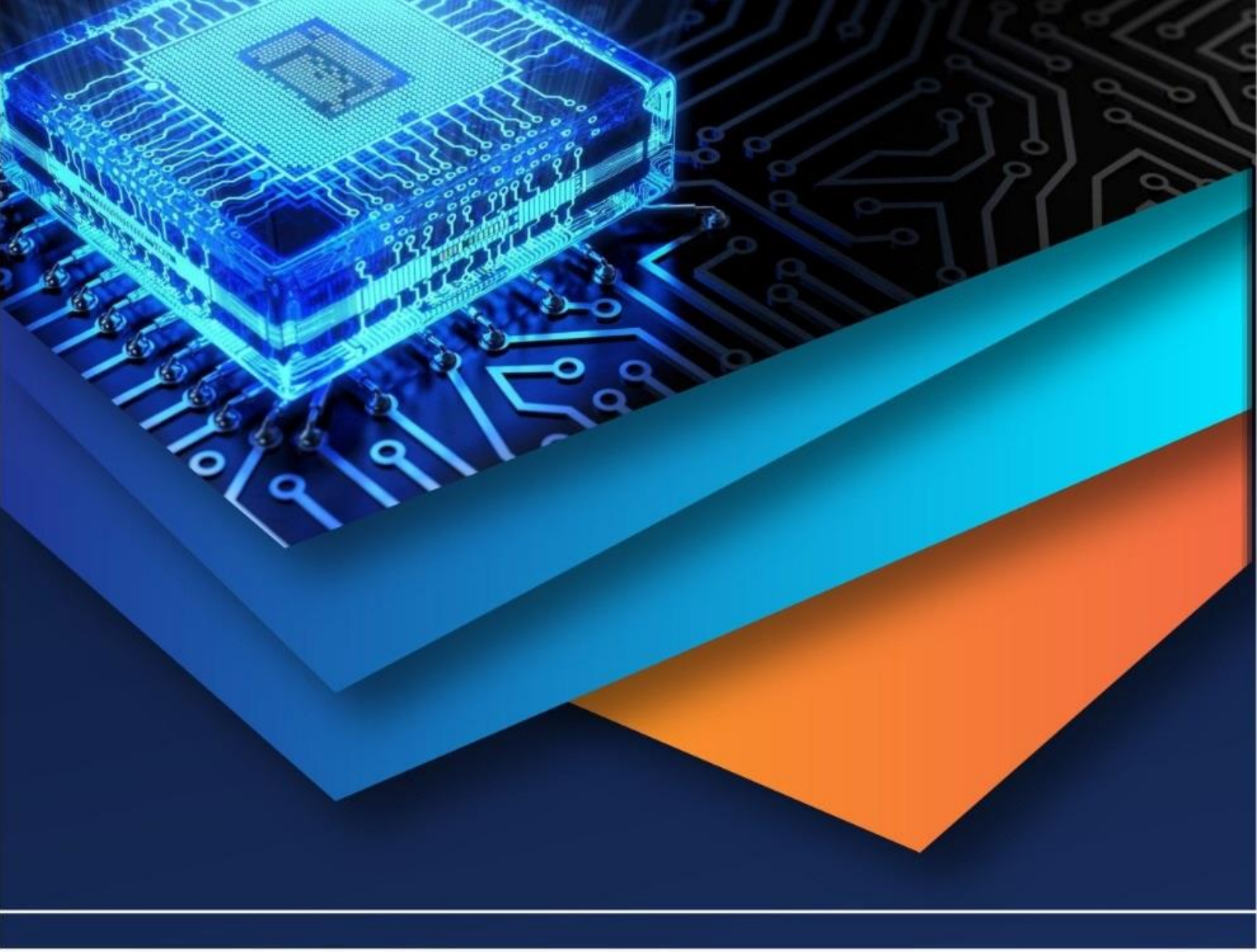

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