Regulatory Perspective and Challenges in The Approval of Nano Pharmaceuticals: A Comparative Study of India and the US

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***Abstract*—Nano pharmaceuticals, which utilise nanoscale carriers, challenge regulatory frameworks intended for conventional drugs. This review contrasts the US FDA's and India's CDSCO's evaluation processes. It references FDA guidance on nanomaterials (April 2022), liposome guidance, and India's 2019 nanopharmaceutical guidelines within its NDCT Rules. The US employs non-binding, product-focused guidance via NDA, 505(b)(2), and ANDA pathways, while India incorporates a specific nano guideline within its existing regulations. Both authorities assess applications on a case-by-case basis, with no formal regulatory definition of nanopharmaceuticals in the US. nanomaterial, whereas the Indian guideline supplies a working definition of a nano pharmaceutical. Shared difficulties are physicochemical characterisation, scale-up, equivalence of follow-on products, immunogenicity and long-term safety. India additionally faces limited implementation capacity, few reference laboratories and a lack of nano-specific pharmacovigilance. Recent updates are reviewed: the FDA final liposome (2018) and nanomaterial (2022) guidance, the FDA platform-technology draft (2024), India's 2019 guideline, and the 2025 EU Innovation Network report. The paper closes with recommendations for harmonisation and capacity building.**

***Index Terms*—nano pharmaceuticals; nanomedicine; regulatory affairs; US FDA; CDSCO; NDCT Rules 2019; nano similar**

I. INTRODUCTION

Nanotechnology has transformed medication delivery since carriers can boost solubility, protect the payload, cross biological barriers, and stay in circulation longer than the free drug [1]. Regulators worldwide have approved approximately 100 nanomedicines, and many more are in advanced development [1]. The US market introduced liposomal doxorubicin (Doxil) and albumin-bound paclitaxel (Abraxane) in 1995 and 2005, respectively [2]. During the COVID-19 pandemic, lipid-nanoparticle mRNA vaccines were introduced.

The FDA and the European Medicines Agency granted emergency authorisation for them [1]. According to a recent comparative analysis, the nanomedicine market the European Medicines Agency within about a year of the first reported infection [1]. A recent comparative review puts the nanomedicine market at roughly USD 241 billion in 2024, with more than 1,000 active clinical trials worldwide [3].

The United States and India make a useful pair. The US has the longest record of approving nanomedicines and the most developed body of product-specific guidance [4,5]. India, which has The United States and India make a useful pair. The US has the longest record of approving nanomedicines and the most developed body of product-specific guidance [4,5]. India, which has a large pharmaceutical industry and an active nanoscience research community, issued its first dedicated guidelines for nano pharmaceuticals in October 2019 [6,7].

This review therefore sets out (i) the regulatory route each country uses, (ii) where the two differ, and (iii) the scientific and administrative obstacles that still delay approval.

1.1 Objectives

The overall aim of this review is to compare the regulatory requirements and approval routes for nano pharmaceuticals in the United States and India, and to show how they can be made clearer and more consistent.

The specific objectives are:

1. To describe the legal and guidance framework each country applies to nanopharmaceuticals: the FDA guidance documents and the NDA, 505(b)(2) and ANDA routes in the US, and the 2019 nanopharmaceutical guidelines and NDCT Rules 2019 in India.
2. To compare definitions, categorisation, quality, non-clinical, clinical, labelling and pharmacovigilance requirements in the two systems.
3. To provide an overview of the FDA, Indian authorities (CDSCO, DBT, and ICMR), European regulators, and international organisations' most recent and updated recommendations and regulatory actions (2018 to 2026).
4. To determine the administrative and scientific obstacles, such as characterisation, scale-up, immunogenicity, equivalency of follow-on products, and regulatory capability, that impede approval.
5. To make doable suggestions for India's capacity enhancement and harmonisation.

II. METHODOLOGY

Instead of being methodical, the review is narrative. In October 2026, the US FDA website, Indian government and CDSCO content, publisher and repository pages, and open web searches were used to find sources. Priority was given to official guidelines, regulations, and government releases; trade-press articles were simply utilised to verify dates, and peer-reviewed reviews were used to evaluate them and highlight recurrent issues [8,9]. The FDA and CDSCO websites should be reviewed again before submission because the literature is not comprehensive and both agencies revise guidelines without prior notice.

III. NANOPHARMACEUTICALS: PLATFORMS, PRODUCTS AND THE REGULATORY QUESTION

3.1 Main platforms

The phrase "nanopharmaceutical" refers to a number of technologies with quite different manufacturing processes, structures, and behaviours. The most well-known platform is liposomes, which are vesicles made of lipid bilayers and account for a large number of oncology treatments sold in the US [2,10]. Tumour delivery and solubility are enhanced by albumin-bound nanoparticles, such as paclitaxel [2,11]. PLGA depot formulations for leuprolide and PEG-protein conjugates such asparaginase are examples of polymer-based systems [2,10]. A more recent type consists of lipid-based RNA carriers like patisiran and the COVID-19 mRNA vaccines, while another class consists of milling-produced nanocrystals [1].

3.2 Products approved by the US FDA

US FDA-approved items: Table 1 provides a list of representative products. Because accelerated approval, full approval, and later extensions are occasionally reported as distinct occurrences, dates are derived from the mentioned sources and may vary amongst them.

Table 1: Selected FDA-approved nanomedicines

Product	Platform	Active substance	Main indication	FDA approval
Doxil / Caelyx	PEGylated liposome	Doxorubicin	Kaposi sarcoma, ovarian cancer, multiple myeloma	1995 [2,11]
Eligard	PLGA polymer depot	Leuprolide acetate	Prostate cancer	2002 [10]
Abraxane	Albumin-bound nanoparticle	Paclitaxel	Breast, lung and pancreatic cancer	2005; pancreatic use 2013 [2,11]
Oncaspar	PEG-protein conjugate	L-asparaginase	Acute lymphoblastic leukaemia	2006 (earlier approval 1994 also listed) [2,10]
Onivyde	PEGylated liposome	Irinotecan	Pancreatic cancer	2015 [2]
Vyxeos	Liposome	Daunorubicin and cytarabine	Acute myeloid leukaemia	2017 [2]
AmBisome	Liposome	Amphotericin B	Fungal and protozoal infections	1997 [12]

3.3 Why these products need special regulatory attention

Two features set nanopharmaceuticals apart from small-molecule drugs. First, the final product is often a structured system in which the active ingredient, carrier and sometimes a targeting ligand act together, so the safety and activity of the whole cannot be inferred from the parts [1]. Second, particle size, surface charge, and release rate can shift with small changes in process conditions or storage, so quality control must follow the manufacturing process as well as the finished batch [1,13]. Regulators therefore require additional characterisation, stability data, and, for follow-on products, additional evidence of equivalence [4,14].

IV. REGULATORY FRAMEWORK IN THE UNITED STATES

4.1 Guiding documents

Nanomaterials are not regarded by the FDA as a distinct legal category. In addition to asking case-specific enquiries regarding whether a product incorporates the application of nanotechnology, it has not established regulatory definitions for "nanotechnology," "nanomaterial," or "nanoscale." This approach was initially outlined in its June 2014 considerations guideline [15].

For pharmaceutical items, even if one dimension is up to 1,000 nm, the FDA may nonetheless consider a material designed to exhibit specific characteristics to be a nanomaterial [13]. The guidelines do not consider proteins, nucleic acids, and other naturally tiny biological components to be nanomaterials [13]. Drug Products, Including Biological Products, that Contain Nanomaterials is the main document. It was released as a draft in December 2017 and finalised in April 2022 under docket FDA-2017-D-0759 [4,16,17]. It applies to human pharmaceutical goods, including biological medicines, where the final dosage form contains a nanomaterial [4]. The FDA examined 13 public comments between the draft and the final language. amended the over-the-counter monograph section to reflect the CARES Act amendments and improved its discussion of shorter applications [16, 17].

The guidelines address clinical, non-clinical, and quality factors in both production and development [16]. Unless it references a statute or regulation, it is a series of recommendations rather than a legally binding mandate, as is the case with all FDA guidelines [4].

4.2 Product-specific guidance for liposomes

The most advanced guidelines apply to liposomal products. The FDA released a draft in 2002, updated it in October 2015 to include follow-on products, and released the final advice in April 2018 [5,18,19,20]. It discusses CMC, human pharmacokinetics, bioavailability or bioequivalence, labelling for ANDAs and NDAs, and points out that bioequivalence is unlikely to be demonstrated by plasma concentration alone [5,18]. Clinical and in vitro research on liposomal doxorubicin is described in a product-specific guideline for generic makers [5].

4.3 Approval pathways

Non-biological complex medications are not officially recognised by the FDA as a class. A liposomal product incorporating an approved medication may employ the 505(b)(2) route [18], whereas originator products use the NDA route and follow-on versions use the ANDA route [5]. Three issues are brought up by subsequent versions: the active ingredient's sameness, the physicochemical qualities' equivalency, and the case-by-case equivalency of in vivo exposure [14]. Stability testing is anticipated; typical issues include aggregation, changes in particle size, shape, or solid state, and the sensitivity of nanomaterials to scale-up [13]. The FDA encourages pre-market communication and keeps an eye on nanomedicines once they are approved [1].

V. REGULATORY FRAMEWORK IN INDIA

5.1 The 2019 nanopharmaceutical guidelines

The Guidelines for Evaluation of Nanopharmaceuticals in India, which were collaboratively developed by DBT, ICMR, and CDSCO, were published on October 24, 2019, by the Union Minister for Science and Technology and Health and Family Welfare [6,7]. Within Schedule Y of the Drugs and Cosmetics Rules, 1945 and the Second Schedule of the NDCT Rules, 2019 [22], their declared goal is a transparent, uniform, and predictable regulatory path [6,21]. A nanopharmaceutical is characterised as a formulation that incorporates nanomaterials intended for internal or external

application in people for therapeutic, diagnostic, or health-related objectives [22]. It pertains to completed formulations and the active component of a novel or modified molecule [6], encompassing aspects from definition and classification to pharmacovigilance [7]. Stability testing should emphasise functionality, integrity, and size range, while also articulating the benefits and potential drawbacks compared to a traditional medication [22]. The writers recognised the absence of universally standardised rules and noted that individual assessments are typically the prevailing agreement.

5.2 The NDCT Rules, 2019

The general new-drug system is used to approve nanopharmaceuticals. The New Drugs and Clinical Trials Rules, 2019 took the place of Part X-A of the Drugs and Cosmetics Rules and Schedule Y on March 19, 2019, governing new drugs and clinical trials in India [23, 24]. Clinical trials, bioavailability and bioequivalence studies for human use, novel medications, and investigational new drugs are all subject to the regulations [23]. New claims, indications, administration methods, dosages, and dosage forms are all included in the broad definition of a new medicine [23, 24]. Therefore, a nano formulation of an existing chemical may be classified as a novel drug [6].

Using forms like CT-04 for permission to conduct a clinical study, CT-06 for permission granted, CT-10 for a test licence, and CT-18 for marketing authorisation of a new drug, the applicant often files through CDSCO's SUGAM portal [24,25]. The Subject Expert Committee (SEC) reviews applications [24]. According to CDSCO presentations, new drug applications take 90 days to process, while clinical trial applications for medications manufactured in India take roughly 30 days [24].

5.3 Status and capacity

The 2019 rules are seen as a significant first step in a 2026 comparative evaluation; however, implementation and capacity are found to be restricted [3]. Federal regulatory testing laboratories were requested earlier by a government scientist [26], and two Indian legal professors continued to characterise the framework for regulating nanomedicine as ambiguous in 2021 [27].

VI. QUALITY, MANUFACTURING AND ANALYTICAL EXPECTATIONS

Both nations' regulators prioritise product quality while evaluating nanopharmaceuticals. The following assumptions apply, in general, to applications in either nation and are derived from a review of translational barriers and FDA material [1,13].

6.1 Active ingredient and excipients

Whether a nanomedicine counts as an active pharmaceutical ingredient (API) depends partly on the sponsor's regulatory strategy and on whether the drug is conjugated to or encapsulated in the carrier [1]. Few are classed as APIs; most are treated as prodrugs or finished products [1]. The safety of each component of a complex therapeutic must be demonstrated unless it has a long record of clinical use, and an excipient that is itself a particle must be characterised as carefully as the API [1]. ICH Q3A to Q3D controls chemical, physical, and biological quality, and limits on sterility, endotoxin, and bioburden [1].

6.2 Manufacturing and scale-up

Moving from tiny laboratory batches to industrial levels and choosing excipients is the most difficult stage of development [1]. There are two families of manufacturing techniques. Approved nanocrystal products have been supported by top-down techniques that reduce bigger material to the nanoscale, such as wet milling or high-pressure homogenisation [1]. Although bottom-up approaches are more adaptable and produce more complex products, they are more difficult to scale up in an industrial setting [1].

Doxil and other liposomal products are manufactured from the bottom up [1]. As a result, quality-oriented production and a quality management system that pinpoints and regulates crucial stages in every process are recommended by the same evaluation [1].

6.3 Quality by design and critical quality attributes

The FDA and ICH developed a risk-based framework called Quality by Design (QbD) to incorporate quality into products instead of testing them at the end [1]. It starts with a quality target product profile and critical quality characteristics (CQAs), then moves on to risk assessment, experiment design, design space, control strategy, and life-cycle monitoring [1].

Particle size, encapsulation efficiency, polydispersity index, zeta potential, and drug release kinetics are the CQAs for nanomedicines that are most frequently investigated; real-time evaluation is supported by process analytical technology (PAT) [1]. Due to technical complexity, few QbD steps have been used thus far [1].

6.4 Characterisation methods

Composition, average particle size, size polydispersity, shape and morphology, and physical and chemical stability must all be assessed in pertinent biological settings where proteins have the power to alter particle size or induce aggregation [1]. Dynamic light scattering, field-flow fractionation, electron microscopy, and zeta potential measurement are common techniques [1].

VII. INTERNATIONAL PERSPECTIVE

Case-by-case examination is also used by other regulators, demonstrating the potential benefits of harmonisation. European Union and United Kingdom. The European Medicines Agency (EMA) applies ordinary medicinal-product legislation to nanomedicines, and the European Commission published a non-binding guideline on the definition of nanomaterial in 2011 [1]. Intravenous liposomal products, block copolymer micelles, and iron-based nano-colloidal products are among the product types for which the EMA has published reflection papers [1]. Additionally, the UK's MHRA promotes early communication with sponsors and assesses nanomedicines on a case-by-case basis [1].

International harmonization

A working group on nanomedicines within the International Pharmaceutical Regulators Program seeks to reach a consensus regarding the information that regulators ought to be provided [1]. India's guidance is an early national move in an area where alignment is still being developed [1,3], as there are still differences in definitions, standards, and test techniques for proving similarity [3].

VIII. RECENT UPDATED GUIDELINES AND REGULATORY DEVELOPMENTS

Since the initial FDA and EMA guidelines from the 2010s, guidance on nanomedicines has evolved. The primary publications about nanopharmaceuticals that were published or modified between 2018 and 2025 are described in Sections 8.1 to 8.3. Before relying on any document given here, applicants should verify the most recent version on the agency website. The status was taken from the pages retrieved in October 2026.

8.1 United States

Finalised liposome guideline (2018).

The FDA completed the October 2015 amended draft and released the final guidance on liposome medicinal products in April 2018. Chemistry, manufacturing and controls (CMC), human pharmacokinetics with bioavailability or bioequivalence and labelling for ANDAs and NDAs are all covered; all components, including lipids, should be listed on the label [19, 20]. Liposomal candidates are directed to this paper by India's 2019 guideline [9].

Finalised general nanomaterial guidelines (2022). On April 22, 2022, the Federal Register published the final advice on drug products including nanomaterials (87 FR 24169), which completes the December 2017 draft [8,28]. It acknowledges that a nanomaterial can be an excipient whose control, like lipid purity in a liposome, can be crucial, adds a lexicon, and updates its discussion of shortened applications [13,28].

Designation of platform technology (2024).

Under section 506K of the FD&C Act, the FDA released draft guidelines on the Platform Technology Designation Program in May 2024 [29, 30]. Examples include lipid-nanoparticle platforms for oligonucleotides, gene therapy products, and mRNA vaccinations. With a 90-day response period, a designation may permit early FDA engagement and the reuse of data from an earlier product on the same platform [29, 30]. It is important to verify the guidance's status because the sources refer to it as a draft.

8.2 India

There was no updated version of the 2019 guidelines available, and the guidelines themselves state that if knowledge of nanomaterial safety increases, the first edition may need to be modified [9]. The following information is added to section 5.1 in the full text.

Four types of regulations.

CDSCO evaluates all nanopharmaceuticals as novel medications, subjecting them to varying levels of

examination depending on their category [9]. Both are classified as investigational novel medications under the Second Schedule of the NDCT Rules [9]. Category I is a new molecular entity with a new nanocarrier, and Category II is a new molecular entity with a nanocarrier already approved elsewhere. A medicine classified as Category III is one that has been approved in India or other well-regulated nations but uses a novel nanocarrier; complete drug data may not be required, but sufficient proof of the nanomaterial and finished product is [9].

Category IV is a product whose drug and nanocarrier are both approved in well-regulated countries but not in India, and it is subject to abbreviated or bridging studies [9].

8.3 European Union and international bodies

EU Innovation Network report (2025). Report from the EU Innovation Network (2025). In January 2025, the EU Innovation Network, which unites state agencies and EMA, released a horizon-scanning paper on therapeutic goods based on nanotechnology [31, 32]. It states that development is moving toward more complex, multicomponent particles and that lipid nanoparticles are now necessary for mRNA distribution. It asks for a risk-based, product-specific approach and identifies the limitations of standardising important qualities and classifying products as medicines or devices [31, 32]. Previous EMA reflection papers on iron-based nano-colloidal, liposomal, and block copolymer micelle products are still in use as statements of current expectations rather than official guidelines [33, 34].

8.4 Implications for the India–US comparison

The next three points are as follows. First, the platform-designation draft adds a potentially quicker route for lipid-nanoparticle products without an Indian counterpart in the evaluated sources, and the US documents in sections 4.1 and 4.2 are now final. Second, unlike the FDA's liposome guidelines, India's Category IV offers a path for subsequent goods but does not include product-specific bioequivalence advice [9,19]. Third, section 13 is in line with the EU's request for unified advice [32].

IX. COMPARATIVE ANALYSIS: INDIA AND THE USA

Although the two systems have a similar case-by-case methodology, they differ in the amount and bindingness of their nano-specific content. The key ideas from sections 4 and 5 are summarised in Table 2.

Table 2. Comparing the laws governing nanopharmaceuticals in the United States and India

Parameter	USA (FDA)	India (CDSCO with DBT and ICMR)
Nano-specific document	Guidance for industry on drug products containing nanomaterials; draft 2017, final April 2022 [4,16,17]	Guidelines for Evaluation of Nanopharmaceuticals, released 24 October 2019 [6,7]
Origin	Issued by the agency (CDER) [4]	Joint effort of DBT, ICMR and CDSCO [6,7]
Formal force	Non-binding recommendations unless a statute or regulation is cited [4]	Prepared to operate within the Second Schedule of the NDCT Rules 2019 [22]; exact legal force to be confirmed from the primary text
Definition	No regulatory definition; case-specific questions, materials up to 1,000 nm may be considered [13,15]	Working definition of a nanopharmaceutical in the guideline [22]; a nanomaterial is generally 1 to 100 nm in at least one dimension, and up to 1,000 nm where size-related effects are shown [9]
Basic legal route	NDA, 505(b)(2) and ANDA [5,18]	New drug application and clinical trial permission under the NDCT Rules 2019 [23,25]
Follow-on products	ANDA with product-specific bioequivalence advice (e.g., liposomal doxorubicin) [5,14]	Category IV products (drug and nanocarrier approved in well-regulated countries but not in India) face abbreviated or bridging studies [9]; product-specific bioequivalence advice not detailed and flagged as a gap [3]

Quality and stability	Size, morphology and aggregation stability expected; sensitivity to scale-up noted [13]	Stability testing focused on functionality, integrity and size range [22]
Labelling	Governed by the product's NDA or ANDA [5]	Advantages and disadvantages versus conventional drug to be stated [22]
Pharmacovigilance	Post-approval monitoring by FDA [1]	Covered in the guideline's scope [7]; nano-specific pharmacovigilance still a gap [3]
Reported main weakness	Guidance remains non-binding and unconsolidated [1]	Limited implementation and capacity [3]

Three contrasts are worth discussing. First, India has chosen a single general guideline that was prepared ahead of a substantial clearance record, whereas the US depends on cumulative product experience and product-specific suggestions [5,6,26]. Second, the labelling guidelines in India are more strict [22]. Third, the US has written more on follow-on goods, which present the most challenging scientific issues for reviewers [14]. Both approaches anticipate characterisation of size, size distribution, shape, stability, and drug release [1,13,22].

X. CHALLENGES IN THE APPROVAL OF NANOPHARMACEUTICALS

10.1 Definition and classification

There is no common description or classification of nanomedicines among agencies, which is mentioned among the key hurdles to regulation and creates fragmentation in terms, test criteria and review procedures [1,3].

The US leaves the topic to case-specific questions [13,15]; India's guideline defines the product class, but its relationship to other legal categories, such as medical devices, is not stated in the sources evaluated [1,22].

10.2 Characterisation, quality and scale-up

Size, polydispersity, surface characteristics, drug loading, free drug, and release kinetics must all be characterised for nanomedicines and assessed in appropriate biological media; the appropriate technique varies depending on the type of nanomaterial [1].

QbD is infrequently used in reality, and one of the most difficult phases is going from small laboratory batches to industrial volumes [1]. Sensitivity to process conditions and scale-up is noted by the FDA itself [13].

10.3 Immunogenicity and non-clinical safety

Nanoparticle biodistribution is difficult to anticipate because early toxicological models and current in vitro models do not adequately represent the complexity of the live body [1]. Immunogenicity testing is identified as a glaring deficiency in the comparative study [3]. Protein-corona analysis and organ-on-a-chip devices could be useful [1].

10.4 Bioequivalence and nanosimilars

Small variations in particle size or the way the drug and carrier are arranged can alter the behaviour of generic versions in vivo. Three obstacles are described by FDA scientists: the active ingredient's sameness, the physicochemical qualities' and exposure's equivalency [14], and the possibility that plasma levels by themselves won't prove equivalency [18]. Similar standards are probably applicable to "nanosimilars" [1], and bioequivalence is still lacking in the US, EU, and India [3].

10.5 Divergent global requirements

Different definitions, test requirements, and follow-up procedures apply to sponsors who intend to file in multiple regions [1, 3]. This is problematic for India's big patient population since it increases development costs and may cause access delays in nations with less developed regulatory frameworks [3,26]. The primary approaches now being pursued are sharing protocols from reference laboratories and harmonisation under the international regulators' program [1].

XI. ILLUSTRATIVE CASE STUDIES

11.1 Doxil: first-in-class and a long approval path

In 1995, the FDA approved PEGylated liposomal doxorubicin as the first nanomedicine for AIDS-related Kaposi sarcoma under accelerated approval; ovarian cancer and multiple myeloma followed in

1999 and 2007, respectively [11]. It was intended to decrease cardiac side effects and increase circulation time [11]. The FDA's subsequent bioequivalence recommendation for generic liposomal doxorubicin demonstrates how early product experience influenced subsequent recommendations [5].

11.2 Abraxane: a reformulation with a new carrier

2005 saw the approval of albumin-bound paclitaxel for breast cancer, and 2013 saw its approval for pancreatic cancer [11]. It decreased the toxicity associated with solvent-based vehicles and increased paclitaxel's solubility [11].

It demonstrates how a nanocarrier can change an established molecule, which is precisely what India's guidelines for an accepted molecule with changed nanoscale features address [6,11].

XII. FUTURE PERSPECTIVES

Three developments are worth mentioning. First, consolidation of guidance: early agency collaboration is beneficial since nanomedicine development will encounter regulatory challenges as long as guidance is imprecise and unconsolidated [1]. Second, fragmentation may be lessened by regulatory intelligence, which is the methodical observation of regulations, approvals, and safety reports [3]. Third, the use of AI technologies for regulatory duties is growing, but this requires appropriate supervision [3,27]. The discrepancy between laboratory results and clinical outcomes could be reduced with improved preclinical models and standard reference materials [1].

XIII. RECOMMENDATIONS

The following proposals are the authors' synthesis of the sources reviewed.

1. Update and combine. The FDA's product-specific strategy for liposomes should serve as the paradigm for India's clear guidelines on shortened and follow-on nanomedicine applications [3,5,14].
2. Increase testing capability. In keeping with recommendations for national testing facilities, specialised reference laboratories, skilled reviewers, and shared analytical techniques should be established [3,26].
3. Increase post-market monitoring. As suggested by the comparative review [3], India's pharmacovigilance system requires nano-specific reporting and follow-up.
4. Use standardised characterisation and QbD. As advised for the development of nanomedicine, applicants should apply orthogonal analytical techniques and identify important quality parameters early [1].
5. Involve authorities as soon as possible. Consultation during development is encouraged by the FDA and other authorities, which reduces the possibility of late-stage surprises [1].
6. Go for harmonisation. Divergent criteria impede global progress; thus, India should continue to participate in international attempts to unify terminology and data needs [1,3].
7. Revise the Indian regulations. Periodic revisions are anticipated in India's 2019 guideline [9]. A new version might incorporate product-specific recommendations for subsequent products, cross-reference the FDA's final 2022 and 2018 liposome guidelines, and take into account the 2025 EU findings [8,9,19,32].

XIV. DISCUSSION

The regulation of nanopharmaceuticals differs between the US and India, with the US FDA following product-specific, non-binding guidance and India adopting dedicated 2019 guidelines under the NDCT Rules. Both countries use case-by-case evaluation, but differences in classification and approval requirements create harmonisation challenges. Key concerns include product characterisation, quality control, manufacturing scale-up, safety, immunogenicity and bioequivalence. In India, limited testing facilities, technical expertise and nano-specific pharmacovigilance further affect regulatory implementation. Future improvements require updated guidelines, advanced analytical techniques, better testing facilities and international regulatory harmonisation.

XV. CONCLUSION

Although they have different structures, the US and India both assess nanopharmaceuticals on a case-by-case basis and demand the same fundamental qualities. The US uses well-developed guidance on liposomes, along with non-binding, product-focused guidelines,

on top of recognised pathways. India has a specific 2019 guideline under the NDCT Rules framework, which offers a clear transparency benefit but is hampered by gaps in immunogenicity and bioequivalence, as well as inadequate implementation capacity. Together with pharmacovigilance. One nation cannot handle common issues like definition, description, scale-up, and the equivalency of subsequent products on its own. Building capability in India, providing more detailed product guidance in both nations, and maintaining worldwide alignment will all be necessary for progress.

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