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Review Article

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Regulatory Frameworks Governing Pharmaceutical Manufacturing Site Transfers: A Comparative Review of WHO, EMA, and US FDA Approaches

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Abstract

Pharmaceutical manufacturing site transfers are critical strategic activities driven by mergers, outsourcing, and supply chain optimization, yet they carry significant risks to product quality and patient safety if not properly regulated. This review provides a comparative analysis of the regulatory frameworks governing site transfers established by the World Health Organization (WHO), the European Medicines Agency (EMA), and the United States Food and Drug Administration (FDA), contextualized within the harmonization efforts of the International Council for Harmonisation (ICH). Publicly available regulatory guidelines, including WHO Annex 7 of TRS 961, EMA Commission Regulation (EC) No 1234/2008, FDA 21 CFR Part 314.70, and ICH quality guidelines Q8-Q12, were systematically reviewed and compared. The analysis reveals that while all three bodies share the fundamental goal of ensuring product quality, safety, and efficacy during transfers, their approaches differ significantly. The WHO provides a process-oriented, knowledge-based blueprint emphasizing Technology Transfer Plans and Analytical Method Transfer. The EMA employs a legally binding, risk-based variation classification system (Type IA, IB, II) with defined procedural timelines. The FDA utilizes a tiered submission pathway (PAS, CBE-30, Annual Report) heavily influenced by facility inspection history and operational parity. Key challenges including harmonization gaps, documentation burden, inspection delays, and supply continuity risks are examined alongside strategic best practices such as early regulatory engagement, robust project management, and inspection readiness. This review concludes that a comprehensive understanding of these distinct regulatory frameworks, combined with the application of ICH principles, enables pharmaceutical companies to execute compliant and efficient global site transfers, ultimately ensuring uninterrupted delivery of safe and effective medicines to patients worldwide.

Conclusion: This review highlights the need for a well-structured regulatory strategy that ensures product quality, patient safety, and efficient global pharmaceutical site transfers.

Keywords: Site Transfer, Technology Transfer; Regulatory Framework; WHO; EMA; FDA; ICH; Variation Classification; GMP Compliance

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1. Introduction

Pharmaceutical site transfer, which encompasses the transfer of drug manufacturing from one facility to another, is a standard business practice that often occurs due to mergers, outsourcing, or optimizing the supply chain. While site transfers may be routine, they can be hazardous, given that the new site's equipment, environment, and personnel all have the potential to impact the product's critical quality attributes. Based on the potential risk to patients, it is clearly essential for the global health authorities to regulate site transfers to protect both patient safety as part of a Good Manufacturing Practice (GMP) compliance framework, and to make sure that the supply of medicines continues without interruption. (1)

This paper reviews and compares the regulatory site transfer frameworks established by three public health bodies: the World Health Organization (WHO), the European Medicines Agency (EMA), and the United States Food and Drug Administration (FDA), starting from the context of the work being developed by the International Council for Harmonization (ICH), which aims to harmonise regulations across the global health authorities. The aim is to consolidate their different requirements - such as classification of variation, type of submission, and support documentation - into a helpful and clear guide for the reader. The goal of this paper is to

clarify each organisation's approach to site transfer, which will inform industry professionals and assist them in the planning and execution of compliant site transfers, in order to facilitate the reliable supply of medicines to patients.

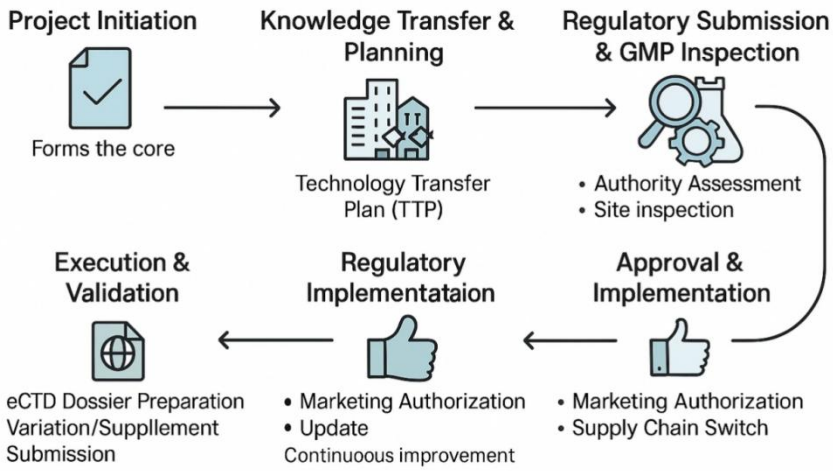

Figure 1. The Integrated Site Transfer Lifecycle

2. Regulatory frameworks for site transfers

Understanding regulatory requirements for a site transfer will require a full understanding of the different, though sometimes overlapping, frameworks laid out by global authorities. (2) We will discuss the specific guidelines of the WHO, EMA, and FDA, and describe the importance of ICH harmonization guidelines that serve as the foundation for modern regulatory rationale.

2.1 World Health Organization (WHO) Framework

The WHO defines its technology transfer approach in Annex 7 of Technical Report Series (TRS) 961 (2011) as a broad universal model, particularly useful for National Regulatory Authorities (NRAs) in developing strong national systems and for manufacturers who operate internationally. Its strength lies in how comprehensive it is as a process and not as a rigid legal classification system, for example. The WHO defines technology transfer as "a systematic procedure that is followed to pass the documented process and knowledge from one party to another." This clearly indicates that it is not just the transfer of equipment, but a knowledge-based process. WHO's Guidelines provide a structured framework to cover all major aspects:

Organization and Management: The WHO emphasizes that the first issue of transfer is always an organizational/management issue. This requires establishing a joint team from both transferring and receiving units, with a transfer coordinator. (3) The joint team is responsible for writing a detailed, project specific Technology Transfer Plan (TTP) as the master document addressing scope, timing, responsibilities, acceptance criteria, and a clear definition of successful transfer.

Process Transfer, Packaging Transfer, and Cleaning Transfer: The central activity of the transfer is to replicate the process at the new location. The guideline specifies validating the process (typically at least three consecutive validation batches) at the receiving location to demonstrate control and consistency. Similarly, packaging and cleaning must be established and validated to defined criteria to demonstrate product integrity and cross-contamination avoidance.

Analytical Method Transfer (AMT): This is a key element, and the WHO states that a product can only be released and made available in the marketplace if it can be accurately tested. The receiving site's quality control (QC) lab must show competence in performing the test in accordance with the transfer of the method, and this is usually accomplished through formal AMT protocol. You may transfer the method and test by comparative testing, and you'll do a co-validation in your lab, or you may have a waiver if previous experience speaks to the method's difficulty and complexity.

The Technology Transfer Report: After the technology transfer has been performed, a complete report will be generated. This report is the only documentation of record for the transfer, and it will summarize all work, all data collected, any deviations, and will provide a summary statement as to the outcome determined on the transfer of the technology. This report will also serve as evidence for internal audits and regulatory inspections, demonstrating that the new site is capable of producing an equivalent product to the original.

The WHO framework intends to consider the product's safety, efficacy, and quality while moving from one manufacturing site to another; however, the WHO also wants to provide improvements in efficiency and ensure to maintain regulatory compliance at all manufacturing sites. (4)

2.2. European Medicines Agency (EMA) Framework

The EU has a very formalized and legally binding regulatory framework. Transfers of sites are classified as variations under Commission Regulation (EC) No 1234/2008, related to the assessment of variations to marketing authorizations. The EMA regulatory framework

is based on risk-based classifications. This determines how submissions will occur and the required timelines.

Variations are classified into:

Type A Variation (including IAIN: Immediate Notification): Changes that do not have a material impact on quality, safety, and/or efficacy.

- **Procedures:** Do & Tell. The change takes effect immediately, and then the MAH notifies the authority after the fact. Type IA notifications must be submitted within 12 months after implementation. However, some changes are designated as "IAIN," which must be notified within 2 weeks of implementation. (5)
- **Examples for Site Transfer:** Additional site to complete secondary packaging.; Additional site for analytical testing, ability to use an existing QC test as a routine method.; Change of site of manufacturing starting material.

Type IB Variation: Changes that do not fall under Type IA or Type II—i.e., those that are not considered high, low, or very low risk.

- **Procedure:** "Tell, Wait & Do." The MAH must notify the authority of the variation and then wait 30 days to implement the change. The waiting period allows the authority time to review the submission and object if they choose. If no objection occurs in the process, the MAH may proceed after 30 days.
- **Examples for Site Transfer:** Change of a site for the sterilization of the active substance; change of a site for the manufacturing of a non-sterile product.

Type II Variation: Major changes that are considered to have significant potential to impact the quality, safety, and/or efficacy of a medicine.

- **Procedure:** "Tell, Wait & Do (with approval)." Approval(s) from the regulatory authority must occur prior to implementation. The assessment process may take up to 6-9 months before an MAH may implement a change. Implementation is only allowable after a 30-day notice of the approval to the MAH must occur.
- **Examples for Site Transfer:** Transfer of the manufacturing site for a biological/biotech product; addition of a site for the manufacture of the finished product that requires a product-specific GMP inspection.

Submissions will be accepted only in the electronic Common Technical Document (eCTD) format. The submissions of importance when transferring are Module 1 (containing application forms, updated GMP certificates, and the Variation Classification form) and Module 3 (Quality). (6) Before transferring the importation or registration and following the initial submission to the receiving site, Module 3 must be updated to include all relevant information for Module 3 for the receiving site, including, but not limited to, revised batch records, process validation protocols/reports, and updated stability data.

Table 1. European Medicines Agency (EMA) Variation Classification for Site Transfers

Variation Type	Impact Level	Procedural Name	Notification/ Approval Procedure	Typical Timeline for Implementation	Examples Relevant to Site Transfer
Type IA	Minor	Do and Tell	Implement the change first, and notify the authority within 12 months.	Immediate	• Addition of a secondary packaging site. • Change of a site for testing of a starting material.
Type IAIN	Minor (requiring immediate notification)	Do and Tell (Immediate)	Implement the change first, and notify the authority within 2 weeks.	Immediate	• Addition of a primary packaging site. • Change of a site for the production of a starting material.
Type IB	Moderate (Not IA or II)	Tell, Wait, and Do	Submit variation, wait 30 days for potential objection before implementing.	After a 30-day review period	• Change of a site for the sterilization of an active substance. • Change of a manufacturing site for a non-sterile product.
Type II	Major	Tell, Wait for Approval, and Do	Prior approval is required before implementation.	After approval (+30 days), the Assessment can take 6-9 months.	

2.3. U.S. Food and Drug Administration (FDA) Framework

The process indicated by the FDA can be found in 21 CFR § 314.70 (Supplements and other changes to an approved application), and the guidance documents related to it. (7) The FDA, like the EMA, utilizes a risk-based tiered categorization for post-approval changes that vary in terms of words/phrases used and specific triggers for each category.

The submission pathways are as follows:

Prior Approval Supplement (PAS): A PAS is required for a major change with a significant potential for adversely affecting the identity, strength, quality, purity, or potency of the product.

- Key Trigger for Site Transfers: A manufacturing site change almost always requires a PAS, except in certain defined lower tier changes. Importantly, if the new manufacturing site has not been previously inspected by the FDA for the same operation type, a PAS is required. Similarly, if a site in operation has a history of GMP non-compliance, a PAS is also a requirement.
- Procedure: The change cannot be implemented until the FDA has approved the supplement. The review clock for a PAS is 4 months, although it can take much longer if they have to request more information or a GMP inspection is needed.

Changes Being Effected Supplement (CBE-30): For a mild trade that would have a moderate potential to adversely affect the product.

- **Procedure:** The supplement is submitted, and the trade may be carried out 30 days after FDA receipt, provided the organization no longer endorses it in any other case at any point during that period.

Annual Report (AR): For a minor trade that has a minimum capability to have a damaging impact.

- **Procedure:** The trade is absolutely documented and suggested in the subsequent annual document submitted to the FDA.

The FDA affords further granularity in its guidance on "Changes to an Approved NDA or ANDA," classifying website modifications into three degrees based on proximity and operational parity:

- Level 1: Change inside a single facility (same equipments, SOPs, personnel). Typically, reportable in an Annual Report. (8)
- Level 2: Change to a contiguous campus or between facilities in adjacent city blocks. May be eligible for CBE-30 submission.
- Level 3: Change to a specific campus. Requires a PAS and assisting statistics, which incorporates updated batch records, and often, comparative dissolution profiles and stability records from at least one batch manufactured at the brand-new site.

Table 2. U.S. FDA (CDER) Classification of Manufacturing Site Changes

Change Level	Description	Operational Parity & Proximity	Typical Reporting Category	Examples
Level 1	Change within a single facility.	Same equipment, SOPs, personnel, and environmental controls.	Annual Report (AR)	• Moving production to a different room within the same building.
Level 2	Change within a contiguous campus or between facilities in adjacent city blocks.	Same equipment, SOPs, personnel, and environmental controls.	Changes Being Effected in 30 Days (CBE-30)	• Moving to a different building on the same company campus.
Level 3	Change to a different campus.	The same equipment, SOPs, and controls are used, but by different personnel and locations.	Prior Approval Supplement (PAS)	• Moving production to a facility in a different city or country. • Moving to a different Contract Manufacturing Organization (CMO).

2.4. ICH Harmonization Guidelines

The International Council for Harmonization (ICH) does not regulate, but provides essential scientific and regulatory concepts that harmonize the approach to its member areas (including the EU, America, Japan, and others). The guidelines form a philosophical and technical basis, as specific rules for the WHO, EMA, and FDA are created.

For the transfer of websites, guidelines for IC quality are the most relevant:

ICH Q8 (R2) Pharmaceutical Development: This guideline introduces the quality concept of Quality by design (QbD). A well -basic product and process, such as a quality target product profile (QTPP), is defined by critical quality attributes (CQAS), and an established design room provides scientific arguments to better understand the effect of a website change. A strong development report is an important source of knowledge for the transfer team.

ICH Q9 Quality risk management: This is the cornerstone of a modern approach to the transfer of the site. It provides systematic risk management principles and tools (eg, FMEA, FTA) to identify and control potential risks associated with transfer. A risk assessment should lead to the necessary validation and depth of verification activities on the new site.

ICH Q10 Pharmaceutical quality system: This guideline describes a model for an effective quality system to spread the entire product's life cycle including technology transfer. This emphasizes knowledge management (the process of capturing and transferring process knowledge) and change management (a formal system for review, approval, and implementation of changes, such as the transfer of websites), which ensures that the control condition is maintained.

ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management: This new guideline is to promote innovation and continuous improvement by proposing more forecasts and effective regulatory procedures for post-approval changes. It introduces concepts like Established Conditions (ECs) (the parameters that must be controlled to ensure quality) and Post-Approval Change Management Protocols (PACMPs), which can be agreed with regulators in advance to streamline the approval of future changes, including certain site transfers. In practice, a successful method of site transfer adheres to the ICH standards. The main aim here is to capitalize on these facts scientifically and rigorously. A risk-based approach for which justifications are formulated into specific EMA or FDA submission frameworks to be handed along to the bureaucrats. (9)

3. Comparative analysis

The following table synthesizes the key differences and similarities between the regulatory frameworks governing site transfers. Understanding this comparative landscape is crucial for developing a global regulatory strategy.

Table 3. Comparative Overview of Regulatory Frameworks for Site Transfers

Aspect	WHO	EMA (EU)	FDA (US)	ICH (Guidance)
Primary Guidance	Annex 7, TRS 961	Regulation (EC) 1234/2008	21 CFR 314.70	Q8(R2), Q9, Q10, Q12
Elaboration	A comprehensive guideline focused on best practices and processes. It is not legally binding but serves as a model for NRAs and a blueprint for companies to ensure a robust, knowledge-driven transfer.	A legally binding regulation that is directly applicable in all EU member states. It provides the mandatory legal framework for classifying and submitting variations to a marketing authorization.	A federal regulation (law) that legally mandates the requirements for supplements to approved applications. It is supported by non-binding guidance documents that provide the FDA's current thinking.	Harmonized guidelines that provide the scientific and technical foundation for quality. They are not laws themselves but are adopted into regional frameworks (EU, US, Japan), making them de facto global standards.
Classification	Process-focused, holistic approach	Type IA, IAIN, IB, II Variations	PAS, CBE-30, Annual Report	Risk-based, science-based approach
Elaboration	Does not pre-classify changes into tiers. The focus is on the thoroughness of the transfer process (validation, analytical transfer, documentation) regardless of the specific change.	Uses a pre-defined categorical system. The type of variation is based on the potential impact of the change, creating predictability but less flexibility.	Tiered system based on potential risk. Classification dictates the submission pathway, influenced by compliance history and inspection status of the new site.	Provides the philosophical approach (e.g., risk management to justify data requirements) to support classification and submission to regulators.
Submission Trigger	Intra-company transfer, new site introduction	Impact on Quality, Safety, Efficacy	Impact on Identity, Strength, Quality, Purity	N/A (Provides foundational principles)
Elaboration	Triggered by the act of transferring knowledge and process between sites, usually within the same company.	Trigger is the potential impact of the change. High-risk (e.g., sterile injectable) = Type II; minor(e.g.,packaging = Type IA.	Similar to EMA, but strong emphasis on the facility's inspection history. New sites with poor history = high risk (PAS).	Triggered by scientific rigor. Guides what data/knowledge to generate to inform submission.

4. Challenges and best practices

The journey of the transfer of the site is filled with operational and regulatory obstacles. Understanding these challenges and implementing active best practices is the key to a successful result.

4.1 General challenges

Coordination intervals: This is the biggest challenge for global companies. A website transfer that is considered a modest, notification-to-change (type IA) in the EU may require pre-approval supplements (PAS) with full stability data in the United States, and another classification in another country. This deviation forces companies to create more field-specific regulatory strategies and data packages for the same technological change, leading to the possibility of disability, costs, and inconsistencies. Significant competence and coordination are needed in these parallel, uneven processes.

Documentation burden: The requirement for electronic submissions (eCTD), while beneficial for regulators, places a heavy technical and administrative burden on applicants. (10) A single variation for the EU requires the

precise assembly of Modules 1 and 3. A PAS for the US demands a complete application section. Each jurisdiction has its own granular requirements for forms, documents, and metadata. Generating, compiling, and formatting this vast amount of information—including complex technical reports, validation protocols, and stability data—is an immensely resource-intensive process that risks delays if not managed meticulously.

Inspection Delays: This is often the most critical and unpredictable bottleneck. A regulatory submission can be technically perfect, but approval is contingent on the new site passing a GMP inspection. Scheduling these inspections can take months due to agency resource constraints. (11) Furthermore, if the inspection reveals observations (483s) or, worse, a Warning Letter, the entire approval process can be delayed by a year or more while corrective actions are implemented and verified. For the FDA, a site with no inspection history for a specific operation will always trigger a pre-approval inspection, making timeline prediction difficult.

Maintaining Supply Continuity: This is the ultimate business and patient-centric risk. A miscalculation in the regulatory timeline can lead to a gap in manufacturing, resulting in stockouts and drug shortages. Companies must perform a delicate balancing act: they cannot sell product made at the new site until approval is granted, but they must also wind down production at the old site to avoid excess inventory. This requires sophisticated supply chain forecasting, inventory management, and precise coordination with regulatory milestones to ensure a seamless transition with no impact on patient supply.

4.2 Best Practices

Early Engagement: Proactively seeking advice from health authorities through meetings (e.g., FDA Pre-Submission meetings) can be invaluable. It allows a company to present its proposed strategy, including validation and stability plans, and receive feedback on the regulatory pathway and data requirements before investing significant resources. This de-risks the project by ensuring the agency agrees with the company's approach, preventing costly missteps and rework later.

Robust Project Management: A site transfer is not just a regulatory activity; it is a major project. Success depends on a dedicated, cross-functional team with representatives from Regulatory Affairs, Quality Assurance, Quality Control, Manufacturing, Supply Chain, and Engineering. This team should be led by a strong project manager who develops a detailed timeline with clear dependencies (e.g., validation activities must be complete before the regulatory submission can be finalized). Regular communication across this team is essential to identify and mitigate risks early.

Leverage ICH Guidelines: ICH guidelines are not just for regulators; they are powerful tools for companies. A well-executed Quality Risk Management (ICH Q9) exercise can systematically identify potential failure modes in the transfer process, allowing the team to focus validation and verification activities on the highest risks, thereby optimizing resources. A strong Pharmaceutical Quality System (ICH Q10) ensures that knowledge from the original site is effectively captured and transferred, and that the change is managed through a formal, documented system. This science- and risk-based approach provides a solid justification for regulatory decisions and can streamline agency reviews.

Preparation for Inspection: The new site should operate as if it is always under inspection. Preparation begins months in advance. This includes conducting thorough internal audits and mock inspections against cGMP standards. All documentation, especially the Technology Transfer Report, validation protocols and reports, and training records, must be complete, accurate, and readily available. (12) Personnel at all levels should be trained on the new processes and prepared to answer questions knowledgeably. Being "inspection-ready" at all times significantly reduces the risk of major findings that can derail approval.

Table 4. Mapping Common Site Transfer Challenges to Strategic Best Practices

Common Challenge	Impact	Recommended Best Practices	How it Mitigates the Challenge
Harmonization Gaps	Inefficiency, multiple submission strategies, increased cost, and regulatory divergence.	Leverage ICH Guidelines: Use Q9/Q10 to build a unified scientific rationale. Early Engagement: Seek alignment with agencies on data requirements.	Creates a strong core dataset that can be adapted for different regions, reducing rework.
Documentation Burden	Resource-intensive, complex eCTD sequencing, high risk of errors causing delays.	Robust Project Management: Use a dedicated team with a detailed document management plan. Leverage ICH Q10: Ensure strong document control within the Quality System.	Ensures efficient, coordinated, and right-first-time generation and compilation of documents.
Inspection Delays	Major timeline bottleneck, high uncertainty, potential for multi-year delays.	Preparation for Inspection: Conduct mock audits. Early Engagement: Discuss inspection timing. Leverage MRAs: Rely on other authorities' inspections where agreements exist.	Significantly increases the chance of a first-pass successful inspection, minimizing delays.

Maintaining Supply Continuity	Risk of drug shortages, revenue loss, and most importantly, patient impact.	Robust Project Management: Develop a detailed, risk-adjusted project plan with clear supply chain milestones. Early Engagement: Get clarity on regulatory timelines to inform planning.	Allows for accurate forecasting and seamless transition between manufacturing sites.

5. Future directions & harmonisation

The regulatory landscape for site transfers is evolving towards greater collaboration, predictability, and efficiency, driven by several key initiatives:

- **ICH Q12 Implementation:** This guideline is a game-changer. It introduces the concept of post-approval change management protocol (PACMPS). A company can submit a protocol for future transfer of websites during the initial assessment of medication. (13) This protocol, when approved, predefines the acceptable conditions for change and reporting categories. When the time comes for a real transfer, the regulatory process can be quite sharp if it is within the agreed protocol (for example, from a passport to CBE-30 or an annual report). This regulator reduces the uncertainty and encourages continuous improvement.
- **Global adoption of ECTD and digital platforms:** The Step against the ECTD format is now almost global. The next step is a complete development towards digital, structured data submission. Initiatives such as the FDA's Knowledge Assessment and Structured Application (KASA) aim to allow automated, data-driven reviews. This will continue the submission process for both industry and regulators, reduce administrative load, and potentially intensify the review time.
- **Mutual Recognition and Reliance:** Agreements such as the EU-USA mutual recognition agreement (MRA) are important for GMP inspections. They allow regulators to rely on each other and eliminate the repetition of the effort. This means that inspection of the FDA and an approved website cannot require a separate EMA inspection for the same operation, and vice versa. (14) This theory of "Reliance" - where a regulator benefits from another's work - expands globally and is important to reinforce the approval for global transmission of the site and reduce the obstacle to inspection.

6. Conclusion

Transfer of websites is a complex, high-point enterprise that is at the intersection of science, regulation, and supply chain management. (15) While the basic goal of all regulatory bodies is unbreakable routes to show the patient's health by ensuring continuous production of safe, effective high quality medicines, it is clearly different.

WHO provides a basic, process-oriented blueprint. EMA provides an estimated, legally defined area.The FDA uses a risk-based approach to assess its operational compliance with regulations. (16) A comprehensive understanding of all system elements is essential to navigate this intricate procedure. The implementation of harmonic ICH principles specifically applies to quality risk management (Q9) and the universal language of a science-based system which enhances all regulatory submissions across different fields.

Successful achievement requires more than simply following established regulations. Strategic planning leads to success through establishing early connections with authorities and executing projects which require multiple disciplines and developing inspection procedures and using advanced ICH Q12 PACMPS tools (Post-Approval Change Management Protocol). (17) Pharmaceutical companies can transform website transfer from a regulatory obstacle into an operational improvement opportunity by implementing strategic best practices and supporting international unification projects which guarantee secure and efficient drug delivery to patients around the world.

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Conflict of Interest

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