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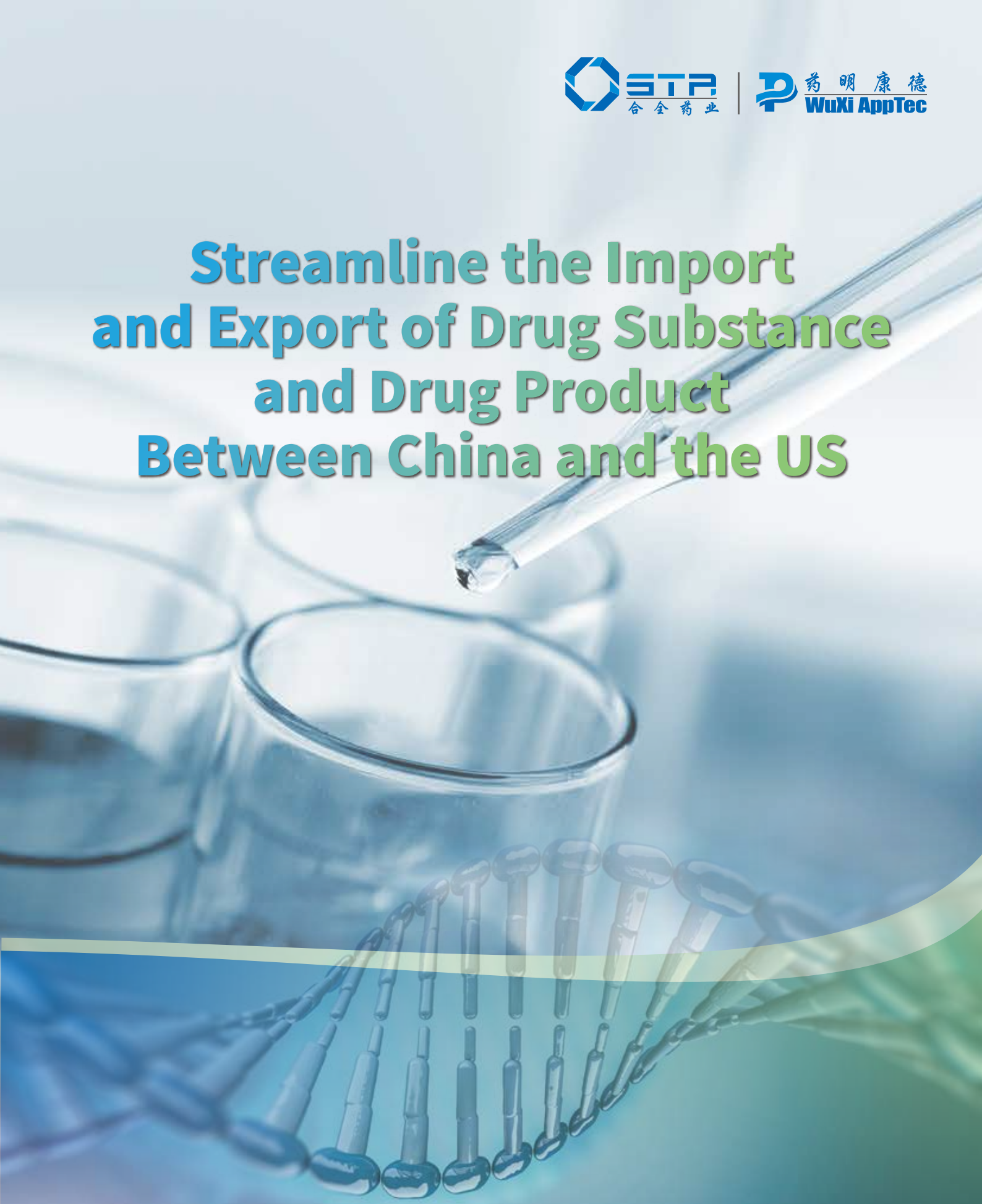
Streamline the Import and Export of Drug Substance and Drug Product Between China and the US



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Do you know fact from fiction: use our checklist to ensure efficient movement of materials between China and the US

For over 16 years WuXi STA's integrated CMC platform has been delivering drug substance and drug product to clients internationally, enabling hundreds of US-based pharma and biotech companies to successfully develop and launch the innovative drug products globally.

With our experience, we have designed this essential checklist for anyone who has not yet imported drug substance or drug product from China, or companies that have had difficulties importing in the past.

We hope you can use this guide as your essential fact check and help you to demystify its complexity.

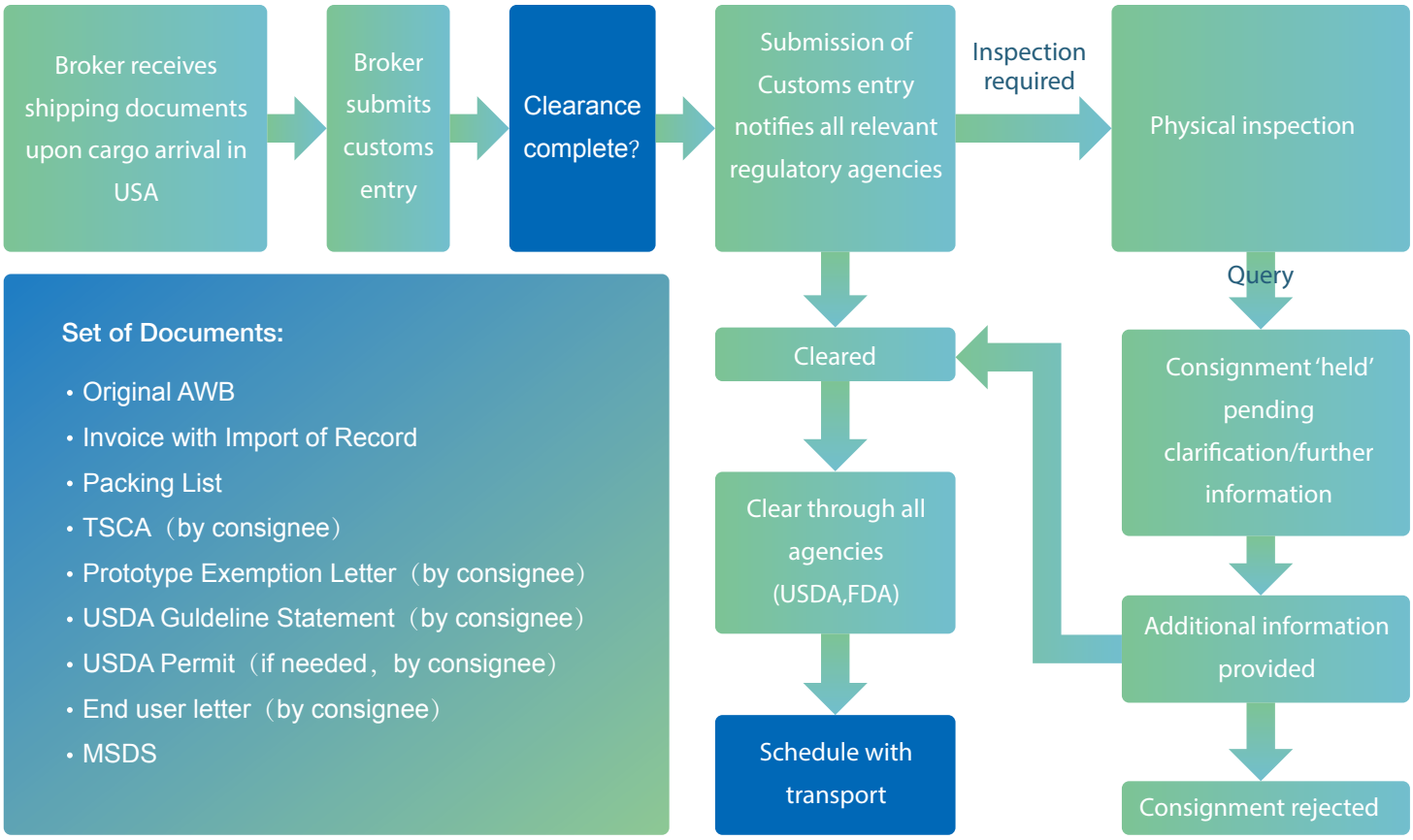
Common perceptions about shipping innovative pharmaceutical materials between China and the US.

Myth	Reality
US-China Trade changes will harm NCE sponsors who import materials from China during the clinical testing phases	**Fact:** Very few ingredients for pharmaceuticals (Harmonized Tariff Schedule chapters 29+30) are affected. IND materials are usually imported to the US under the exemption code 9817.85.01 – which states that R&D materials are duty free for drug substance and drug product
Customs and FDA holds will prevent my trial from starting on time?	**Fact:** With advanced planning, delays can be avoided and the receipt of materials can be predicted with high confidence. In fact, the average shipping cycle time is just 5 working days from finished product to delivery
Exporting my starting materials to China will delay the timeline for development	**Fact:** The vast majority of reagents and starting materials are free from restrictions; and rare cases can be addressed prior to shipment

What documents are required to import your materials to the USA?

Perhaps the best way to understand how to import smoothly is to visualize the flow of documents required, and all shipments follow a standard path upon receipt at the US port of entry (Fig 1). So making sure all documents are included and completed accurately will expedite clearance (Table 1).

/ Import Flow for USA



/ Import Document Check List

API	Agency	Drug product
Toxic Substance Control Act Statement	CBP	Toxic Substance Control Act Statement
Harmonized Tariff Schedule（Chapter 29）	CBP	Harmonized Tariff Schedule（Chapter 30）
USDA Guideline 1105 Statement	USDA	USDA Guideline 1105 Statement
Missing lines	USDA	USDA Guideline 1107（e.g.Lactose excipient） Statement
Missing lines	USDA	Gelatin capsule Apply permit + Statement
Prototype Exception Letter（9817.85.01） End Use Statement	CBP	End Use Statement
	FDA	IND Application

CBP-US Customs and Border Protection
USDA-US Department of Agriculture
FDA-US Food & Drug Administration

/ Which Agencies Review Importation Documents?

US Customs reviews the tariff number and assesses the value

Our tips:

a. Be as accurate and prescriptive as possible in your descriptions: i.e. '# of capsules of XYZ drug for clinical testing' or 'xyz chemical for testing or further processing purposes' only. Remember the higher the monetary value, the more details will be required.

b. Include a Prototype Exemption Letter (drug substance) confirming that materials are safe and for testing purposes or an End of Use statement (drug product).

c. TSCS (Toxic Substance Control Act Statement) declaration.

USDA reviews any ingredients of animal origin

Our tips:

For example, the excipient lactose or the capsule-shell ingredient gelatin are common for pharmaceuticals. Lactose requires a simple statement. Gelatin requires a permit. Make sure to file for the permit of any ingredient of animal origin 30 days prior to shipment.

US FDA ensures the safety of human and veterinary drugs

Our tips:

a. Imported drug product requires an "End Use Letter" (which should indicate the FIRST use upon arrival) and open IND # (Note: the US FDA has a 30-day waiting period after IND application is filed).

b. Drug substance requires a Prototype Exemption Letter (the same as is provided to US Customs)

Finally, we advise our pharma and biotech clients to engage an experienced broker such as DHL Global Forwarding and World Courier. Then with your entire paperwork package ready and safety submitted, facility-to-facility shipment typical takes only 5 days. But most importantly, you will need a trusted partner whose Import & Export department will work with you at all stages for any questions or concerns you have.