From Concept to Compliance: A TÜV Rheinland insider on avoiding costly U.S. mistakes — and how consultancies such as WAG Compliant Quality, Inc. help German companies get it right.

Summary

The U.S. remains one of the most attractive – yet most demanding – export destinations for German manufacturers. In this interview, Joshua Nunn, Laboratory Supervisor at TÜV Rheinland North America, explains which inquiries he sees most frequently from international companies and why many firms still underestimate the complexity of the U.S. regulatory system.

He highlights how the assumption “EU-compliant = U.S.-compliant” often leads to shipment delays, unexpected costs, or even enforcement measures. Mr. Nunn also outlines which steps companies should take well before product development and long before the container is shipped, which mistakes are most common, and what compliance and testing costs companies should realistically plan for.

The interview also underscores the value of early involvement from specialized consultancies such as WAG Compliant Quality, which support manufacturers in navigating U.S. requirements from the outset - helping exporters enter the market faster, safer, and with greater confidence.

Interview conducted by WAG Compliant Quality, Inc. with TÜV Rheinland North America.

Interview Partners

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1. Background and Experience:

Mr. Nunn, your professional background is impressive, as you have worked for renowned, international testing laboratories and now hold a key position at TÜV Rheinland North America. Given this wide-ranging experience: Which inquiries – particularly from foreign companies – currently dominate your professional routine?

In my current role, most of the inquiries I receive from international companies relate to understanding and demonstrating compliance with regulatory requirements for the U.S. and Canadian markets—particularly for children's products and toys. In the United States, this typically involves guidance on meeting CPSC (Consumer Product Safety Commission) regulations, including CPSIA requirements for lead and phthalates, as well as specific tests such as 16 CFR 1500.48 and 1500.49 for sharp points and sharp edges, 16 CFR 1500.50–1500.53 for use and abuse evaluations, and the widely recognized ASTM F963 Standard Consumer Safety Specification for Toy Safety.

European manufacturers also frequently request testing according to EN 71 standards, particularly EN 71-1 for mechanical and physical properties and EN 71-3 for the migration of certain elements—to ensure their products meet all relevant safety expectations when marketed abroad.

Overall, the focus of these inquiries reflects a strong and growing commitment among global manufacturers to proactively ensure product safety, meet regulatory obligations, and achieve market access with confidence.

Inquiries which come from companies: Are they already that specific, or are they more high-level? Do these companies come prepared with the right regulations in mind, or do they ask very basic questions like "What do we have to do for the U.S.? Do we have to do testing?

It's definitely a mix. Some companies reach out with a solid understanding of the regulatory landscape and already know which standards apply to their products. But we also see many who contact us with very broad questions like, "We want to enter the U.S. market—what do we need to do?" Those cases require more time because we need to guide them from the ground up and build an appropriate testing plan for their specific product.

2. Timing of Contact:

When companies aim for market entry into the USA and contact TÜV Rheinland USA: At what point in this process – from the initial idea to loading the container – do they usually seek your expertise?

Most companies approach TÜV Rheinland North America when their product has already progressed well beyond the conceptual phase. In most cases, they are already selling the product in another market and are now preparing to expand into the United States. While we occasionally work with companies that are still in the prototype stage and have not yet launched in any market, this is less common.

Typically, by the time they reach out to us, they already have a finished product or a functional prototype in hand, and they seek our expertise before the container is loaded for shipment to

the U.S. This timing allows them to ensure that all applicable regulatory requirements are met prior to market entry, reducing the risk of delays, non-compliance, or costly corrective actions once the product arrives in the country.

Do companies sometimes come to you when it's too late - when they already have a problem?

Yes, that does happen, and you can immediately hear the frustration in their voices. Sometimes a shipment is already being held at a port, or regulatory authorities have initiated enforcement actions. At that point, companies may be facing daily fines or calculating lost revenue from being unable to sell their product. We then work with them to identify the necessary steps and test to help them move forward, but it's always more challenging once the issue has escalated to that stage.

3. Strategic Planning and Costs (Product Compliance):

Assuming a management team decides to export to the USA: What specific, initial steps regarding Product Compliance should the company take immediately? And what financial framework (cost calculation) must one realistically anticipate for such an undertaking in the area of product compliance?

The very first step a management team should take when considering entry into the U.S. market is thorough market research. Companies need to fully understand the landscape into which they plan to expand: Are similar products already being sold? How are those products packaged and labeled? Which regions of the United States are they targeting, and will distribution occur directly or through third-party retailers? If a retailer or vendor is involved, companies must also determine if that partner has specific compliance or documentation requirements.

If a company lacks internal expertise in U.S. product compliance, engaging a specialized consultancy early in the process is highly recommended. Regulatory expectations vary significantly between markets—for example, the European Union and the United States do not apply identical compliance frameworks. A consultant familiar with U.S. requirements can help reduce delays, clarify regulatory obligations, and guide companies in identifying mandatory testing and documentation.

This support becomes especially valuable when navigating laboratory quotations. Many companies are surprised by the complexity involved during the initial quotation phase, which often requires detailed product information, multiple adjustments, and extensive clarification. A knowledgeable consultant can streamline this process by ensuring the testing laboratory receives complete and accurate information from the start, shortening the timeline from initial inquiry to actual testing and ultimately to the issuance of final reports.

From a financial standpoint, costs vary widely depending on the product category. For example, non-powered children's products or toys typically involve more extensive testing, especially chemical and physical safety evaluations—and may range from USD 1,000 to 3,000 for full market compliance. For electrically powered toys, the scope of testing increases, and costs often fall between USD 5,000 and 10,000. Factors such as product complexity, inclusion of textiles, liquids, or art materials, and applicable regulatory standards will all impact the final cost.

In short, early preparation, expert guidance, and realistic budgeting are essential to achieving a smooth and compliant entry into the U.S. market.

4. Common Pitfalls and Consequences:

In preparing products for the US market, you surely encounter similar challenges repeatedly: What are the most common mistakes you observe in companies when they want to make their products 'US-Ready'? Could you give us one or two compelling examples of the consequences a company faces for non-compliance of regulatory requirements?

One of the most common challenges we see is the assumption that compliance achieved in another market—particularly the European Union—automatically translates into compliance in the United States. While EU regulations are robust and valuable, they do not align one-to-one with U.S. requirements. For example, certain chemical compounds may not have been tested, U.S. regulatory limits may be stricter, or the required testing methodology may differ—for instance, a soluble migration test acceptable in Europe may not meet U.S. requirements, which could demand a total digestion approach. Physical and mechanical testing can also vary. The U.S. market may require compliance with specific standards such as ASTM (American Society for Testing and Materials) or ANSI (American National Standards Institute), which are not applicable in many other regions.

Labelling is another frequent issue. Depending on the product type and the regulatory agency overseeing it, additional warning statements or safety labels may be required—either on the packaging, on the product itself, or in the accompanying documentation. Companies often overlook this, which can create significant problems at Customs or during retailer approval.

The consequences of non-compliance can be severe. Shipments may be detained at U.S. ports due to missing or insufficient documentation, and companies may face fines or sanctions from regulatory authorities. In more serious cases, products may even be barred from entering or being sold in the U.S. market. We have also seen situations where products already in containers at the port require relabeling, resulting in substantial unplanned costs, delays, and disruption to distribution schedules.

More recently, enforcement pressure has also increased on major retailers, who are being held accountable for selling non-compliant products. As a result, many retailers have tightened their

own compliance controls, requiring additional proof of regulatory conformity from suppliers. We frequently see companies approaching us only after their products have been pulled from store shelves, resulting in lost revenue and urgent timelines to complete testing to return to the market.

In short, assuming compatibility between markets, neglecting labeling requirements, and engaging too late in the process are among the most common and costly mistakes. Early, market-specific preparation is key to avoiding regulatory disruption and safeguarding access to the U.S. market.

Have you received phone calls from companies that are in trouble because they did not adhere to regulatory requirements?

Yes, and unfortunately those calls are quite difficult because by the time they reach out, the situation is already critical. The stress and urgency are very real. At that stage, there's only so much we can do - primarily offering support through the necessary testing and guiding them on what steps are needed to demonstrate compliance. But once enforcement has begun, options are limited.

Do you support necessary rework of non-compliant products that have been flagged by regulatory bodies?

No. Aside from performing re-tests, we do not assist with the physical re-work or modification of products. That responsibility lies entirely with the client and their internal team or service provider. In such situations, our role begins and ends with testing and providing the technical data needed to show whether the product meets the relevant requirements.

5. Role and Limits of the Testing Laboratory:

Importers often require comprehensive support for their projects: In which areas can a testing laboratory like TÜV Rheinland USA particularly effectively support the importer – and where are the clear limits of this support or the laboratory's responsibility?

A testing laboratory such as TÜV Rheinland USA can provide significant support to importers by delivering accredited and highly specialized testing services that demonstrate compliance with U.S. regulatory requirements. With decades of global experience and a recognized leadership position in product safety, TÜV Rheinland brings not only technical capability but also deep familiarity with the standards and expectations of the U.S. market. For products regulated by the Consumer Product Safety Commission (CPSC), this may include the issuance of a Children's Product Certificate (CPC) or a General Certificate of Conformity (GCC). As a CPSC-accepted laboratory, we perform the mandatory physical and chemical testing that forms the technical basis for these certifications, helping ensure products meet applicable U.S. standards before entering the market.

Our role is to provide impartial, confidential, and reliable testing backed by internationally recognized accreditation. Importers can rely on TÜV Rheinland to generate valid and defensible test results that support compliance, smooth customs clearance, and meet the increasingly strict requirements of retailers and regulatory bodies. This credibility and independence are essential elements of successful and sustainable market access.

At the same time, it is important to recognize that even a leading laboratory has defined limits within the regulatory process. While TÜV Rheinland can test and evaluate products against U.S. requirements, our involvement typically ends with the testing itself. We do not approve, enforce, or regulate products, nor do we determine how test results are applied. Responsibility for interpreting results correctly, ensuring proper labeling, submitting mandatory documentation, and maintaining ongoing market compliance remains with the importer or manufacturer.

In short, TÜV Rheinland USA provides the trusted, accredited testing foundation needed for U.S. market entry, while the broader regulatory strategy and market stewardship rest with the company placing the product on the market. Our expertise allows companies to enter the market with greater confidence, reduce the risk of setbacks, and maintain compliance throughout the product's lifecycle.

6. Added Value of Specialized Consulting Companies:

We are also discussing companies like WAG Compliant Quality today: What specific added value or essential function does a company like WAG Compliant Quality fulfill for an importer that goes beyond the services of a testing laboratory?

While I have not worked personally on the consultancy side, there are clear advantages that consulting companies in general offer beyond the scope of a testing laboratory. A laboratory's role is to evaluate a product through accredited testing and provide reliable, impartial results—but by the time a product reaches the laboratory, many key design and strategic decisions have already been made.

A consultancy can support importers much earlier in the process. For example, a company with only a concept or initial design can engage a consultant to understand which regulations, testing requirements, and compliance obligations may apply before the first prototype is even produced. This can influence critical decisions such as whether the product is viable for a particular market, whether design modifications are necessary, or whether certain materials or components should be reconsidered to avoid costly testing failures later on.

Consulting firms can also provide broader guidance on product design, documentation, regulatory strategy, labeling requirements, supplier readiness, and market expectations—areas that fall outside the typical scope of a testing laboratory. In this way, they bridge the gap between concept and compliance, helping companies avoid expensive missteps, reduce development cycles, and enter the market with greater confidence and efficiency.

In short, while a testing laboratory validates compliance, a consultancy supports importers in preparing for compliance—often saving time, cost, and effort long before the product reaches the test bench.

7. Concluding Advice for Success:

Finally, Mr. Nunn: Based on your profound experience – What is your key piece of advice for a company to not only achieve market entry into the USA, but to ensure it adheres to the U.S. regulatory requirements?

My key piece of advice is to take a proactive and disciplined approach to compliance. First and foremost, ensure that your products are tested by a CPSC-accepted laboratory. For toys and children's products in particular, companies must remember that compliance is not a one-time requirement—annual and periodic testing is mandatory to demonstrate continued conformity with U.S. regulations.

Equally important is maintaining strong internal oversight. An engaged quality and compliance team that actively monitors regulatory updates and market expectations is essential to avoiding costly issues. When entering a new market or navigating unfamiliar requirements, partnering with a knowledgeable consultancy can provide valuable guidance.

In short, consistent testing, internal vigilance, and strategic collaboration are the pillars that not only enable successful market entry but also ensure long-term adherence to U.S. regulatory requirements.

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