BSMA

Bio Supply Management Alliance

QUESTIONS RAISED BY CLINICAL TRIALS EXECUTIVES OF BSMA
June, 2023

1. What are some watch-outs for early phase trials and import/export requirements?

2. What are the most common issues that lead to customs delays with pharmaceutical shipments in US entry, EU etc.)

3. What role does the sponsor play in an international transaction from an IncoTerms perspective? Presumably the buyer, but then what role is the receiving site?

4. What other advice and recommendations do you have for pharma companies that don't have internal trade compliance departments but need to navigate these issues?

5. What are some issues that hold up FDA clearance into US under IFE, FTZ, other types of imports, etc.?

6. Are you aware of more companies needing to request EORI #s for shipments into EU or OK?

7. What are the Importer of Record requirements for shipments into the UK, EU, and Latin America? Does the IoR always need to be a local entity?

8. What is direct vs. indirect representation, and when is an indirect representative required (for US, UK, EU, China, Japan, LatAm)?

9. What valuation methodology do you recommend to avoid scrutiny from customs agents?

10. Have valuations been scrutinized more heavily in your experience?

11. Do you have any experience to share on CBPs' view on companies making **significant** changes to their intercompany transfer prices (used as basis for import value) into US (for non-dutiable products)?

Devendra Mishra
Executive Director, BSMA