

QUESTIONS AND ANSWER SEGMENT

QUESTION

How do you view the responsibility of the entire supply chain, also including pharmacists, on monitoring the conditions of the medicines after delivery at the patient's home?

ANSWER

"I believe major changes are coming for the entire supply chain and this will be stated shortly (USP updates). I believe we as an industry need to come together and make sure products are being protected all the way to the patient. I also believe we need to provide better education for patients and enable patients with the tools to properly protect drugs at home and when they travel. To that end we have qualified patient carry packs."

Most of these standards, guidance and practices are mostly US related. Can you elaborate more on why there seems to be no such thing as a global standard?

"There are some harmonization efforts and I believe what USP is updating will bring the US closer to the EU guidance. I'd have to solicit guidance from some others in answering this question with real specifics."

This Controlled Cold Temperature range, do you know if Ph. Eu. is planning to adapt also?

"I do not currently know the answer to this. If any attendees would like to answer this, by posting a new question to me, then I will share with the entire group. I will also see if I can find a solid answer prior to the email follow up in the coming days."

Would you reckon the equality of necessary conditions for medicines, might be a solid foundation for developing certain equal standards?

"I think we will get there with the USA and EU. I think Brazil (ANVISA) and Saudi Arabia, as two examples, may continue to have their own standards for the foreseeable future. I'm not convinced we'll get "all" countries of the world to harmonize but I think we'll continue to see harmonization in major economies, and this will largely be driven by the manufacturers working in and shipping to/from each of those countries."

What about the impact on our environment using EPS? Some states (NY) have banned EPS. Do you have other solutions instead of EPS?

"Yes! Reuse is the best option. For applications that do not allow for reuse we have sustainable single use options. I will also point out this is something we track and quantify for our clients. Just one of our client reuse applications has eliminated ~300K cubic feet of EPS from landfills. That's ~250 40 yard dumpsters full!"

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