Halloran
A ProductLifeGroup Company

Life science *insight*, life-changing *impact*

DSI INPHARMATICS
A ProductLifeGroup Company

**Thank you for joining us!**

**It was a pleasure to have you attend our Town Hall in partnership with DSI**

*Navigating the Shifting Landscape of Drug and Device Development During Uncertain Times*

## OUR OBSERVATIONS

It is essential we remain connected as a community to remain focused on our science and processes, continuing to push development forward.

**Regulatory Timelines and Responses**

- With the recent changes at the U.S. FDA, we observe the Agency is still committed to bringing therapies to patients, and in this present time, we have not witnessed a change in FDA review timelines nor the Agency's commitment to provide responses on submissions we have supported to date. As of now, engagement with the agency remains business as usual.

**Balancing Development in the U.S. and Other Countries**

- There are many factors contributing to the location of product development, and the recent change at FDA is bringing clinical development outside the US (OUS) into stronger focus. Initiating clinical development in Australia is not a new approach given its lean application, review timelines, and tax incentives. Companies must balance and mitigate risk accordingly. It is advised to keep the FDA in view and weigh options for a meeting interaction prior to applying to conduct a clinical trial.

**Patterns in Inspection Readiness**

- In recent years, Halloran has consistently observed three-to-four months rather than two months from NDA/BLA submission to FDA inspection notification. But it is advised to have an inspection readiness state of mind from the onset of development, moving beyond a checklist mentality.
- As of now, there are no anticipated changes to the BIMO manual.

**Anticipated Interruptions – Logistics and Supply Chain**

- Plan for operational and administrative scheduling interruptions at the FDA, resulting in potential delays.
- Delays often result in budget increase. Consult your Broker and/or Supply Chain Expert to understand what materials may be exempt from tariffs, and where not, the costs associated.

**Additional Resources**

- New Tariffs Regarding US Imports Update (see attachment)
- Annex-I and Annex-II

## SPEAKERS

- Sheila Gwizdak, VP, Consulting, Halloran
- Nicole Gallo, Principal Consultant, Halloran
- Meaghan Marchand, Senior Consultant, Halloran
- Karen Travers, Principal Consultant, Halloran
- Steve Kornher, Senior Consultant, Halloran
- Joseph Ivan, Head of Supply Chain Services, DSI

## ABOUT HALLORAN

Halloran Consulting Group is a life science consulting firm providing strategic development, regulatory, quality, clinical, and organizational support to industry leaders in the pharmaceutical, biotechnology, and medical device sectors. Our consultants are subject matter experts with technical and strategic expertise, who deliver a tailored approach to each engagement, successfully propelling our clients to their next inflection point.

**Recommendations and Advice**

- Consider multiple paths forward to propel your product development. Risk management is the strategy and will be your competitive advantage.
- Cooler heads will prevail! What we know today may not be relevant tomorrow. Control what you can control and stay focused on the signals and not the noise.
- Follow precedent. It's not changed until we're told it's changed.

Contact us
with your questions.
We're here to partner with you.