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ICDRA Plenary 1 – Recommendations from 18th ICDRA: How Well We Are Doing?
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- Good morning.
- I'm Kimberlee Trzeciak, the Deputy Commissioner for Policy, Legislation, and International Affairs at the U.S. Food and Drug Administration.
- I would like to thank the World Health Organization and the Central Drugs Standard Control Organization for their leadership in global public health for putting together this 19th Annual International Conference of Drug Regulatory Authorities and for inviting me to speak with you today.
- For those of us here today it is our important responsibility to ensure that people around the world can benefit from safe, effective medical products.
- Since 1980 ICDRA has served as the leading platform to improve the access and availability of high-quality medicines.
- Its mission is very important to the FDA.
- In fact, 44 years ago, FDA hosted the very first ICDRA.
- And now, the WHO has brought us together once again to convene as partners with a common priority of advancing public health through efficient and robust regulatory systems.
- Together this week, we will focus on how we can use regulation to deliver quality assured medical products to everyone.

- At FDA, our long-term vision is for there to be a global marketplace which consistently offers high-quality medical products for consumers and patients regardless of where they are located.
- Industry is ultimately responsible for abiding by the regulatory standards set by our organizations, committing to high-quality standards, and delivering safe and effective medical products.
- However, as regulators, one of the challenges we face is that the supply chains we oversee are dynamic, increasingly complex, and span the globe.
- We also all face new and aggravated threats to product quality and safety, alongside increasing public health demand for these products.
- As we look toward the future to meet our regulatory responsibilities, we all must adapt to the rapidly changing global landscape in which we work.
- I'm going to focus today on three key themes that will enable us to respond to these challenges and maintain a strong regulatory space for medical products.
- First, risk mitigation.
- Second, building partnerships among regulatory authorities, which rely on and generate similar information to make regulatory decisions.
- And third, the potential of regulatory harmonization.
- Today, products travel from country to country in an increasingly complex path from raw source materials to finished products.
- For example, looking at the medical products market in the United States, over 80% of active pharmaceutical ingredient manufacturers are located outside of the U.S.
- And nearly half of the medical devices used in the U.S have been imported.

- Risks can arise at any step in the supply chain.
- Whether it's the sourcing of active pharmaceutical ingredients, key starting materials, or other components used to make a product, the manufacture, storage, transit, sale, and distribution of medical products involve numerous entities.
- When unexpected medical product shortages or safety problems arise in one manufacturer, country, or region, its compounded impacts can be felt around the world.
- These stresses are especially felt during public health emergencies, as we all saw recently with the supply chain challenges during the COVID-19 pandemic.
- Additionally, industries face increasing economic pressure to grow output, which often happens at the expense of quality.
- Pressures also include the need for a timely response to emerging public health needs as well as the need to keep up with changes in how products are being made.
- As industry practices adapt to meet the demands of an evolving world, the traditional model of batch manufacturing drugs is slowly being phased out in favor of new advanced manufacturing technologies.
- These changes open new opportunities and risks for the safety and availability of drug and vaccine products, and as regulators it is our responsibility to support innovation but also monitor and mitigate risks for the products we regulate.
- This all leaves us with a complex regulatory environment and further underscores the need for international collaboration to protect public health and respond quickly and effectively to risks to medical product safety and availability.

- Because of the complex nature of the production and distribution of the products we regulate, it is impossible for every national regulatory authority to inspect every facility it regulates every year or sample every imported product.
- Inspecting our way to quality is not a feasible approach.
- Given that so many pieces of the supply chain impact products, it is more important for all of us to work toward encouraging a culture of quality that carries all the way through the global supply chain.
- In sum, no regulatory authority can do everything on its own.
- Every member of the supply chain plays a critical role in its success.
- Whether that's the industry developing the product, or the federal, state, and local agencies that regulate the marketplace.
- This is why FDA seeks to develop cooperative partnerships with regulatory counterparts and international organizations like the WHO.
- These partnerships better position FDA and our counterparts to mitigate the numerous risks that could impact access to high-quality medicines and vaccines.
- One example of regulatory authorities coming together is the Member State Mechanism on Substandard and Falsified Medical Products.
- This collaboration brings countries together to address the public health impacts of substandard and falsified products, and by doing so, ultimately helps countries around the globe better protect their patients.
- Finally, I want to take some time to emphasize the power and potential of regulatory harmonization, which I know will be a big part of our conference discussions.

- As stated by FDA Commissioner Robert Califf earlier this year: “It is important for each of our agencies to embrace the essential principles of convergence and the harmonization of regulatory expectations among nations and across areas of medical product innovation.”
- A list of the benefits of international harmonization is long but here are some of the most prominent.
- Working collaboratively enables public resources to be used more effectively in the oversight of products we regulate, helps ensure equitable access to medical products, and maintain the integrity of our supply chains, both domestically and internationally.
- It improves efficiency in the regulatory review process and lessens the time to get a product to the market.
- And, finally, it reduces the patient burden by preventing unnecessary duplication of clinical trials and postmarket clinical evaluations.
- The FDA commends the World Health Organization for its continued leadership in driving harmonization efforts.
- One recent example being the introduction of the WHO Listed Authority framework.
- In March, the FDA was honored to join regulatory authorities from the European Economic Area, Switzerland, Singapore, and the Republic of Korea in receiving the WHO Listed Authority designation.
- The FDA supports the listed authorities approach because it sets common standards and furthers international regulatory harmonization and convergence, both of which will facilitate access to products and maintain the integrity of our supply chains domestically and internationally.

- By setting up an objective quantitative framework, this program sets attainable targets for regulators who are still developing their capabilities, while also building confidence and trust in the decisions, methodologies, and oversight from the countries that have gone through the process and become WHO Listed Authorities.
- By leveraging the resources, experience and expertise of listed authorities, regulators can use their limited resources to focus on critical regulatory responsibilities that need to be addressed locally such as oversight of manufacturing facilities and laboratories and pharmacovigilance.
- Such an approach is consistent with seeking to advance to higher maturity levels under the global benchmarking tools, and more importantly, enables regulators to use all the resources available to them to ensure access to safe and effective products and the protection and promotion of the public health.
- None of us can go it alone.
- We can all benefit from leveraging the capacities of our counterparts.
- FDA is committed to enhancing our impact and engagement in the international arena to effectively mitigate public health risks, and build strong, durable partnerships where regulators can learn from each other and benefit from cooperation.
- Achieving our long-term vision of a strong global marketplace is only possible if it is underpinned by strong, consistent, harmonized regulatory frameworks with robust oversight of the global supply chain.
- And, where appropriate, close collaboration between regulatory authorities, including the sharing of information.

- I look forward to our discussions over the next few days and the steps we can take together to reach this vision.
- Thank you.