



# MANUFACTURING, SUPPLY CHAIN, AND DRUG AND BIOLOGICAL INSPECTIONS DURING COVID-19

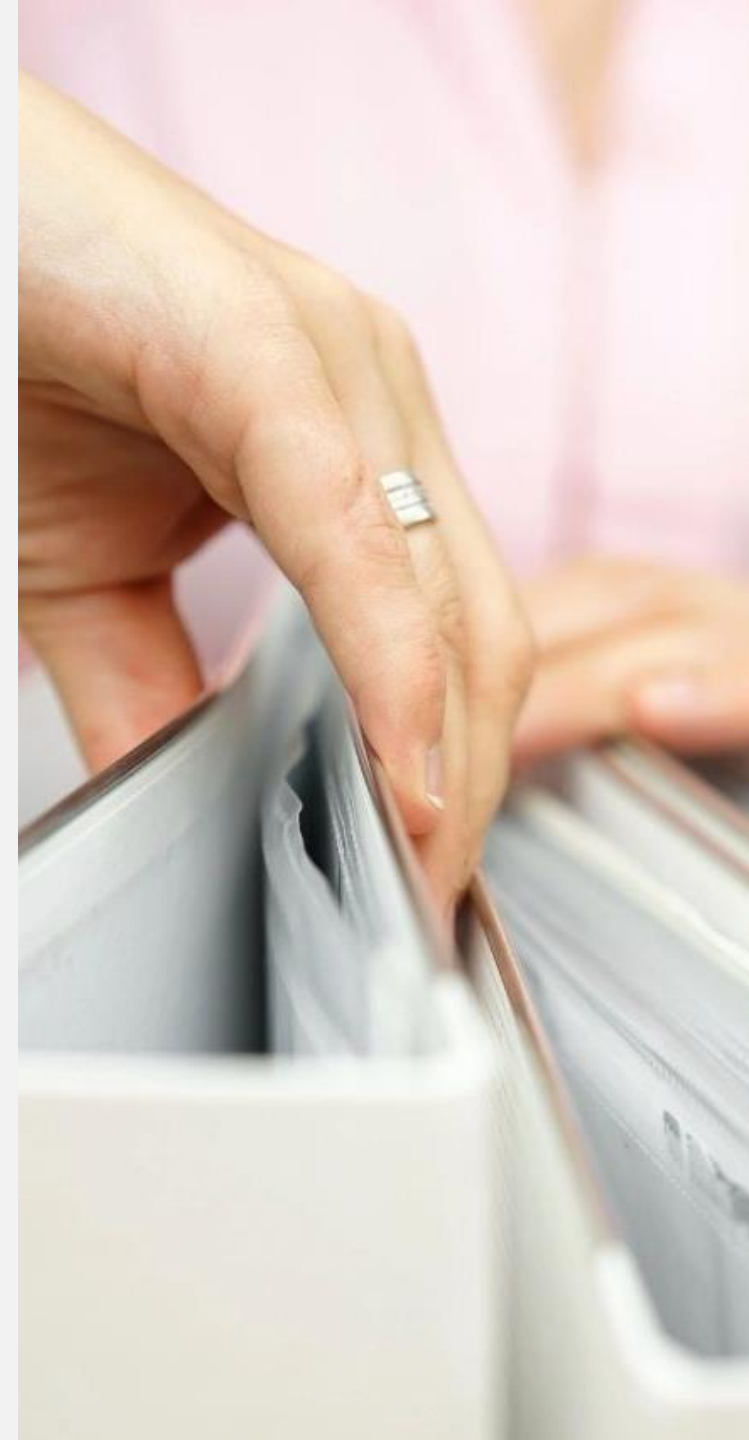
A GLOBAL LEADER IN PUBLIC HEALTH AND SAFETY

**NSF INTERNATIONAL**

789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA

# Inspections

- > In March 2020 FDA announced it was postponing all domestic and foreign routine surveillance facility inspections.
- > Pre-Approval inspection will continue with FDA using other tools and approaches, including requesting existing inspection reports through the Mutual Recognition Agreements.



# Inspections

- > FDA resumes domestic inspections with new risk assessment system in July 2020.
  - Case by case basis only “Mission Critical” inspections.
  - Prioritized Inspections which generally include pre-approval and surveillance inspections.
  - Consistent with the National Guidelines for Opening Up America Again-criteria must be met before proceeding to phased operations.
  - Inspections will be pre-announced.
- > Foreign pre-approval and for-cause inspection assignments that are not deemed “Mission Critical” remain temporarily postponed while those deemed mission critical will be considered on a case-by-case basis.

## Mission Critical

- > Subject to many factors and include:
  - Breakthrough therapy designation
  - Regenerative medicine advanced therapy designation
  - Products to diagnose, treat, or prevent a serious disease or medical condition where there is no other appropriate substitute
  - Pre-approval
  - For-cause
- > Same factors will be applied whether domestic or foreign

# Imported Products

- > FDA is expanding the use of other tools and approaches of drug products imported into the United States. These may include:
  - physical examinations of products arriving at U.S. borders.
  - product sampling and testing before release into commerce.
  - compliance histories of facilities.
  - using information shared by trusted foreign regulatory partners through mutual recognition.
  - requesting records directly from facilities “in advance of or in lieu of” certain drug inspections.
- > If a product appears not to meet applicable standards for safety, effectiveness, or quality based on these approaches, FDA has the authority to refuse admission of the product into the United States.

# Imported Products

- > FDA continues to work with U.S. Customs and Border Protection to target products intended for importation into the United States that violate applicable legal requirements for FDA-regulated products.
- > FDA has the ability through its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening tool to focus its examinations and sample collections based on heightened concerns of specific products being entered into U.S. commerce.
  - The PREDICT screening has continued to adjust product risk scores as necessary throughout the COVID-19 outbreak.

# Quality Assessment

- > FDA will continue the quality assessment of all applications per normal assessment operations for all disciplines, where all manufacturing facilities will be evaluated using a risk-based approach consistent with existing guidelines.

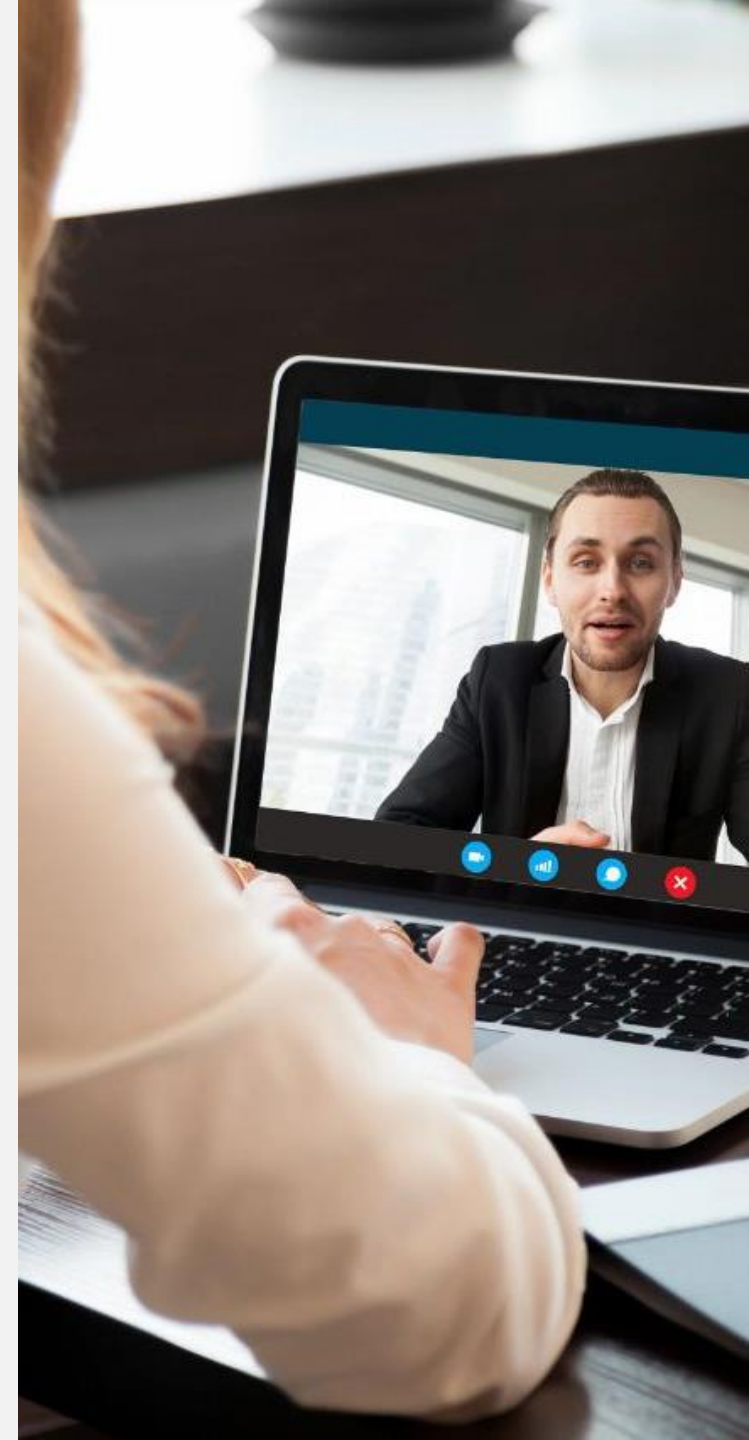


# NSF's Approach



# 3<sup>rd</sup> Party Remote Auditing

- > NSF is currently conducting remote auditing and gap assessments.
  - Using Zoom and or Microsoft Teams.
  - Secure Platform to exchange information.
  - Interviews of Personnel.
  - Facility tour where possible using applications.
- > Downsides.
  - Takes longer.
  - Time Zone challenges.
  - Cannot see everything.



# Training

- > NSF has a number of eLearning and hybrid trainings that can be conducted remotely.
  - Works well.
  - Knowledge checks and assessments included.
  - Interactive.
  - Certificate of Completions provided.





## Consulting

- > Strategic consulting can be done remotely.
- > Complex issues can be resolved.
- > Hybrid approaches for virtual activities.



# GET IN TOUCH

For more information, please contact:

**Maxine K. Fritz, Executive Vice President**

**M + 1 202 716 9550**

**E [mfritz@nsf.org](mailto:mfritz@nsf.org)**