



**14<sup>th</sup> EBF Open Symposium**  
**Science – Our Universal Language**

**Regulatory framework for Remote HA inspection: an overview**

**Tsvetelina Ivanova, on behalf of the EBF**

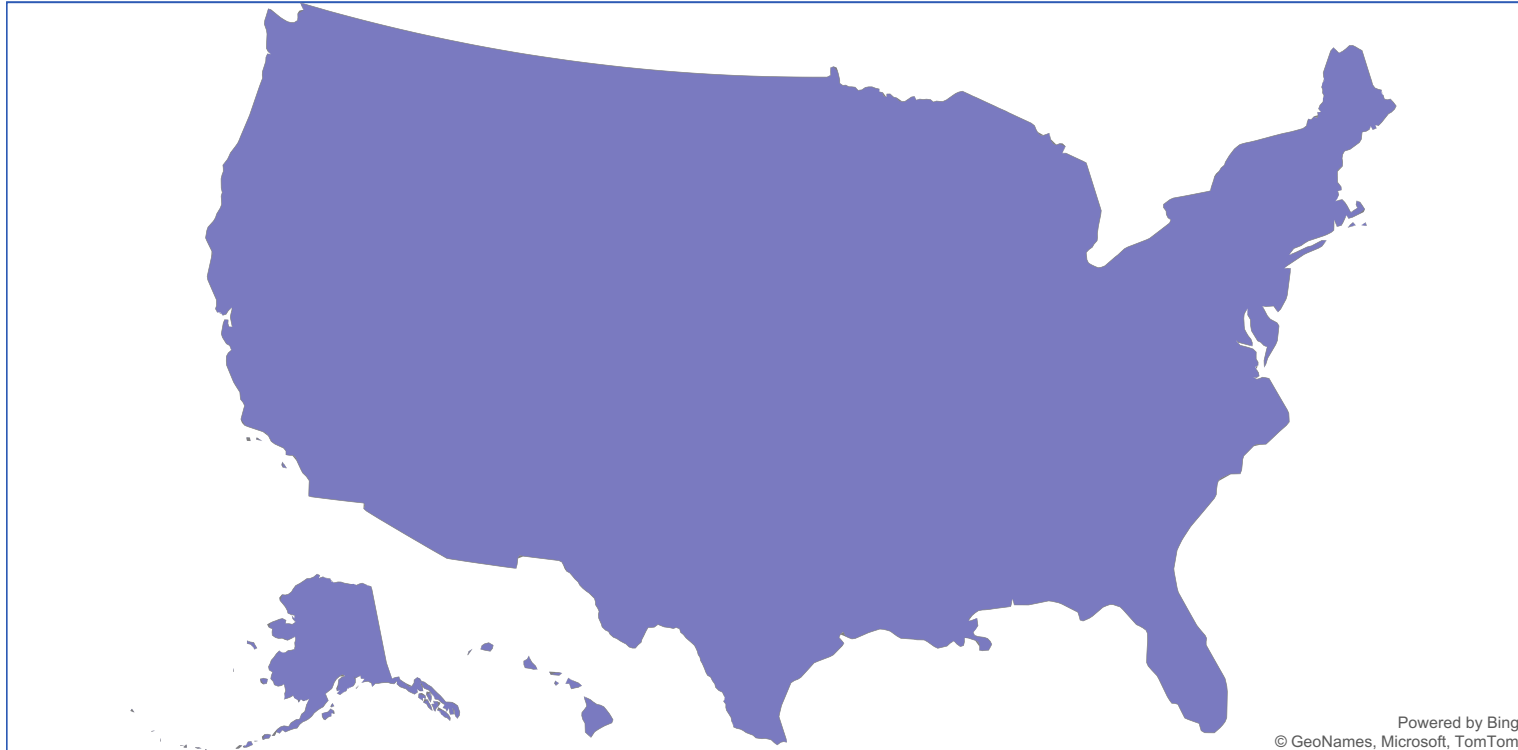
**24-26 November 2021, Barcelona**

# COVID-19 challenge

- March 2020 Pandemic halted routine on-site inspections
- It has prompted regulatory authorities to consider new ways of working and has driven them to implement and adopt more agile or flexible approaches
- Transformation of inspection model to remote



# US Food and Drug Administration (FDA)



# US Food and Drug Administration (FDA)



## ➤ Guidance:

Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency – April 2021

## ➤ Scope:

- facilities 2 where drugs 3 are manufactured, processed, packed, or held;
- facilities covered under FDA's bioresearch monitoring (BIMO) program
- outsourcing facilities registered under section 503B of the Federal Food, Drug, and Cosmetic Act

# Health Canada (HC)



# Health Canada (HC)

- Guidance:
  - Canada's approach to onsite inspections during COVID-19: Notice—April 2021
- Scope:
  - All inspections type;

# Agência Nacional de Vigilância Sanitária (ANVISA)



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# Agência Nacional de Vigilância Sanitária (ANVISA)

- Guidance:  
RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC N° 449, DE 15 DE DEZEMBRO DE 2020
- Scope:
  - Good Clinical Practice activities;



# Medicines and Healthcare products Regulatory Agency (MHRA)



# Medicines and Healthcare products Regulatory Agency (MHRA)



- Public Communication:  
MHRA Good Practice (GxP) inspections during the COVID19 outbreak
- Scope:
  - All type of inspections;

## Conduct of remote inspections: challenges and progress

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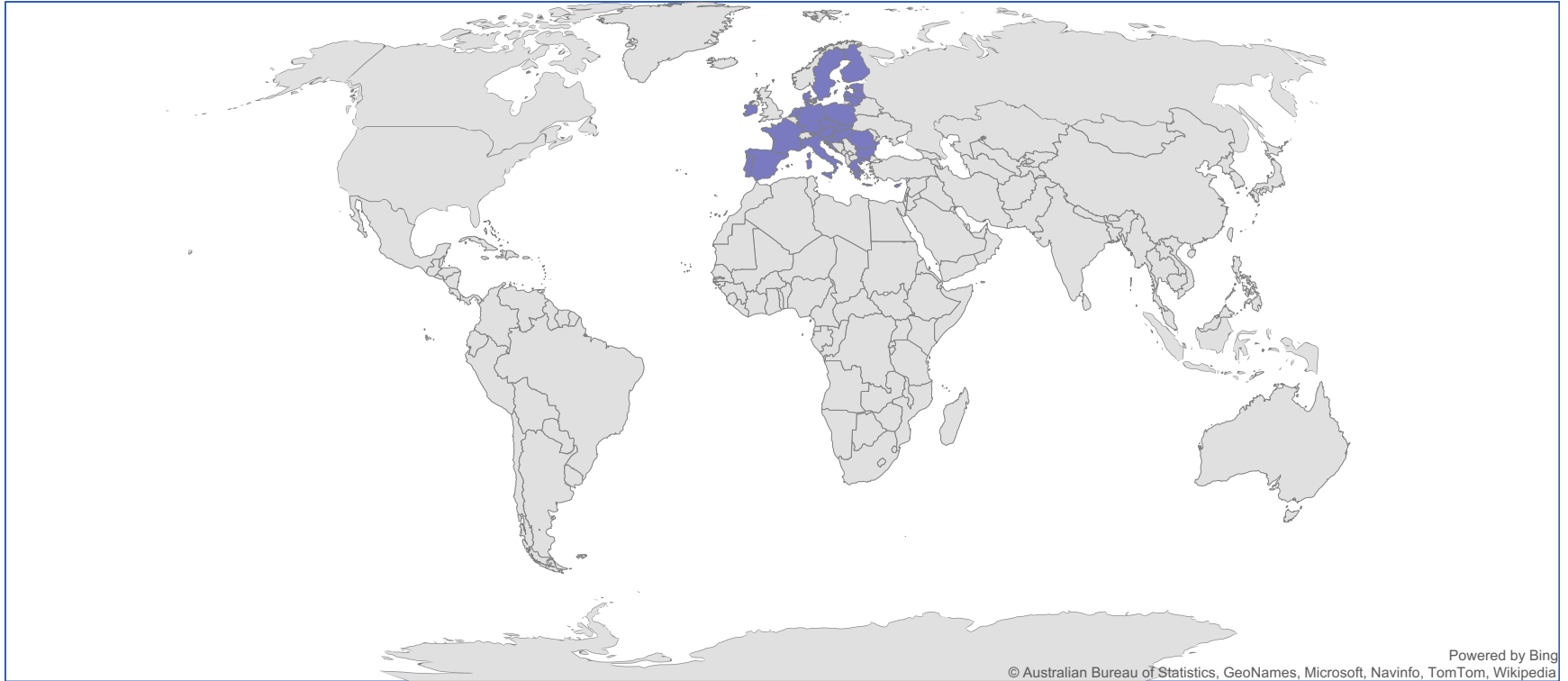
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# European Medicines Agency (EMA)

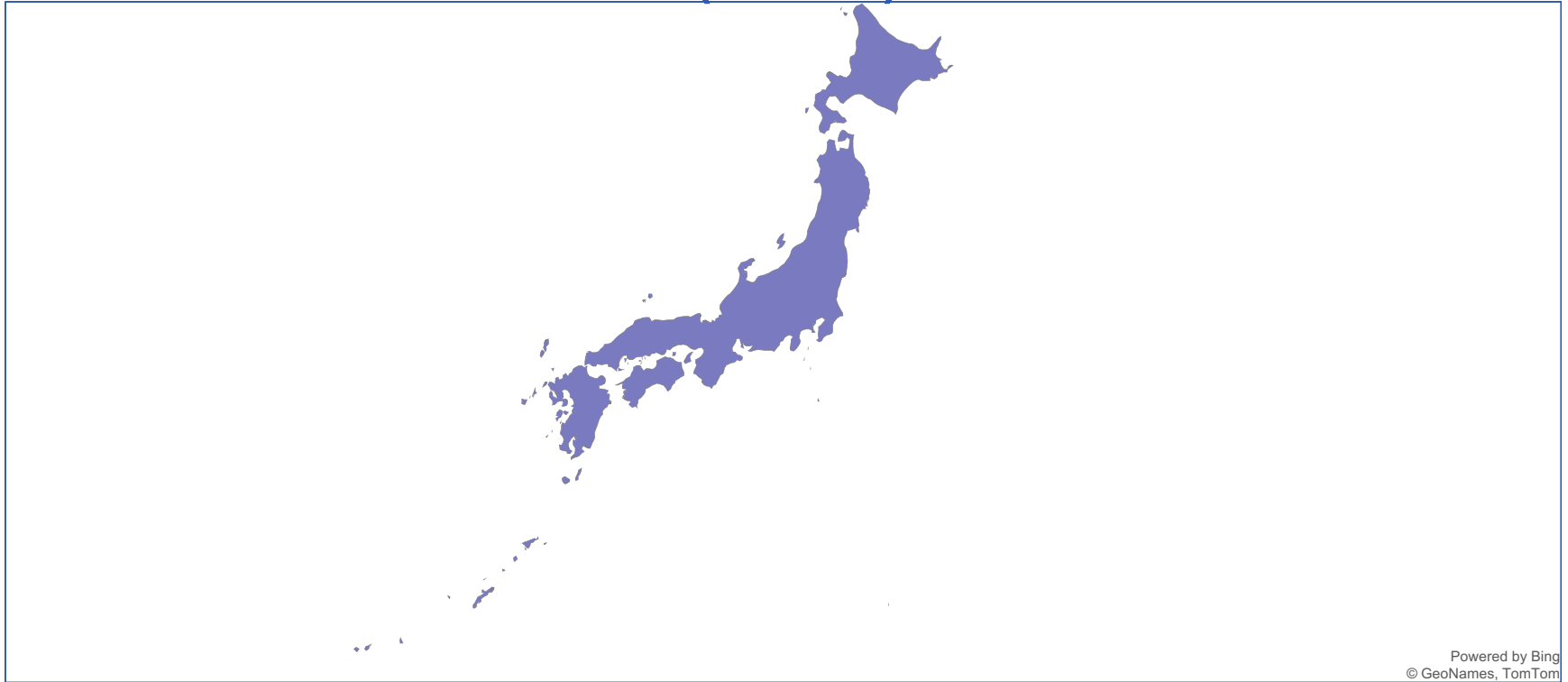


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# European Medicines Agency (EMA)

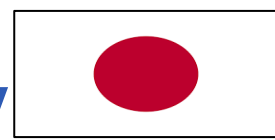
- Guideline:
  - Guidance on remote GCP inspections during the COVID-19 pandemic -  
18 May 2020
- Scope:
  - Sponsors, CROs and service providers (e.g. medical imaging, central laboratories) in general;

# Pharmaceuticals and Medical Devices Agency (PMDA)



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# Pharmaceuticals and Medical Devices Agency (PMDA)



## ➤ Public Communication:

New guidance on implementation procedures for remote GCP and GPSP inspections in medicines and regenerative medicine products – November 2020

## ➤ Scope:

- Document-based inspection and GCP on-site inspection for approval of drugs and regenerative medical products
- Document-based inspection and GPSP on-site inspection for interim evaluation, reexamination, and reevaluation of drugs
- Document-based inspection and GPSP on-site inspection for approval review after conditional and time-limited authorization, reexamination, and reevaluation of regenerative medical products



The image shows a large, dark, irregularly shaped object, possibly a piece of wood or a rock, covered in dense, handwritten text in a cursive script. The text is written in a light color, likely white or light gray, and covers the entire surface of the object. The handwriting is very dense and appears to be a form of shorthand or a highly stylized cursive. The object has a rough, textured surface and a small, lighter-colored mark or hole near the bottom center.

# Are we speak the same inspection language?





# Are we speak the same (inspection) language?

	FDA	ANVISA	MHRA	EMA	PMDA
Scope	GMP and BIMO program	GCP inspections	All inspections	GCP inspections on Sponsors, CROs, service providers	GCP and GPSP inspections
Technology accepted	MS Teams, Zoom and Adobe connect	Not specified	Not specified	Not specified	Not specified
Tour of Facility	Use livestream and/or pre-recorded video	Not specified	Not specified	Not specified	Not accepted
Pre-inspection activities	Yes	Not specified	Yes	Yes	Yes (a separate phase)

## Is this all?

- TGA issued: expectations for overseas manufacturing sites hosting remote inspections during the COVID-19 pandemic
- EMA has a second guidelines for remote inspections: Remote pharmacovigilance inspections of MAHs during a crisis situation- points to consider
- Since the onset of the pandemic, the Russian GMP Inspectorate appears to have focused on remote inspections as evidenced by the fact that it has conducted a total of 111 remote inspections

# Post-COVID inspections

- Back to on-site model or hybrid Inspections
- Alignment on their approaches and methods for conducting remote inspections

OR....

We took the temperature of our community - **Rob to enlighten you**





# Acknowledgements

➤ EBF Community

# Contact Information

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