EBF

14th EBF Open Symposium

Science – Our Universal Language

Regulatory framework for and challenges for industry with remote HA audits

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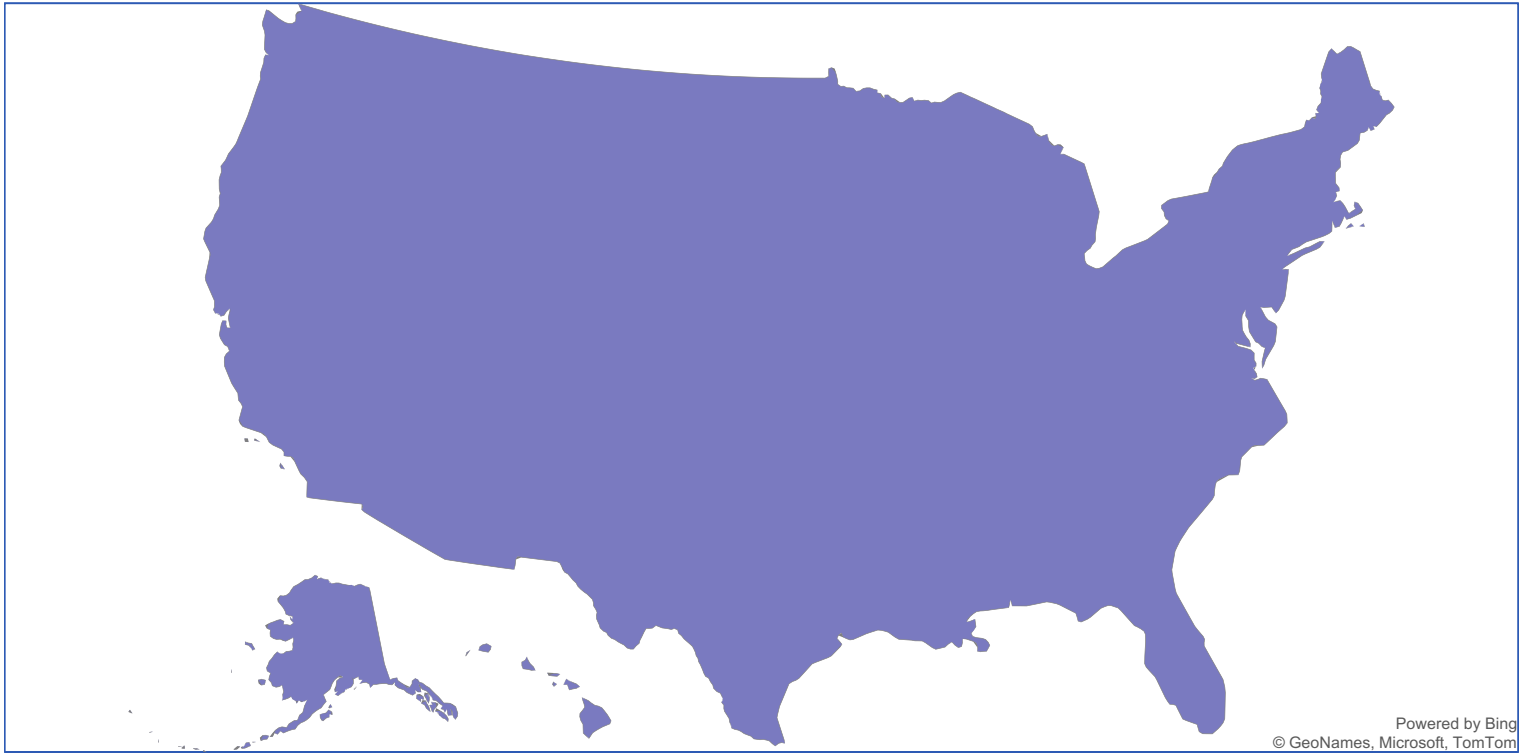
03 December 2021

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 where drugs 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)

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- Guidance:

  Canada's approach to onsite inspections during COVID-19: Notice– April 2021

- Scope:
  - All inspections types;

Agência Nacional de Vigilância Sanitária (ANVISA)

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- Guidance:

  RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC Nº 449, DE 15 DE DEZEMBRO DE 2020

- Scope:
  - Good Clinical Practice activities;

Medicines and Healthcare products Regulatory Agency (MHRA)

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- Public Communication:

  MHRA Good Practice (GxP) inspections during the COVID19 outbreak

- Scope:
  - All types of inspections;

Conduct of remote inspections: challenges and progress

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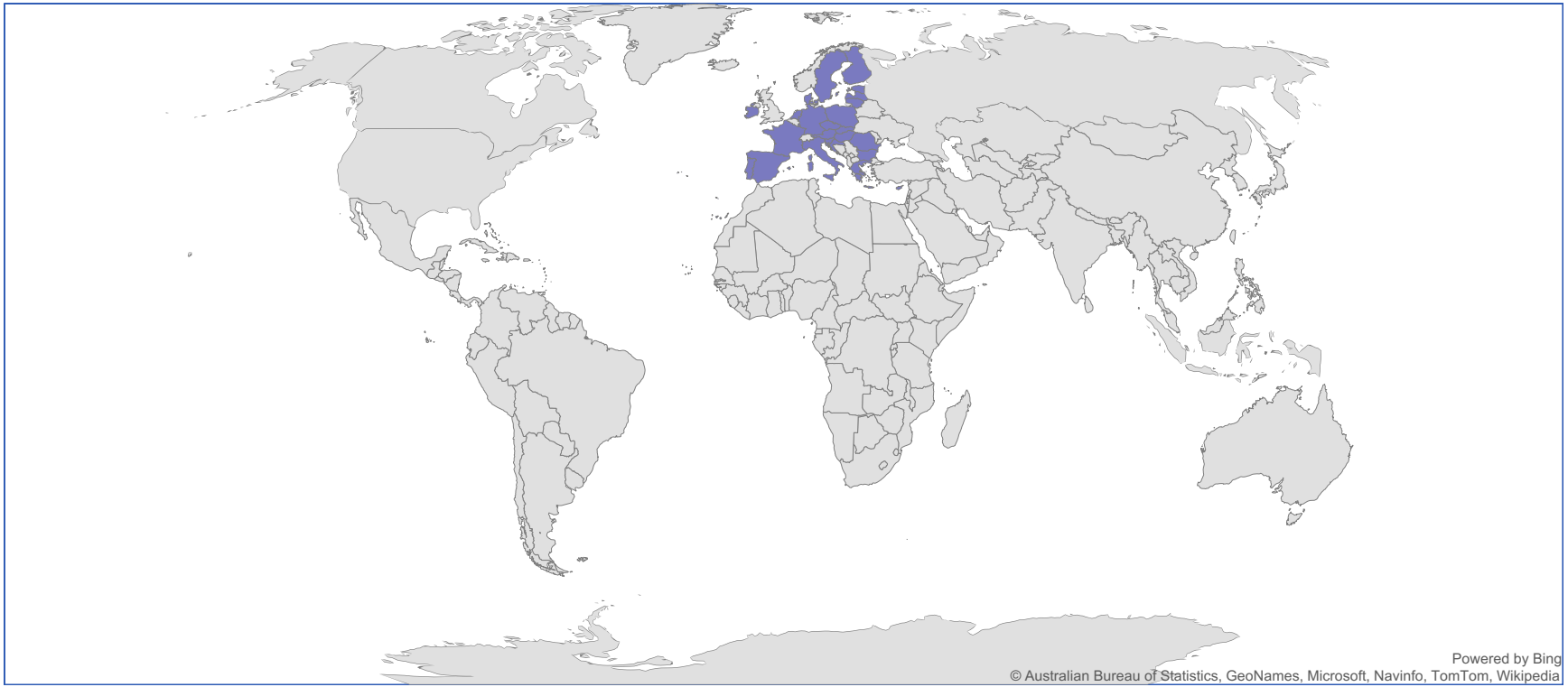
European Medicines Agency (EMA)



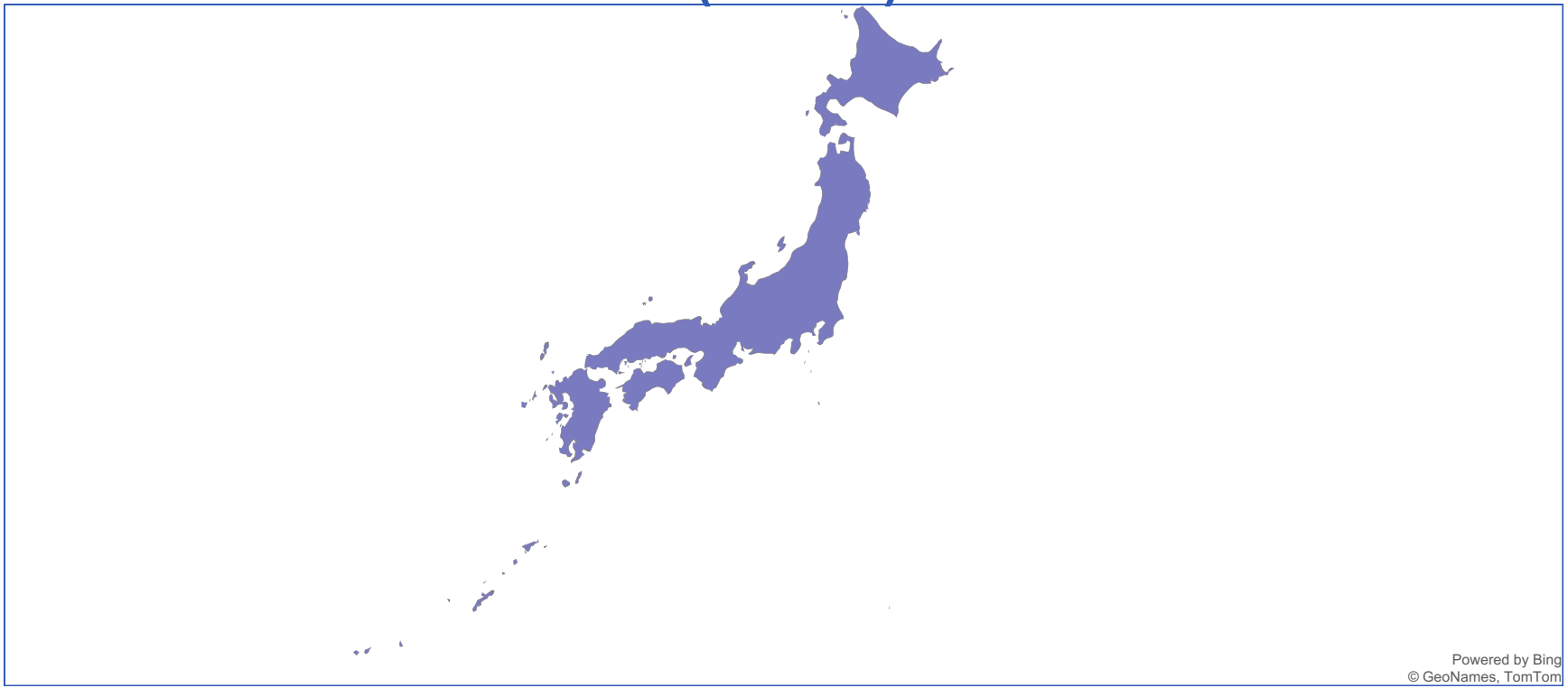
European Medicines Agency (EMA)

- 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)



Pharmaceuticals and Medical Devices Agency (PMDA)

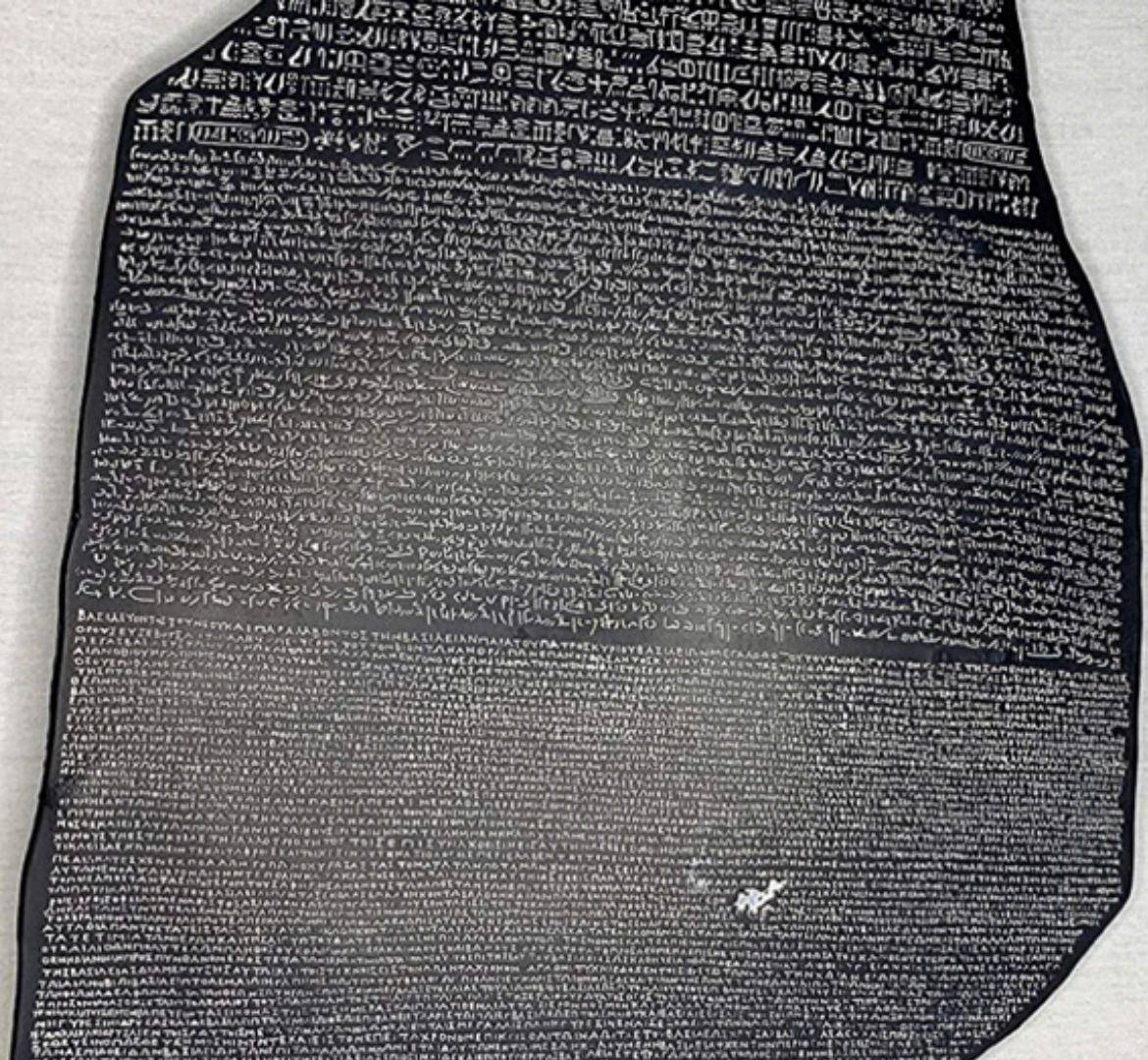
- Public Communication:

  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

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



Are we speaking 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)

To be or not to be remote?

Discussion feedback from the last week

- Remote inspections are not considered as a alternative approach to on-site ones by all HA
- Requirements for remote inspections needs to be aligned
- Remote HA inspections could not fully replace on-site ones, but could be considered for low risk facilities
- Paper records are challenging to be reviewed during a remote inspections


Arigato
Mahalo
Grazie
Spasiba
THANK YOU
Thoinks Moite
Gracias
Merci
Danke
Shukran

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- EBF Community

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