EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA IRIS

Industry training for GVP Inspections

7 September 2022, 10:00 – 11:30 Central European Time (CET)
Webinar: WebEx

AGENDA

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	Item	Duration	Presenter
1	Welcome / Introductions	10:00 – 10:05 *5 mins*	***Dunja Vukić*** *EMA*
2	Introduction to IRIS	10:05 – 10:10 *5 mins*	***Dunja Vukić*** *EMA*
3	Access Management	10:10 – 10:25 *15 mins*	***Dunja Vukić*** *EMA*
4	GVP Inspections Business Process	10:25 – 10:45 *20 mins*	***Dunja Vukić*** *EMA*
5	Guidance & Support	10:45 – 10:50 *5 mins*	***Cristina Pepato*** *IRIS Inspections Change Manager*
4	Q&A Session	10:50 – 11:25 *35 mins*	***Cristina Pepato*** *IRIS Inspections Change Manager*
5	Closing	11:25 – 11:30 *5 mins*	***Dunja Vukić*** *EMA*

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Send your questions via Slido

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1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and managed live in the Q&A session

Welcome

Dunja Vukić, EMA

AIM OF THIS SESSION

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Part of our change management strategy and plan aimed at:

1. **Explaining the changes in the GVP inspection process due to IRIS**
2. **Demonstrating the system and requirements for access and use**
3. **Answer your questions**

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Introduction to IRIS

Dunja Vukić, EMA

WHAT IS IRIS?

A **cloud-based software** tool to manage scientific and non-scientific procedures at EMA

Based on integrated **Microsoft Dynamics 365** (a CRM) and **Sharepoint online** (document repository)

Intended to **replace separate systems** with different technologies:

- Inspections (Oracle, Eudralink, Outlook)
- Orphan database (Microsoft Access)
- Scientific Advice Database (Oracle)
- Parallel Distribution tool (Filemaker)
- ITF (Excel)
- Marketing Status (E-mail)
- Veterinary Signal Management (Excel)
- SIAMED2 (Oracle)
- PedRA (Oracle)

IRIS COMPONENTS

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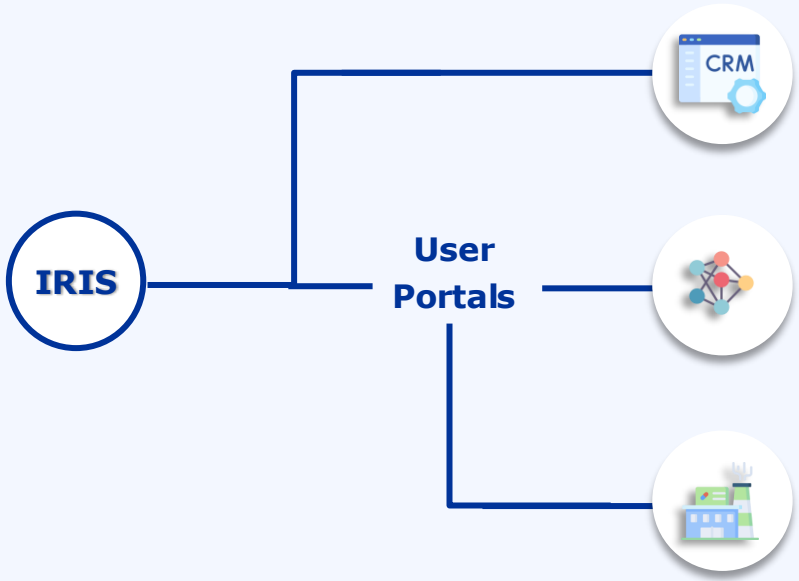

CRM Interface
Access restricted to EMA case workers

Network Portal
Accessible by EMA staff, regulatory network (NCAs, EC, EMA committees)

Industry Portal
Accessible by Industry

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STATE OF PLAY FOR INSPECTIONS

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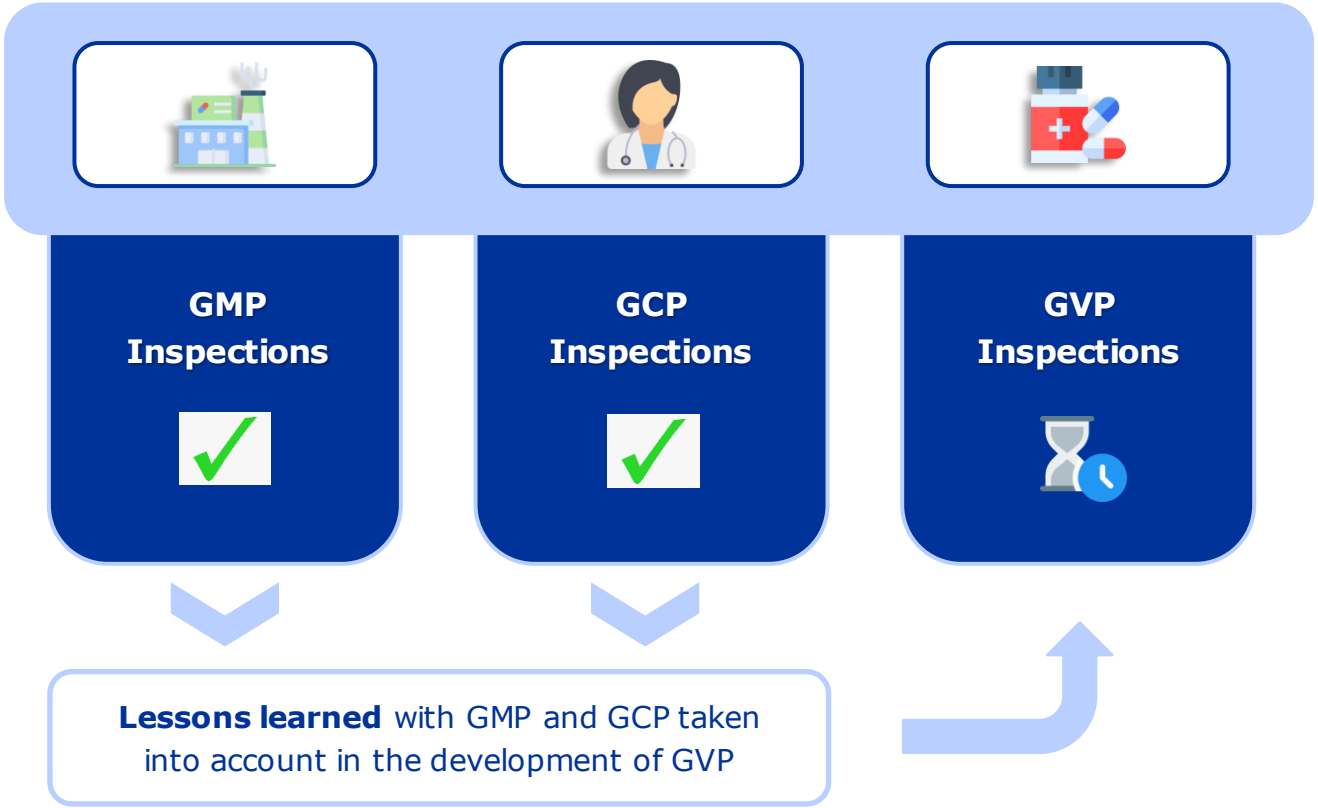

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SCOPE OF IRIS FOR GVP INSPECTIONS

EMA coordinated CHMP/CVMP requested inspections for centrally authorised product:

- global pharmacovigilance sites in third countries
- additional sites within EU that require joint inspections involving the Member State supervisory authority;
- based on a PRAC recommendation
- when a particular Member State supervisory authority prefers to follow this route;
- in a case of a "for cause" inspection

SCOPE OF IRIS FOR GVP INSPECTIONS

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Inspections of centrally authorised products conducted as part of the national programmes

Inspection of PV systems without any centrally authorised products

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Access Management

Dunja Vukić, EMA

WHO SHOULD HAVE ACCESS TO IRIS FOR GVP INSPECTIONS?

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All the QPPVs for CAPs as they will be the ones receiving the inspection announcement and will be able to see the data in IRIS

Deputy/back up arrangements need to be taken into account

Depending on the organisational structure, employees involved in inspection preparation and conduct

Unlimited number of users can be added to an inspection submission

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ACCESS MANAGEMENT

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Access to IRIS is requested via EMA account management system by adding an IRIS role to your EMA account

To access and use IRIS, the platform needs to know:

1. **Who are you?**
   (Do I have an EMA account?)
2. **What organisation do you represent?**
   (Is my organisation(s) registered in OMS?)
3. **Which user access roles do I have?**
   (What role(s) do I need to request?)

1. EMA ACCOUNT

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If you are **already using other EMA applications** like Eudralink, SPOR, EudraVigilance, UPD, Service Desk, you have an EMA account.

A **new account** can be created by completing the Self-service Registration form.

There is an option to **recover your username and password** and also reactivate your account as accounts are automatically disabled after 6 months of inactivity.

2. ORGANISATION LOOK UP AND AFFILIATION

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Is an organisation on whose behalf I will be acting listed in EMA's OMS?	**Yes**	Proceed with your request for an appropriate IRIS user role via the EMA Account Management portal
	Yes, but it needs to be updated	Raise a request in OMS to have your organisation data updated
	I don't know	Look up your organisation during the IRIS user access request process in the EMA Account Management portal or search for it in the IRIS homepage or EMA OMS
	No	Raise a change request to have your organisation registered

2. ORGANISATION LOOK UP AND AFFILIATION

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QPPV and any other users need to be affiliated to all MAH legal entities for CAPs.

- For example, if the CAP MAHs in your PV system are Super Pharma B.V., Super Pharma GmbH and Ultra Pharma d.o.o., users need to request affiliation for all of those organisations.
- A CRO employee can be affiliated to different MAHs, either by using a CRO e-mail address or an MAH e-mail address.

3. IRIS USER ROLES

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Is there at least one person with the IRIS Industry User Admin role in the organisation on whose behalf I will be acting?	**Yes**	Request the role you need in the EMA Account Management Portal: • **IRIS Industry Manager** • **IRIS Industry Contributor**
	No	Before you request a role, ensure that at least two people from the organisation are set up as **IRIS Industry User Admin**. If no person with an Admin role has been set up, all role requests will be automatically rejected by the EMA Account Management Portal. While approval of the "IRIS Industry Manager and Contributor" is done by the "IRIS Industry User Admin" of your organisation, the approval of the first "IRIS Industry User Admin" is done by EMA and takes two working days.

MANAGING CONTACTS

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Contributors can **view and edit**, but **cannot submit** the submission or manage contacts for the submission. **Managers** are able to complete **all** steps.

- There can be any number of Industry managers and Industry contributors associated to a single submission, but only one of them is the "Submission contact", also called the "portal contact", i.e. the primary contact person to whom all communication is sent, the QPPV.

The **"Submission contact" role can be reassigned** at any moment, and repeatedly, by any of the Industry managers associated to that submission.

- **E.g.** deputy QPPV can be assigned as the "Submission contact" as required, for example before a period of leave of the "Submission contact" (i.e. QPPV).

NEW! IRIS INDUSTRY COORDINATOR ROLE

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The new IRIS affiliation type "IRIS Industry Coordinator" can now be requested in IAM

- Users with this role can visualize and edit any submission/application made on behalf of the specific organization of affiliation, in addition to those where the user has been added as a manager/contributor.
- If the QPPV is absent, the Global Coordinator can still see the submission and add a back up/deputy to the submission and change the submission contact.

GVP Inspections Business Process

Incl. Old vs New and Demo

OLD vs NEW

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OLD	NEW
Announcement of inspections via **Eudralink** - content in attached letter	Announcement of inspections via **an e-mail notification from IRIS** - content in IRIS platform
Changes/cancellations/closure communicated via **Eudralink** and updated letter	**Changes/cancellations/closure** communicated via an e-mail notification from **IRIS** – updated content on IRIS platform
Recipient of communications is the **product contact** for an example product	**Recipient** of communications and the IRIS Portal Contact is the **QPPV**
Documents shared with inspectors and EMA via **Eudralink**	**Documents** shared with inspectors and EMA via **IRIS** (upload function)
Inspection report shared via **Eudralink**	**Inspection report** accessible in **IRIS** platform

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SITE REGISTRATION IN OMS

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All the sites in GVP inspections need to be **registered in OMS**.

- If upon creation of a case, EMA notices the site is not registered, it will temporarily create the site in IRIS, but an inspection cannot be closed until all sites are in OMS.
- If this is the case, MAH/Applicant will be notified and requested to make sure all sites are registered as soon as possible.
- We are not expecting many of these cases as PV sites are often involved in other processes and therefore already in OMS.

DOCUMENTS FROM APPLICANT/MAH

Documents for EMA (e.g. Acceptance letter) and PSMF will need to be **submitted through IRIS**.

- Inspection team can then decide whether they want the other documents to be uploaded to IRIS or sent to them in a different way.
- Every document that is uploaded can be immediately accessed by EMA and inspectors. However, there is no notification until you "submit the submission".

System Demo

Dunja Vukić, EMA

WHAT IS THE START OF THE PROCESS FOR INDUSTRY? (1)

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Dear QPPV,

We would like to inform you that an inspection for your pharmacovigilance system has been adopted by CHMP/CVMP.

The details can be accessed via the IRIS Industry portal, under draft submissions.

Please let us know if you have any questions/comments by replying to this e-mail without changing the subject line.

Kind regards,
EMA GVP Inspection Coordinator

An e-mail like this will be sent to the QPPV e-mail address as stated in Art57/UPD (SIAMED) from the e-mail address EMA-IRIS@id.ema.europa.eu

WHAT IS THE NEXT STEP? (2)

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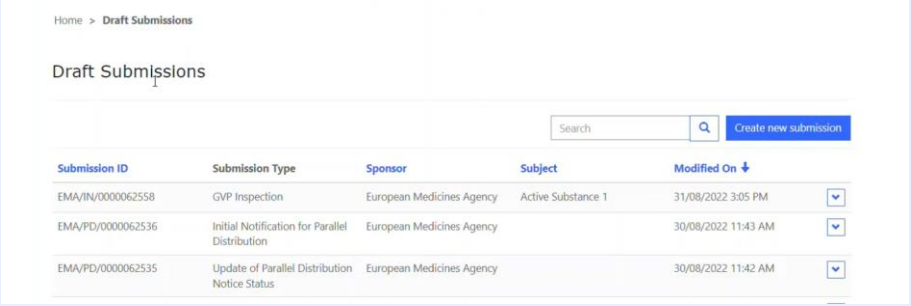
- If IRIS access had not been requested before the inspection announcement, this is the first step
- If you have access to IRIS, sign in at iris.ema.europa.eu

1. Click on Submissions – My Draft Submissions
2. A list of submissions will open



WHAT IS THE NEXT STEP? (3)

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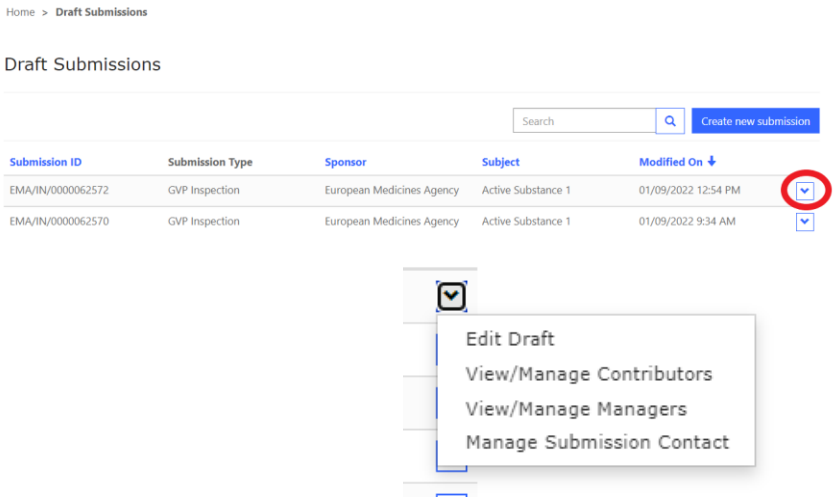
- Click on the **arrow** at the end of the submission
  - Choosing "edit draft" takes you to inspection details
  - Choosing the other three options lets you manage contacts for the submission
- You can **add as many colleagues** as needed to the submission (for detailed steps see IRIS guide for applicants)



INSPECTION INFORMATION

EUROPEAN MEDICINES AGENCY

Submission Form

GVP Inspection

Reference: EMA/IN/0000062558

Customer Name : European Medicines Agency
Address : Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands

Inspection Overview

Inspection Details

Documents from Applicant

Documents from EMA

Declare and Submit the changes

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INSPECTION OVERVIEW

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Inspection Overview

GVP Inspection

Reference: EMA/IN/0000062558

PSMF Code	Inspection Sub type	Reporting deadline
MFL12434	Post-authorisation inspection	09/01/2023

Lead Inspectorate	Supporting Inspectorate	Supporting Inspectorate 2
European Medicines Agency	—	—

Case Contacts

Contact	Role	Email (Contact)	Organisation
Cristina Rusu	Supporting Inspector	Cristina.Rusu@ema.europa.eu	European Medicines Agency
Dunja Vukic	Reporting Inspector	dunja.vukic@ema.europa.eu	European Medicines Agency
Miguel Rodriguez	Expert	Miguel.Rodriguez@ema.europa.eu	European Medicines Agency

INSPECTION DETAILS

EUROPEAN MEDICINES AGENCY

Inspection details

GVP Inspection
Reference: EMA/IN/0000062558

Site	Address 1 - composite (Site)	Site type	Number of fees	Inspection Scope
Test Location	Street 1 City 2 non-European Economic Area	Third Country Site	1	In scope
European Medicines Agency	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands	PSMF Location	1	In scope

Centrally authorised products covered by inspection

Invented name (Product)	Active substance(s) (Product)	EMA Number (Product)	Applicant/MAH/Sponsor
Authorised Product 1	Active Substance 1	EMEA/H/C/00XXXX	European Medicines Agency
Authorised Product 2	Active Substance 2	EMEA/H/C/00XXXX	Test Location

Customer Purchase Order Number

Please note that if you do not have a purchase order number, please include the text 'Not applicable' instead.

1234abcd

Return

DOCUMENTS FROM APPLICANT

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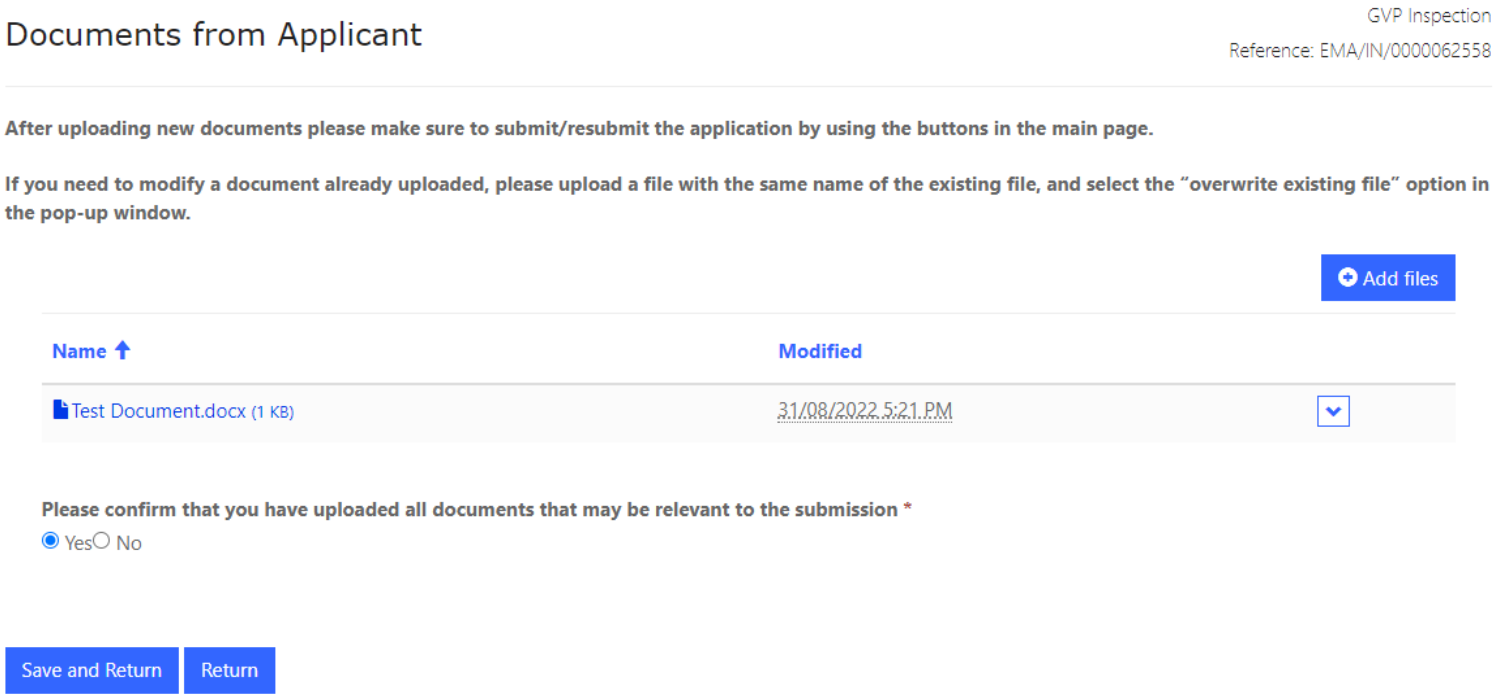

DOCUMENTS FROM EMA

EUROPEAN MEDICINES AGENCY

Documents from EMA

GVP Inspection

Reference: EMA/IN/0000062558

Name	Modified
Test Inspection Report.pdf (12 KB)	31/08/2022 4:34 PM

Return

DECLARE AND SUBMIT THE CHANGES

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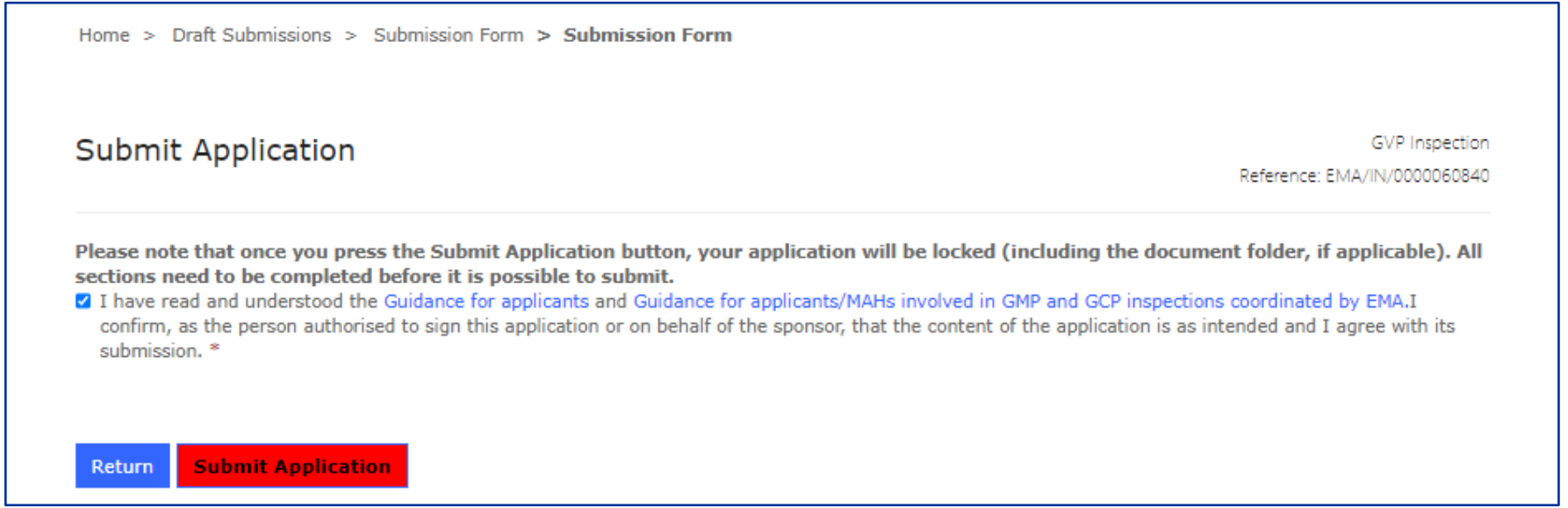

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INSPECTION MODIFICATION

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Dear QPPV,

We would like to inform you that the details of the inspection for your pharmacovigilance system have been modified.

The updated details can be accessed via the IRIS Industry portal.

If you have any questions, do not hesitate to contact us by replying to this e-mail without changing the subject line.

Kind regards,
EMA GVP Inspection Coordinator

TYPES OF CHANGES

- Change of sites
- Extension of reporting deadline

INSPECTION FINALISATION

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Dear QPPV,

We would like to inform you that an inspection for your pharmacovigilance system has been finalized.

The details of the outcome of the inspection can be accessed via the IRIS Industry portal.

If you have any questions, do not hesitate to contact us by replying to this e-mail without changing the subject line.

Kind regards,
EMA GVP Inspection Coordinator

ACTIONS

- Inspection moved to „Completed submissions"
- Inspection Report available in „Documents from EMA"

INSPECTION CANCELLATION

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Dear QPPV,

We would like to inform you that the inspection for your pharmacovigilance system has been cancelled.

Please note that the number of fees, if applicable, will be recalculated and an invoice will be sent to you accordingly.

If you have any questions, do not hesitate to contact us by replying to this e-mail without changing the subject line.

Kind regards,
EMA GVP Inspection Coordinator

ACTIONS

- Inspection moved to „Completed submissions" with status „Cancelled by EMA/System"

Guidance & Support

Cristina Pepato, IRIS Inspections Change Manager

This guidance contains information that was previously sent in the Announcement letters, e.g.:

- Information on document request and submission
- Information on fees
- Accessible at EMA website: Link

This guidance contains information about:

- Preliminary requirements for all IRIS submissions
- Requirements for substance and Research Product Identifier registration
- Accessible at EMA website: Link

This guidance contains information about:

- How to create and submit scientific applications, for industry and individual applicants
- Section 7 updated for GVP Inspections
- Accessible at EMA website: Link

SUPPORT

Use the IRIS Stakeholder Forum for questions of general interest

Contact the EMA Service Desk (https://servicedesk.ema.europa.eu/) for technical problems. If you cannot **access** IRIS at all, make sure you specify *"EMA Account Management"* as the software in the ticket, rather than "IRIS".

USEFUL LINKS

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GUIDANCE/TOPIC	LINK
IRIS webpage	Link
IRIS guide to registration	Link
IRIS guide to applicants	Link
Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA	Link
EMA Account Management System webpage	Link
Organisation Management Service (OMS) webpage (description of the system)	Link
Organisation Management Service (OMS)/SPOR webpage (log in)	Link
Overview of OMS change request process guidance	Link

Q&A Session

Cristina Pepato, IRIS Inspections Change Manager

Closing

Dunja Vukić, EMA

NEXT STEPS – GO LIVE AND SUPPORT

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- First inspections using IRIS to be adopted at **September CHMP** and **October CVMP**.
- EMA GVP inspection coordinators will be in touch with the first MAHs/QPPVs after the automatic notifications to troubleshoot any issues and provide guidance and clarifications.
- For **any questions about the specific case** at any time point, reply to the emails received from IRIS. (**Important**: do not change the subject line so the email gets correctly routed to the applicable case).

We are here to support and guide and also learn together with you!

CONTACTS

EUROPEAN MEDICINES AGENCY

Any other question?

Contact us by sending an e-mail to:

- dunja.vukic@ema.europa.eu
- miguel.rodriguez@ema.europa.eu