7 September 2022

EMA IRIS Industry Training for GVP Inspections

Questions & Answers

Disclaimer

This Question and Answer (Q&A) document is for information only and is based on insights available at the time of the IRIS Industry Training for GVP Inspections held on 7 September 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the Inspections project team.

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Contents

1. Will the slides be provided to the participants? 7

2. Does EMA provide an overview of all the EMA gateways relevant for pharmaceutical companies? How do they interact (e.g. IRIS, EVWEB, Eudralink, Article 57)? 7

3. Which were the most common lessons learned from GMP and GCP inspections via IRIS? 7

4. Will the participants receive any certificate for the participation to this GVP training? 7

5. How many GCP inspections have already been entered in IRIS? And are these sponsor inspections, CRO inspections and/or site inspections? 7

6. Which role needs to be assigned to a user to see the Inspection-related data? 7

7. Should QPPVs of MAHs who do not have a centralised MA have access to IRIS? Can they have access? 8

8. Can QPPVs currently without CAPs register for IRIS? 8

9. Does IRIS functionality need to be used for submitting inspection reports and status of Corrective and Preventive Action (CAPA) or will it be managed via e-mail only? 8

10. Can the submission contact also be assigned to a generic mailbox? 8

11. If a company has an IRIS Admin for GMP & GCP, is it needed to request one for GVP in IRIS? .. 8

12. Will Eudralink still be used for other regulatory purposes or will this platform be closed in the future? 8

13. What information is considered for a site to be registered in the OMS? 9

14. Are the inspections entered in IRIS publicly available/ accessible? 9

15. Is there any confirmation that documents have been uploaded successfully? What back-up procedures are available in case IRIS should not be accessible? 9

16. What is the tentative timeline for implementation for IRIS inspection process? 9

17. Are there any virus scans running during the document submission in IRIS as in Eudralink? 9

18. If you are representing more than one PV system, will the e-mail identify in the PV system that will be inspected? 10

19. How can the IRIS Industry Coordinator role be applied for? 10

20. In case of an orphan drug designation, is the inspecting agency represented by the EMA or the NCA? 10

21. When adding colleagues/contacts to the submission, do these contacts need to be registered in IRIS for them to be added? 10

22. If an IRIS account is deactivated after no use for 6 months, is there a need to create a new account that should be approved? 10

23. How does the portal work when one person is QPPV for more than one company? 11

24. From which "database" EMA takes contact details on QPPVs for sending the inspection announcement? Assuming IRIS e-mail is automated, how will the EMA know that the back-up person needs to be contacted? 11

25. Do additional contacts/managers need to be added manually for each individual submission? 11

26. Will the IRIS platform be used only for GVP inspections on CAPs or also for inspections done by NCAs on any other type of products? 11

27. Which file types are allowed to be uploaded? 11

28. Can zip files be uploaded as documents? 11

29. How can users know which documents should be uploaded? 12

30. Is there a step for QPPVs for several companies to choose which company's IRIS portal to access? 12

31. How the inspection's participants will be managed when joining outside EU territory in case PV activities are managed at different locations? 12

32. Is there a way to see what has changed in a summary view rather than checking each field in IRIS to see what has changed upon e-mail notification? 12

33. What are the fees? 12

34. Will this new IRIS inspection process also be used for veterinary GVP inspections? 12

35. Can a QPPV not registered in IRIS be notified for an inspection and then proceed with the first registration in IRIS? 13

36. Is it planned to incorporate to IRIS the non-centralised products in the future? 13

37. In case of submission of RFIs, for example, PSUSA or PRAC response for Signal, will Eudralink be replaced with IRIS or will it remain unchanged? 13

38. Is it allowed only for the QPPVs to delegate acting as submission contact in case of absence? 13

39. Will the IRIS Industry Coordinator at a MAH also receive by default the GVP Inspection notification e-mail that is sent to the QPPV? 13

40. Is it correct that the submission contact will be QPPV for GVP and for GMP & GCP inspections the submission contact is the person authorised for communication on behalf of the applicant, during the procedure that is commonly entered in eAF? 13

41. Would the products that are subject to an GPV Inspection need to reside in the IRIS portal (under the "Marketing Status") as well or is IRIS connected directly with the Article 57.2 for the products?....14

42. Should the QPPV be indicated as a contact in IRIS at the time of an inspection announcement or should IRIS be set up in advance with the contact person for GVP inspections? 14

43. Is IRIS intended to manage responses to inspection report and follow-up action plan as well? 14

44. When does IRIS go live for GVP?....14

45. Should the e-mail address for xEVMPD be a personal e-mail?....14

46. Does the Industry coordinator also get copied in the e-mail from IRIS to the EU-QPPV announcing the inspection and/or subsequent e-mails?....15

47. Can you replace already submitted documents (e.g. in case of errors) or should you submit new versions?....15

48. What does OMS stand for?....15

49. Will IRIS be used also for national GVP inspections in the future in order to avoid duplications in the inspections of companies by different European National Authorities? 15

50. What role applies to the Deputy QPPV? 15

51. Will IRIS only be used for supervisory authority GVP inspections for MAHs with CAPs?....15

52. What is the regular frequency of GVP inspections for MAHs with CAPs?....16

53. Since a user can have only 2 roles, how shall this work in small companies with only a few available people to manage different procedures (SPOR, IRIS, eAF, i-SPOC, etc.)?....16

54. Can QPPVs be registered in IRIS with CRO e-mail for different companies?....16

55. Will users need several IRIS accounts when responsible for more than one company?....16

56. Is the QPPV e-mail address taken from Article 57 from the field called "Pharmacovigilance enquiries e-mail address"?....16

57. If a national HA inspects on behalf of EMA (supervising authority) would it use IRIS or, for example, Eudralink? 17

58. Should users communicate with inspectors during or prior to an inspection through e-mail or the portal? 17

59. Should a QPPV for many MAHs have one EMA account or different e-mails address for each MAH for IRIS registration? 17

60. Will all inspection-related documents (such as reports) remain forever in IRIS? What is the retention period of the documents uploaded on IRIS? 17

61. Will the GVP Training Q&A session be recorded for later use or printed as a guidance document? 17

62. Can the QPPV address also be entered in OMS (as it is the PSMF location) if it is a private home office address but not an "official" company address? 18

63. Is it correct that a QPPV does not need to register in IRIS because EMA will assign the IRIS manager role to all the QPPVs based on Article 57 information? 18

64. Can IRIS also be used to exchange document requests during the inspection? 18

65. What exactly the Article 57 refers to with regards to the QPPV e-mail address? Can the full reference be provided? 18

66. Since for human CAPs QPPV contact details are collected from Article 57, are QPPV contact details collected from UPD for vet CAPs? 18

67. Will IRIS also be used in Clinical Trials or only for authorised products? 19

68. Will only the QPPVs receive a notification? If they are on leave, should the coordinator keep checking IRIS for inspection notification? 19

69. Is there a QPPV role for IRIS specifically? 19

70. How can users search if their companies have already an IRIS coordinator role? 19

71. Can multiple IRIS Industry Coordinator roles be assigned for one company? 19

72. Would it possible to add more managers/contributors at one time in IRIS? 19

73. Is there an overview (e.g., EMA Homepage) of which permissions the IRIS Industry Coordinator has? 19

74. There is one guidance document about GMP only and another one with information about both GMP and GCP. Since the GMP information is duplicated, will one of the documents be withdrawn? 20

75. Will IRIS work 24/7? Can we receive any communication on weekends or bank holidays or out of business hours? 20

76. Can the new IRIS role also view completed submissions? 20

77. Can the same generic e-mail address be used by several colleagues in different accounts? 20

78. What does the "Reporting deadline" correspond to? Is it the limit date for submitting pre-inspection documents? 20

79. Will QPPV receive an e-mail notification for other submissions as well (e.g. when inspection report will be available)? 20

80. Can all users added to a specific GPV Inspection view the Inspection report (under the "view submission" function), or is this restricted to the contact of this specific Inspection, i.e. the QPPV? ... 20

1. Will the slides be provided to the participants?

Yes, they have been uploaded on the EMA event page.

2. Does EMA provide an overview of all the EMA gateways relevant for pharmaceutical companies? How do they interact (e.g. IRIS, EVWEB, Eudralink, Article 57)?

You can read more about EMA information management and IT systems on this link.

3. Which were the most common lessons learned from GMP and GCP inspections via IRIS?

Inspections are the first process in IRIS where the EMA starts the case, while in all the other processes industry would start the submission (e.g. scientific advice, orphan designation, parallel distribution). Therefore, the key lesson learned is the importance of contacts management. This was addressed also with the global coordinator role to make sure no inspection announcements are missed.

4. Will the participants receive any certificate for the participation to this GVP training?

No, certificates will not be issued for the participation to this training. However, the recording will be available online for people who missed the training or want to re-watch it.

5. How many GCP inspections have already been entered in IRIS? And are these sponsor inspections, CRO inspections and/or site inspections?

Currently, around 10 GCP inspections have been entered in IRIS since April. Every inspection is a mix of different inspection sites, based on the scope and responsibilities.

6. Which role needs to be assigned to a user to see the Inspection-related data?

Either IRIS industry manager or contributor. Both of these roles can see the inspection data.

7. Should QPPVs of MAHs who do not have a centralised MA have access to IRIS? Can they have access?

For GVP Inspections, QPPVs of MAH without CAPs do not need to have access because there will be no GVP Inspections for them. They can have access to IRIS because there will be also other procedures in IRIS, where NAPs will be involved.

8. Can QPPVs currently without CAPs register for IRIS?

Yes, QPPVs without CAPs can register for IRIS. However, in the case of EMA coordinated CHMP/CVMP requested GVP inspections there is no need for it.

9. Does IRIS functionality need to be used for submitting inspection reports and status of Corrective and Preventive Action (CAPA) or will it be managed via e-mail only?

The process of CAPA management and interactions is only between an MAH and the inspectors. Inspectors will submit to EMA the final report and, after the review and validation by EMA, it will be shared with the MAH.

10. Can the submission contact also be assigned to a generic mailbox?

When EMA is gathering information to create a submission with the QPPV as the contact, the QPPV e-mail address used is the one that has been provided in the Article 57 database (field: QPPV e-mail that is also used in EMA Account management for QPPV's EMA account). This e-mail address will need to have an IRIS account to access the inspection data.

11. If a company has an IRIS Admin for GMP & GCP, is it needed to request one for GVP in IRIS?

No, if a company already has an IRIS admin to approve requests, this also applies to users needing access for GVP inspections.

12. Will Eudralink still be used for other regulatory purposes or will this platform be closed in the future?

Currently, Eudralink is still under use. The EMA is gradually moving to IRIS for all of its procedures, but for the time being there is no plan to stop the use of Eudralink.

13. What information is considered for a site to be registered in the OMS?

In the OMS (Organisation Management System) there is a search function where the user can search for an organisation. If an organisation is present there, it means that everything is registered correctly. You can find more information on the OMS and the change request process at the following link.

14. Are the inspections entered in IRIS publicly available/ accessible?

No, this is confidential information which is not publicly available. Users can see information only about their own inspections. However, NCAs in the EEA regulatory network can see all the CHMP & CVMP requested inspections in the Network Portal.

15. Is there any confirmation that documents have been uploaded successfully? What back-up procedures are available in case IRIS should not be accessible?

Once the document is uploaded, users will see it in the list of documents as a confirmation of uploading. In case IRIS is inaccessible, the EMA can revert to Eudralink or another way can be agreed with inspectors to share documents.

16. What is the tentative timeline for implementation for IRIS inspection process?

GMP inspections have been live for a year, GCP has been live since April. The first case for pharmacovigilance inspections will be adopted at the September CHMP. This completes the implementation of inspections. GLP inspections and Plasma Master File (PMF) inspections will not transition to IRIS.

17. Are there any virus scans running during the document submission in IRIS as in Eudralink?

IRIS uses Microsoft 365 virus detection engine for scanning files that users upload to SharePoint Online. You can read more about it on this link.

18. If you are representing more than one PV system, will the e-mail identify in the PV system that will be inspected?

As inspection data is confidential, the PV system will not be identified in the e-mail. The notification will only state that an inspection has been adopted and that the details can be seen in IRIS.

19. How can the IRIS Industry Coordinator role be applied for?

Users can request it in the EMA account management system (register.ema.europa.eu). More details on the requesting access can be found at the following link.

20. In case of an orphan drug designation, is the inspecting agency represented by the EMA or the NCA?

The inspections are always performed by the national competent authorities. Orphan drug designations are normally centrally authorised products. However, these inspections can be performed either through the national programme (i.e., national competent authorities perform it following national procedures) or in some situations a CHMP/CVMP route might be followed. It depends on different factors, but the inspectors are always from national competent authority, while the EMA has the coordinating role in some inspections.

21. When adding colleagues/contacts to the submission, do these contacts need to be registered in IRIS for them to be added?

Yes. All the colleagues will need to have an IRIS account and they will need to be affiliated to the user's organisation for the user to be able to see them in IRIS as well. When users perform the lookup, they only get the names of colleagues with properly set IRIS accounts. If a colleague is not visible, there may be problems concerning the account or the affiliation to the organisation.

22. If an IRIS account is deactivated after no use for 6 months, is there a need to create a new account that should be approved?

If user is not using the e-mail account, not just for IRIS, but in general for any other applications for 6 months, then it automatically becomes deactivated. However, it can be reactivated. Therefore, there is no need to create a new account. The detailed instructions on how to do that can be found at the following link.

23. How does the portal work when one person is QPPV for more than one company?

The QPPV needs to associate themselves with all the applicable CAP MAH legal entities in their EMA account to be able to see the information in IRIS. If different e-mail addresses are used for different clients, inspections will also be visible under different EMA/IRIS account.

24. From which "database" EMA takes contact details on QPPVs for sending the inspection announcement? Assuming IRIS e-mail is automated, how will the EMA know that the back-up person needs to be contacted?

EMA is taking information from Article 57 for human and UPD/SIAMED for veterinary medicinal products. If an "out of office" notification is received, the back up person will be contacted as stated in the message. Moreover, there is now a new role - IRIS Global Coordinator - who can see all the submissions for the company. Even if the QPPV is absent, IRIS Global Coordinator can see that a new GVP inspection was announced and add other colleagues to the submission.

25. Do additional contacts/managers need to be added manually for each individual submission?

Yes, for every GVP, GCP or GMP inspection additional colleagues need to be manually added.

26. Will the IRIS platform be used only for GVP inspections on CAPs or also for inspections done by NCAs on any other type of products?

IRIS will be used only for EMA-coordinated inspections, namely for inspections which are requested either by CHMP or CVMP for CAPs, not for other types of products.

27. Which file types are allowed to be uploaded?

Users can upload Word documents, PDFs, Excels and zip files. Subfolders cannot be created.

28. Can zip files be uploaded as documents?

Yes, you can upload this type of files.

29. How can users know which documents should be uploaded?

The list of documents is available in the Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA.

30. Is there a step for QPPVs for several companies to choose which company's IRIS portal to access?

The QPPV needs to associate themselves with all the applicable CAP MAH legal entities in their EMA account to be able to see the information in IRIS. If different e-mail addresses are used for different clients, inspections will also be visible under different EMA/IRIS account.

31. How the inspection's participants will be managed when joining outside EU territory in case PV activities are managed at different locations?

This question should be addressed at the inspection team. EMA identifies the sites when creating an inspection request, but logistical aspects rest with the inspection team.

32. Is there a way to see what has changed in a summary view rather than checking each field in IRIS to see what has changed upon e-mail notification?

Currently, there is no option to see the changes. The only changes that users will see are either the reporting deadline or the change in the sites. There are no other sections that users need to review. Since there is not much data, it should be easy to identify the changes. In case of any doubts, please reach out to the EMA GVP Inspection coordinator for this case.

33. What are the fees?

Please consult the Explanatory note on general fees payable to the European Medicines Agency.

34. Will this new IRIS inspection process also be used for veterinary GVP inspections?

Yes, it will be used for CVMP requested veterinary inspections as well, starting from the October meeting.

35. Can a QPPV not registered in IRIS be notified for an inspection and then proceed with the first registration in IRIS?

Yes, of course. If a QPPV gets the notification and does not have an IRIS account, the first step would be to request an account. However, it is preferable not to be rushed and have an account before.

36. Is it planned to incorporate to IRIS the non-centralised products in the future?

There are no plans to extend the use of IRIS for non-EMA coordinated GVP inspections at the moment.

37. In case of submission of RFIs, for example, PSUSA or PRAC response for Signal, will Eudralink be replaced with IRIS or will it remain unchanged?

EMA is gradually moving its processes and procedures to IRIS, so these processes will probably also move in the future. Industry will be timely informed about the next steps.

38. Is it allowed only for the QPPVs to delegate acting as submission contact in case of absence?

The initial notification will be always sent to the QPPV. Later on, QPPVs can change the submission contact to another colleague with the Industry manager role.

39. Will the IRIS Industry Coordinator at a MAH also receive by default the GVP Inspection notification e-mail that is sent to the QPPV?

No, the notification will only be sent to the QPPV. However, the coordinator will be able to see the submission as soon as it is uploaded on the industry portal. Therefore, as soon as the QPPV gets the notification, the submission is available on the industry portal.

40. Is it correct that the submission contact will be QPPV for GVP and for GMP & GCP inspections the submission contact is the

person authorised for communication on behalf of the applicant, during the procedure that is commonly entered in eAF?

Yes, that is correct. The contacts for GMP and GCP inspections are the product contacts because these inspections are product-focused. Pharmacovigilance inspections are mostly system-focused and QPPV is the contact point as mandated by the legislation so IRIS was set up in this way.

41. Would the products that are subject to an GPV Inspection need to reside in the IRIS portal (under the "Marketing Status") as well or is IRIS connected directly with the Article 57.2 for the products?

GVP inspection data is not linked to the marketing status data.

42. Should the QPPV be indicated as a contact in IRIS at the time of an inspection announcement or should IRIS be set up in advance with the contact person for GVP inspections?

There is no option for an organisation to set up a contact person for GVP inspections in IRIS. The contact is the QPPV as stated in Art. 57/UPD (SIAMED).

43. Is IRIS intended to manage responses to inspection report and follow-up action plan as well?

No, this part of the process stays as it was in the old process. This is a communication between the company and the inspectors. Only the final report is shared by the inspectors with the EMA, which then shares it with users after the validation.

44. When does IRIS go live for GVP?

IRIS went live for GVP inspections on Monday 12 September 2022, but the first notifications to the industry will be sent after the CHMP/CVMP adoptions.

45. Should the e-mail address for xEVMPD be a personal e-mail?

The e-mail should be the one that the QPPV normally uses and to see the data in IRIS there should be an EMA account with this e-mail.

46. Does the Industry coordinator also get copied in the e-mail from IRIS to the EU-QPPV announcing the inspection and/or subsequent e-mails?

No, the Industry Global Coordinators can see the submission as soon as the e-mail to the QPPV is sent out, but they will not be in addition also receiving this e-mail.

47. Can you replace already submitted documents (e.g. in case of errors) or should you submit new versions?

Yes, already submitted documents can be replaced.

48. What does OMS stand for?

OMS stands for Organisation Management Service. You can find more information on this link.

49. Will IRIS be used also for national GVP inspections in the future in order to avoid duplications in the inspections of companies by different European National Authorities?

IRIS is EMA's system for EMA coordinated inspections. The National Competent Authorities have their own systems. Authorities should be coordinated to avoid duplicities, however, every NCA has a remit and an obligation to inspect in its territory.

50. What role applies to the Deputy QPPV?

The Deputy QPPV can choose the industry manager or industry contributor role. The only difference between these roles is that the industry manager can also make a submission, while the contributor can only see the data. The EMA suggests the Deputy QPPV to request the manager role.

51. Will IRIS only be used for supervisory authority GVP inspections for MAHs with CAPs?

IRIS will be used for EMA coordinated CHMP and CVMP requested inspections of MAH with CAPs.

52. What is the regular frequency of GVP inspections for MAHs with CAPs?

The routine CAP cycle is four years, however, this time can be shortened in case the previous inspection identified serious non-compliance or any triggers. A risk-based approach is applied to managing CAPs inspections programme.

53. Since a user can have only 2 roles, how shall this work in small companies with only a few available people to manage different procedures (SPOR, IRIS, eAF, i-SPOC, etc.)?

A user can request only 2 roles in IRIS to view the data - contributor and manager. However, it does not limit the user to any specific procedure. The user just needs an IRIS technical role in order to perform all the procedures that are available in IRIS.

54. Can QPPVs be registered in IRIS with CRO e-mail for different companies?

The QPPV needs to associate themselves with all the applicable CAP MAH legal entities in their EMA account to be able to see the information in IRIS. If different e-mail addresses are used for different clients, inspections will also be visible under different EMA/IRIS account.

55. Will users need several IRIS accounts when responsible for more than one company?

The QPPV needs to associate themselves with all the applicable CAP MAH legal entities in their EMA account to be able to see the information in IRIS. If different e-mail addresses are used for different clients, inspections will also be visible under different EMA/IRIS account.

56. Is the QPPV e-mail address taken from Article 57 from the field called "Pharmacovigilance enquiries e-mail address"?

When EMA is gathering information to create a submission with the QPPV as the contact, the QPPV e-mail address used is the one that has been provided in the Article 57 database (field: QPPV e-mail that is also used in EMA Account management for QPPV's EMA account). This e-mail address will need to have an IRIS account to access the inspection data.

57. If a national HA inspects on behalf of EMA (supervising authority) would it use IRIS or, for example, Eudralink?

If it is the supervisory authority on behalf of EMA, meaning that it was adopted by CHMP or CVMP, it would need to use IRIS. If the supervisory authority inspects as part of their national programme, without a CHMP/CVMP request, it will not be managed via IRIS. Eudralink can be used for a simple exchange of documents according to the inspectors' preferences, but IRIS provides an option to exchange documents too. Please note that information on the inspections will be in IRIS, no announcements will be sent by Eudralink anymore.

58. Should users communicate with inspectors during or prior to an inspection through e-mail or the portal?

The communication with inspectors should happen via e-mail. The IRIS portal can be used for the submission of documents. Some of the documents need to be submitted through IRIS. For other submissions, users will agree with inspectors if using IRIS or not. IRIS can be used both during and prior to an inspection to submit documents.

59. Should a QPPV for many MAHs have one EMA account or different e-mails address for each MAH for IRIS registration?

The QPPV needs to associate themselves with all the applicable CAP MAH legal entities in their EMA account to be able to see the information in IRIS. If different e-mail addresses are used for different clients, inspections will also be visible under different EMA/IRIS account.

60. Will all inspection-related documents (such as reports) remain forever in IRIS? What is the retention period of the documents uploaded on IRIS?

Yes, the reports will stay there. The current IRIS policy is that the documentation will not be removed, and this applies to all EMA procedures.

61. Will the GVP Training Q&A session be recorded for later use or printed as a guidance document?

Yes. First of all, the recording of this training is available via a YouTube channel video and EMA event page. The Q&A document will be made publicly available through the registration page.

62. Can the QPPV address also be entered in OMS (as it is the PSMF location) if it is a private home office address but not an "official" company address?

EMA gets the information on the sites by taking the PSMF location. The EMA assumes that this is the location of an inspection. If once the EMA announces the inspection the address is a home office address where inspection cannot be done, there is always an option to change the site. Therefore, the inspection request can be modified, and the EMA can adjust the sites accordingly.

63. Is it correct that a QPPV does not need to register in IRIS because EMA will assign the IRIS manager role to all the QPPVs based on Article 57 information?

No. The QPPVs need to register themselves.

64. Can IRIS also be used to exchange document requests during the inspection?

Yes. Users can use IRIS to upload the documents if the inspectors have agreed to proceed this way.

65. What exactly the Article 57 refers to with regards to the QPPV e-mail address? Can the full reference be provided?

When EMA is gathering information to create a submission with the QPPV as the contact, the QPPV e-mail address used is the one that has been provided in the Article 57 database (field: QPPV e-mail that is also used in EMA Account management for QPPV's EMA account). This e-mail address will need to have an IRIS account to access the inspection data.

66. Since for human CAPs QPPV contact details are collected from Article 57, are QPPV contact details collected from UPD for vet CAPs?

Yes, information will be taken from UPD once the full data set is available and from the internal database SIAMED until then.

67. Will IRIS also be used in Clinical Trials or only for authorised products?

EMA coordinated GCP inspections for CAPs are managed in IRIS since April 2022.

68. Will only the QPPVs receive a notification? If they are on leave, should the coordinator keep checking IRIS for inspection notification?

If an "out of office" notification is received from the QPPV, the back-up person will be contacted as stated in the message.

69. Is there a QPPV role for IRIS specifically?

When it comes to access, there is no specific role for a QPPV. QPPVs should request Industry Manager role.

70. How can users search if their companies have already an IRIS coordinator role?

IRIS Administrator users can perform the search in the EMA Account Management system.

71. Can multiple IRIS Industry Coordinator roles be assigned for one company?

Yes, there is no limit.

72. Would it possible to add more managers/contributors at one time in IRIS?

At this time, this is not technically possible.

73. Is there an overview (e.g., EMA Homepage) of which permissions the IRIS Industry Coordinator has?

Please consult the IRIS guide to registration. In short, users with this role can access any submission/application made on behalf of an organisation, and not only those where the user is the creator or has been added as a manager/contributor, with the functions of IRIS Industry Manager. Please note that this role does NOT allow to create new submissions of any kind: for that, it is necessary to also have the role of Industry Manager, for the same organisation.

74. There is one guidance document about GMP only and another one with information about both GMP and GCP. Since the GMP information is duplicated, will one of the documents be withdrawn?

There is only one guidance that now involves all three inspection types: GMP, GCP and GVP, accessible at the following link.

75. Will IRIS work 24/7? Can we receive any communication on weekends or bank holidays or out of business hours?

Automatic notifications and e-mails from inspection coordinators will be sent out during EMA working hours. Please note that EMA holidays might differ from yours.

76. Can the new IRIS role also view completed submissions?

Yes, the IRIS Industry Coordinator can see completed submissions and access any documents.

77. Can the same generic e-mail address be used by several colleagues in different accounts?

No, one e-mail address is one account.

78. What does the "Reporting deadline" correspond to? Is it the limit date for submitting pre-inspection documents?

Reporting deadline is the deadline for the inspection team to provide the inspection report to EMA.

79. Will QPPV receive an e-mail notification for other submissions as well (e.g. when inspection report will be available)?

Yes, there will be an automatic e-mail notification for changes, cancellation and modification of the inspection, in addition to the adoption.

80. Can all users added to a specific GPV Inspection view the Inspection report (under the "view submission" function), or is

this restricted to the contact of this specific Inspection, i.e. the QPPV?

All users added to the submission can see the inspection report.