



**PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

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COVID-19 RISK ASSESSMENT FOR NATIONAL ROUTINE ON-SITE INSPECTIONS

Prepared by the PIC/S Working Group on Inspectors Safety

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COVID-19 RISK ASSESSMENT FOR NATIONAL ROUTINE ON-SITE INSPECTIONS

Introduction

Risk Assessment covers announced GXP inspection of national sites.

It is to be completed during the inspection planning phase, in consultation with the site to be inspected, prior to the inspection taking place.

The site must confirm that the necessary measures identified in the risk assessment will be implemented

Consideration should also be given to Covid testing of Inspectors / Investigators pre and post inspection and may be requested by some sites.

Site:

Assessor Carrying out Risk Assessment:

Name(s) and Job Titles of employees consulted:

Number of people at risk:

Groups of people at risk:

Description/Operations/ Activities covered by this assessment

For any un-announced inspections an individual bespoke risk assessment must be completed to take account of the more complex risks – this risk assessment should not be used for these types of inspections.

The operations covered by this assessment include all inspections under the GxP routine inspection programme; the same principles should be applied for inspectorate meetings held at offices where inspectors will need to travel and/or stay overnight.

COVID-19 RISK ASSESSMENT FOR INSPECTIONS

Task/Hazard Analysis

No	Task/Hazard/Effects	People at Risk (per hazard)	Current Controls	Likelihood (L) Severity (S)		Risk Rating
				(L)	(S)	(L x S)
1.	Exposure to Covid19 through contact with other persons (including other members of the inspection team)		<p>Maintain appropriate social distance from other persons.</p> <p>Inspector to confirm with site that appropriate distancing is in place and can be maintained during the inspection.</p> <p>Number of hosts present within the same space and interacting directly with the inspector at the same time should be limited and should maintain a safe distance to avoid crowded conditions that may be prone to transmission of infection.</p> <p>Time on site kept to the minimal amount possible. Maximum daily duration of the inspection should be eight hours.</p> <p>Meeting rooms should be of an appropriate size to maintain social distance.</p> <p>Participation via video conference should be explored if a large number of attendees are required to be present.</p> <p>It is recommended that prior to going to the site all jewellery, including watch and rings, be removed. Wear clothes that should withstand a wash at 60°C and closed waterproof shoes (in case foot baths or sanitising mats are in use at the site).</p> <p>Wipe down the area of the table and chair (if applicable, i.e. hard surfaces) where you're working at the beginning and end of the day. Dispose of the wipes in a bin after each clean.</p>			

		<p>While in an office/ meeting room the required social distance should be maintained. If in an enclosed space numbers and dwell time to be kept to essential personnel only, while also maintaining the required social distance .</p> <p>Other personnel can be present using remote technology/ video links.</p> <p>Rooms should be well ventilated – Inspectors to request windows or doors to be left open whenever possible or when there is need to operate air conditioner or heaters, that the air flow of the air conditioner or heaters should be maintained to promote sufficient ventilation.</p> <p>Inspector to review the site’s Covid-19 procedures prior to arrival.</p> <p>Inspector to maintain regular hand sanitation and general guidance on avoiding touching face.</p> <p>Inspector to wear a face covering at all times during the inspection unless other acceptable control measures are in place e.g. use of plastic screens, only person in room, etc.</p> <p>Face covering should be of an appropriate type in accordance with national guidelines. Training and fit testing may be required dependant on the type used.</p> <p>If any of the company personnel do not co-operate with the requests of social distancing and the additional current government guidelines or become uncooperative to the NCA personnel, the inspector will leave the site immediately.</p>			
2.	Exposure to Covid19 through contact with infected surfaces	<p>Inspector must only take into the inspection what is necessary to conduct the inspection. This will include: Laptop, Mobile, Notepad and Pen. All equipment should be wiped down prior to leaving the site and again on their return home.</p> <p>If equipment, documents or objects/samples are required to taken from the facility, where possible, securely quarantine for several days to ensure decontamination where possible, or follow prescribed disinfection procedures to minimize risk.</p>			

		<p>Site to have confirmed they are following national / government guidance for continued operation of facilities with respect to social distancing, disinfection, ventilation etc. as applicable.</p> <p>Working surfaces should be disinfected regularly</p> <p>Inspector will avoid contact with surfaces unnecessarily and to implement regular hand cleansing. E.g. during document review</p> <p>Inspector should consider reviewing documents electronically where possible.</p> <p>When possible avoid contact with door handles.</p> <p>Inspector to carry disposable gloves with them and use as required if they must touch any surfaces.</p>			
3.	Exposure to COVID 19 when travelling to the site	<p>Inspector to carry hand sanitiser and disinfectant wipes with them and use as required.</p> <p>Inspector will travel to site in own car where possible; hire cars are permitted.</p> <p>Car sharing by inspectors should be avoided.</p> <p>Inspector to ensure parking is available at site.</p> <p>If parking not available on site then a taxi may be used to reach the site from a main public transport hub.</p> <p>Where public transport is used, including air travel, government guidance should be followed, including wearing a face covering and social distancing as far as possible.</p>			

4.	Exposure to COVID 19 through contamination on clothing and PPE	<p>Inspector should utilise a face covering. Hand sanitiser and gloves and disinfectant wipes should be taken with the inspector and used as deemed necessary.</p> <p>Inspector should make use of hand washing facilities and use as per government guidance and as needed.</p> <p>Inspectors should retain replacement Personal Protective Equipment (PPE) should it be required.</p> <p>Inspector to ensure they take all necessary precautions when they arrive home to reduce contamination risks, such as removal (and washing) of clothing, and safe disposal of PPE</p>			
5.	Exposure to COVID 19 through eating and drinking.	<p>Inspectors should evaluate risks and only if comfortable, obtain food and beverages that may be available at the site</p> <p>Inspectors may also bring their own food to the inspection site if they prefer.</p> <p>Inspector will avoid and not eat in any canteen areas and maintain social distance.</p>			
6.	Non-specific exposure to COVID 19	<p>Inspector to check the geographical location of the inspection to ensure it has not entered a local lockdown prior to travel both one week prior, and then 24 hours in advance of the inspection and in the morning prior to leaving for the inspection.</p> <p>Inspector to request the site notify the inspector immediately if any local restrictions or lock down measures that impact on the inspection are imposed. Inspector should take necessary action to ensure their own safety while complying with local restrictions e.g. inspection may need to be stopped to allow inspector to return home.</p> <p>Prior to each inspection day, the inspector will conduct a self-assessment and should not continue on-site activities if they feel unwell/present with symptoms.</p>			

		<p>The site will be requested to advise the NCA and/or Investigator if any staff member has been exposed to someone with COVID-19, or tested positive for COVID-19 before, during, or within the post inspection notification window adopted by the NCA.</p> <p>Where post-inspection letters are sent, this requirement should be included in the post inspection letter sent to the site.</p> <p>The inspector will inform the site should they test positive for COVID-19 within the prescribed notification window adopted by the NCA.</p> <p>Hand washing and/ or sanitising must occur regularly in line with government guidance.</p> <p>Inspector must only take into the inspection what is necessary to conduct the inspection. This will include: Laptop, Mobile, Notepad and Pen. All equipment should be wiped down prior to leaving the site and again on their return home.</p> <p>In line with standard GxP planning procedures, the inspector will announce the inspection and ensure appropriate COVID 19 measures can be complied with.</p>			
7.	Use of hotel facilities	<p>The inspector should limit time in communal areas and limit this to movement through areas to room.</p> <p>The inspector should aim to minimise any risk of transmission by ordering room service with no direct face to face interaction. If eating in restaurants/ cafes is permitted by government guidance at the time this is also permissible.</p> <p>The inspector will wear a face covering in all public accessible areas of the hotel.</p> <p>The inspector will limit guest interaction by restricting social activities.</p> <p>The inspector will seek confirmation via the hotel that the hotel is operating within government guidelines to ensure ongoing risk mitigation.</p>			

		<p>The inspector will provide details to the hotel to allow for appropriate track & trace</p> <p>The inspector will immediately leave the hotel if notified of any sick staff or guests and seek alternate accommodation in line with the risk assessment.</p> <p>The inspector will only undertake contactless pay methods.</p> <p>The inspector will ensure they have travel agent contact details with them so that travel booking amendments can be made immediately should there be any issues with the standards of the initial hotel booking made (in line with standard inspector-travel process).</p>			
8.	Exposure to COVID 19 through inadequate PPE	<p>Any PPE identified as required for the visit must be checked prior to use for condition and correct fit.</p> <p>Facilities hosting the inspection should facilitate clean, adequate, and dedicated PPE for the inspectors. When PPE is reused, there should be controls in place to prevent mix-up of PPE, and for cleaning and disinfection between uses. Every person coming in close proximity to the inspector should use adequate mask covers to reduce risk of transmission of infection.</p> <p>Single use PPE should be disposed of in the correct manner after use and not re-used.</p>			

HEALTH & SAFETY RISK ASSESSMENT FORM

Where the existing control measures are inadequate or non-existent, detail the action required to eliminate the hazard or reduce to an acceptable level

Residual Risk Rating after new control measures

No	Further Control Measures	Target Completion Date	Person Responsible	Date Completed	Residual Risk Rating after new control measures		
					Likelihood (L) (L)	Severity (S) (S)	(L x S)

HEALTH & SAFETY RISK ASSESSMENT FORM

Risk Factors

Likelihood

- | | |
|---|--|
| 1 | Remote - Extremely unlikely to occur i.e. may occur in exceptional circumstances |
| 2 | Unlikely - Expected to occur in a few circumstances |
| 3 | Possible - Expected to occur in some circumstances |
| 4 | Probable - Expected to occur in many circumstances |
| 5 | Highly Probable - Extremely likely to occur |

Severity

- | | |
|---|--|
| 1 | Insignificant - No visible effects, minor injury e.g. bruise |
| 2 | Minor - Injury or ill-health requiring first aid or medical advice |
| 3 | Moderate - Injury or ill-health leading to more than three days off work |
| 4 | Major - Severe injury, ill-health or possible loss of life |
| 5 | Catastrophic/Extreme - Loss of more than one life or multiple casualties |

HEALTH & SAFETY RISK ASSESSMENT FORM

		Severity				
		1	2	3	4	5
Likelihood	1	1	2	3	4	5
	2	2	4	6	8	10
	3	3	6	9	12	15
	4	4	8	12	16	20
	5	5	10	15	20	25

1 - 6	Low Risk (acceptable)	Once approved, the risk assessment can be placed on Safety Organiser
8 - 12	Medium Risk (acceptable)	Additional controls may be required but once approved can be placed on Safety Organiser
15 - 25	High Risk (unacceptable)	The work cannot commence. Additional control measures must be put in place and the risk reduced to medium