



MHRA Desktop Inspections

Ewan Norton - Lead Senior GMDP Inspector



I, E&S Division Ref:	6 th Advanced GMP Workshop - IPA
Prepared by	Ewan Norton
Date	20 th October 2021
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Presentation Outline

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- How it started....

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- What we decided to do...

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- What went well...

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- What we learned...

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- What now and where next...

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How it started...

OBI Process

How it started...



How it started...

- Potential challenges with desktop inspections:



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The _____ (candidate)	
INTERVIEW	
Subject: English Language for the 10th Grade, 1st and 2nd Semesters (10th Grade)	
Question	Answer
1. What is the main purpose of the interview?	To assess the candidate's English language proficiency.
2. How do you prepare for an interview?	I prepare by reviewing grammar rules, vocabulary, and practicing speaking and writing exercises.
3. What are the common topics discussed in an interview?	Common topics include personal information, education, hobbies, and future plans.
4. How do you handle nervousness during an interview?	I take deep breaths, focus on the questions, and try to speak clearly and confidently.
5. What are some tips for improving English speaking skills?	Regular practice, listening to native speakers, and using language learning resources are helpful.
6. How do you improve your English writing skills?	I practice writing essays, letters, and reports, and seek feedback from teachers or peers.
7. What are the challenges you face in learning English?	Challenges include understanding complex grammar rules and expanding my vocabulary.
8. How do you stay motivated to learn English?	I set goals, track my progress, and remind myself of the importance of learning the language.
9. What are the benefits of learning English?	Benefits include better communication skills, access to global information, and career opportunities.
10. How do you use English in your daily life?	I use English for reading books, watching movies, and communicating with friends.
11. What are the differences between British and American English?	Differences include spelling (e.g., color vs. colour) and pronunciation (e.g., elevator vs. lift).
12. How do you learn new vocabulary words?	I use flashcards, read English materials, and keep a notebook for new words.
13. What are the importance of grammar in English?	Grammar is essential for constructing correct sentences and understanding the meaning of texts.
14. How do you practice listening skills?	I listen to English podcasts, watch YouTube videos, and use language learning apps.
15. What are the common mistakes made by learners of English?	Common mistakes include incorrect verb tenses, wrong prepositions, and poor pronunciation.
16. How do you improve your reading skills?	I read English newspapers, magazines, and books to improve my comprehension.
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Pre – Inspection Requests

IMPORTERS

Cut and paste the first table below into the Pre-Inspection Letter (which can be found in this folder - [LINK](#))

Request	Format
1. Site Master File	
2. Completed pre-inspection compliance report (see link in letter).	
3. Batch certification procedure.	
a. list of batches certified in the last	Excel or Word
4. PQR procedure	
a. List of Product Quality Reviews showing target date and completion date since last inspection and copies of relevant PQR's available.	Excel or Word
5. Deviation procedure	List in Excel
a. List of deviations since the last inspection - formatted to show classification, root cause, date opened, planned closure date and actual date closed.	
6. CAPA procedure (if separate from the deviation procedure)	
a. list of CAPA since the last inspection at your site formatted to show date opened, planned closure date and actual date closed	List in Excel
7. Change control procedure	
a. List of change controls since the last inspection formatted to show classification, date opened, planned closure date and actual date closed.	List in Excel
8. OOS procedure	
a. List of all OOS investigations (not just confirmed OOS) since last inspection formatted to show investigation conclusion, root cause, date opened and actual date closed.	List in Excel
9. Procedure identifying process for assessing EU importation testing results against manufacturer C of A	
10. List of batches rejected since last inspection.	Excel or Word
11. Complaints procedure and list of complaints since last inspection - formatted to show classification, root cause, date opened and date closed.	List in Excel
12. Recall procedure and list of any recalls since the last inspection.	Excel or Word
13. Quality agreements procedure	
a. List of agreements held identifying review dates.	List in Excel
14. List of procedures including version number, effective dates and review dates.	Excel or Word
15. Update on commitments since last inspection identifying dates communicated to previous inspector for completion and actual completion dates	
16. Supplier Qualification procedure	
a. Approved supplier list	
b. List of supplier audits planned for last year and this year showing the status of the audits and whether they were physical or paper-based audits.	
c. Supplier complaint procedure	

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a. Approved supplier list	
b. List of supplier audits planned for last year and this year showing the status of the audits and whether they were physical or paper-based audits.	
c. Supplier complaint procedure	
d. List of supplier complaints (if not incorporated in deviation process)	List in Excel
17. Customer approval procedure, including Bona Fide confirmation process	
18. Training procedure.	
19. Self inspection procedure	
20. Self inspection schedule for this year and last year showing dates each carried out	
21. Management review procedure	
22. TSE procedure	
23. Procedure that identifies approach to Excipient risk assessments	
24. Procedure that identifies approach to Elemental Impurities (ICH Q3D)	
25. Sampling procedure identifying where samples are taken i.e. at site or upon importation	
26. Artwork control procedure	
27. A number of photographs of key areas from different angles (please identify the areas in the file title, or on the pictures themselves):	
a. Warehouse areas (if applicable)	
b. QC areas (if applicable)	
c. Stability Storage areas (if applicable)	
d. Retention sample storage area	
28. Governing (top level) procedure for distribution and shipments	
29. Indication of current staffing levels	

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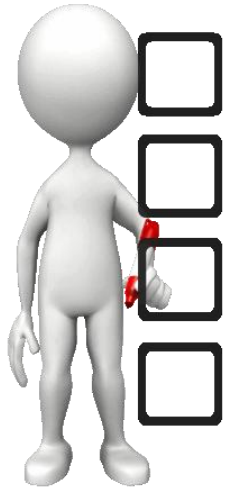
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What went well...



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What we learned...



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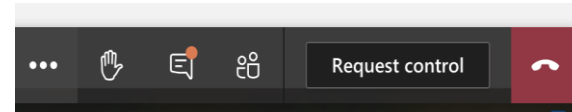
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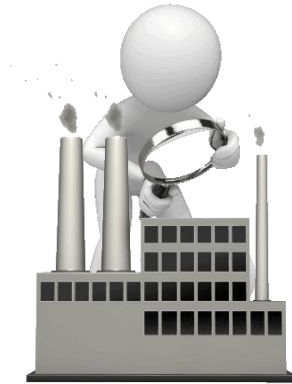
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What now and where next... (I)



What now and where next... (II)





Thank you for listening.