HOSTING REGULATORY VISIT AND COMPLIANCE

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PURPOSE

- It defines uniform procedure to handle External Agency GMP inspections -Standards Organization of Nigeria (SON), National Agency for Food and Drugs Administration and Control (NAFDAC) and other Great West Africa (GWA) regulatory bodies

SCOPE

- It applies to all Procter & Gamble, EGIL, ASPIRA and other Partners Finished Products regulated by SON, NAFDAC and other GWA regulatory bodies that are produced in UGEE Chemicals ltd Ibadan Plant..

RESPONSIBILITY

- **Site Regulatory Leader** is responsible for liaising with NAFDAC and for registering all regulated products with NAFDAC, SON and other Products regulatory products (as applicable). He/She is responsible is responsible to monitoring registration, certification validity for all products registered with NAFDAC and SON.
  The Plant will provide logistics for NAFDAC inspection visits to the Plant for registration of locally manufactured products.
- **Partner Regulatory Spoc:** is responsible for registration and re-certification of the applicable products and provide all needed documentation applicable to his/her products.
- **Site Leader (or designee):** Supports site QA manager and **participates** as determined by the host, in appropriate inspectional activities. He participates in close out meeting and reviews any inspectional observation report, if available
- **Site QA** will provide technical support including documents for the registration of locally manufactured products. Site QA is the primary host for all regulation visits while on premises. He / She also involve appropriate resources from within site, within the company, to host visits. He ensures all site personnel involved in the hosting of regulation are trained and qualified. He / she ensure that all required items are in place for the SON officials. He /She ensure that recommendation and observation emanating from the visits are logged into appropriate data base and resolved on time. He/She also leads collection of

required document for NAFDAC registration and update list of all regulatory bodies (Nigerian and GWA) requirements quarterly and deploy to LPT.

- **Departmental Managers**: are responsible to ensuring their departments are complaint with all regulations and that outages are resolved promptly.

POTENTIAL RISKS

NA

REGULATIONS

- No regulated product can be manufactured, imported, displayed for sale or advertised unless registered with NAFDAC and SON or other Regulatory bodies (as requested by the Country of Shipment). Regulated products for Ugee Chemicals ltd. Ibadan plant is laundry (cosmetics).
- All products to be produced by Ugee Chemicals are to be duly registered as regulated products prior to commencement of production.

PPE REQUIRED

- Not Applicable

PROCEDURE :

1. Upon the receipt of visit notification from Regulatory (NAFDAC/SON/Other GWA regulatory bodies) the Regulatory leader communicates via email and verbally to department/site leaders in preparation for the planned visit
2. The Site QA informs receptionist and security personnel at the plant reception about the visit. He/She ensures both personnel have been trained and qualified on hosting regulatory visit. A separate sign in logbook will be used for investigator / inspectors during visit.
3. The receptionist will immediately contact the host (Site QA Manager or designee) and the site manager or designee if not around when regulatory officials are around.
4. Site QA ensures adequate provision for needed PPE for inspection. He / she also ensure that the rooms to be used for entry and exit conferences are fully booked ahead of time.
5. Dos & Don'ts on responses are shared with leaders prior to meeting with regulatory, only Site QA is permitted to talk with regulatory except otherwise.
6. Below is a guideline for the order of proceedings during the visit:
    - Site QA picks up the regulatory visitors at the reception to conference room of the department to be inspected.
    - Site QA hands over of safety PPEs and guidelines
    - Site QA leader leads the regulatory officials on a line tour and then into the laboratory where QC tests are done on some samples and results are tabulated by laboratory leader and submitted to the officials.
7. If the operations management team are requested by the regulatory officials for any conference, the operations spoc will be allowed to introduce himself only. All other correspondences shall be handled by the Site QA.

Procedure and Material Sampling:

1 The Shift QA leader picks requested number of cases of products made on the line as stated in Sampling specification for Factory Inspection and Testing Laboratories and, signs off the exit authorization for the products to be taken out of the plant.

2 Duplicate samples will be taken by Ugee Chemicals, the same time and in the same manner as the investigators/inspectors. Samples are to be placed in a secure area.

3 Sample request for a product not yet in commercial distribution (e.g. EO product will not typically be provided. Legal has to be contacted for additional direction). If legal indicates the sample is to be provided, the sample will be clearly marked "Confidential-Experiment Formulations". This information will be documented in the audit wrap-up report

4 Retain samples of a product or materials will not be provided without direction and alignment from legal in advance.

Documents (Including appropriate records)

5 Regulatory will have access to all records by applicable regulations/law subject to the external agency inspection. The following record types are not required by regulations and are not required to be shared with an regulatory officials and will not be shared without prior clearance from legal and the Site Leadership:

- Financial Data
- Sales Data
- Pricing data
- Personnel data, except data relating qualification to do the job function and training documentation
- Research documents,
- Self audit /Self inspection done on any site or Ugee Chemicals supplier site

Note: This list is not all inclusive, and any question or potential conflicts regarding regulatory's authority to inspect specific documents including specific request made to review such documents should be directed to Legal and Site Leaders.

6 Regulatory will also be provided access to common documentation such as calibration and maintenance records, IQOQ of equipment under validation if requested for. All questions should be directed to site QA during the audit. The host will use their judgment to determine which record must be made available.

7 The host will answer all questions or direct another person as the host determines appropriate. The host or designee should answer the questions that are asked , but not volunteer additional information

8 In the case of unannounced inspection, and if the company personnel to host the inspection are not around, a request may be made to reschedule or postponed the inspection to reasonable timing explaining the absence of these individual and how it may impede the process of inspection otherwise, inspection will be done.

9 All information/documentation that is to be provided will be given to the host, he/she determines if it is appropriate information/documentation, if so the host will hand over the information to regulatory.

10 The host or designee will accompany the regulator at all times

11 The Site QA ensures that the results that could not be completed during the visit are sent to SON office either physically or by mail.

12 SON conducts line inspection every quarter.

1 Inspection close –out and Exit Interview

- At the conclusion of the inspection, the host will confirm that the regulatory has no unmet request.
- An inspection close-out meeting will be conducted. At a minimum, the site QA Manager or designee and the Site Manager or designee will attend.
- If an observation is an expectation or isolated incident, respectfully point that out again during the discussion even if it has been pointed out several times during the course of the inspection.
- Disagree only to observation that are misleading or factually incorrect as noted above
- Request the regulator to note in the inspection report any observation that have been corrected during the inspection
- Accept the inspection report but do not initial or sign the document. Inform the regulator that P&G is committed to follow up to the observation and will do so in writing. Do not commit to any specific follow up s or additional actions or timing at this time.
- When the wrap up is completed , the host or designee will escort the regulatory officials back to the reception and waits until the officials have left the premises of the company

2 All outages from the outcome of Regulatory inspection must be actioned and shared with site leadership.
3 Regulatory report must be uploaded on appropriate data base.
4 Site Leadership must be consulted before release of any other documents asides Quality analysis report
5 Upon receipt of a pay advice from regulatory on the visit, the Site Regulatory Leader processes the document with Finance and ensures the required fee is paid into the account of Regulatory and hands the teller over to the regulatory accountant.

MANCAP CERTIFICATION OR RECERTIFICATION.

1 The Site Regulatory leads the SON certification or recertification of the different SKUs produced in the plant every 3years together with the appropriate Partner Regulatory Spoc.
2 SON Product Certification Scheme document shall be followed strictly for certification or Re certification
3 The regulatory leader works with Finance Team to ensure that the certification or recertification fee is paid.
4 Inspection of the product to be certified and recertified is done during the normal plant tour done by SON.
5 When certification is obtained, the certification logo is handed to the Site Regulatory Leader by SON and he / she in turn hands it over to the Site QA Leader for communication to GPS after making a copy for his file. A copy of the MANCAP logo is then handed over to the QA leader and Technical Packaging Leader of the certified department for the incorporation into artworks.
6 All certified products must bear the logo of MANCAP on them indicating that they have been certified by SON.

PROCEDURE FOR NAFDAC REGISTRATION

General:

1 Site will comply with all regulatory requirements. Exception will be sought via GPS in cases of inability to meet any of the requirements.
2 Once NAFDAC has registered the product and issued the registration number; ONLY THEN CAN products be shipped to the market .NAFDAC registration number shall always be part of the artwork. The number

should be on the product pack in the format: **NAFDAC Reg No. xx – xxxx** where **x** stands for specific digits in the registration number issued. This number will be communicated by GPS team.

3 All documents to NAFDAC must be issued in English and where not possible, English translation must be provided along with the original non-English version of the document.

4 Starting the registration process right the first time (including right documents and right products) to eliminate rework of any of the steps in the process is key to timely conclusion of the registration.

5 Once the product has been registered, the registration is renewable every 5 years, following the same procedure outlined above. If changes are planned, Experimental Order (EO) must be completed.

6 Administrative Approval may be given ahead of conclusion of registration process at the discretion of the Director General of NAFDAC. This is an exception and not the rule. When given, the administrative approval allows business to continue while the formal registration processes take their normal full course. It does not replace registration. Success rate in getting Administrative Approval is about 70% and these prerequisite conditions must be met:

- Delayed registration due to NAFDAC's failure to meet regularly
- Satisfactory lab reports
- Satisfactory line inspection (GMP) reports.

Locally Manufactured Products:

1 NAFDAC involvement in a new line installation or EO will be approved /clarified by GPS. The officials of the regulatory agency are invited to inspect, witness the production and take registration samples along with requested documents .The purpose of this is basically to check the GMP conditions of the production facilities. Products can only be shipped after completion of registration and validation close out.
This takes about 12 weeks and is monitored by GPS.

2 All operations must comply with regulatory requirements and compliance is maintained during initiatives and changes to current operation.

3 Leadership ensures design of work systems and organizational structure is based on regulatory requirements both in initiative load and organization capability. Also put control in place to ensure all acquisitions and licensing agreements comply with regulatory requirement.

4 SON Regulatory requirements across all departments must be audited annually to ensure compliance. This audit is done by both department QA and Site Lab Leader, see attachments using NIS: 376:2013

5 SON conducts facility inspection every quarter.

SON REQUIREMENT FOR EACH BU

1. **For F&HC: Follow SON Standard in NISARS 496:2019**

Abbreviation:

- F&HC: Fabric & Homecare
- GPS: Global Product Stewardship
- SON: Standard organization of Nigeria
- NAFDAC: National Agency for Food and Drugs Administration and Control
- GMP : Good manufacturing Procedure

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- F&A: Finance and Accounting
- GWA: Great West Africa

REASON FOR UPDATE

VERSION 0: New SOP

End Of Procedure

SOP RELATED ATTACHMENTS
Attachment 1 – Qualification sheet Attachment 2 – Model Answers