Guidelines

Central Administration of Drug Control

Accreditation programs unit

Guidance on enrolling Proficiency Testing as one of the mechanisms of evaluation of Good Laboratory practice (GLP)

For 2022

Code: EDREX: GL. CADC.007
Version No: 1/2022
Issue Date: 15/8/2022
Effective date (if needed): 15/8/2022

Table of contents

1. Introduction

In the context of the Egyptian Drug Authority's keenness to support the pharmaceutical industry and continuously update the regulatory mechanisms in line with the latest international quality standard, regarding the ministerial decree no 273 year 2022 about enrolling proficiency testing schemes provided by the accreditation programs unit as one of the mechanisms for evaluation of good laboratory practice in quality control laboratories in the Egyptian pharmaceutical companies aiming at tightening the supervision on the performance of these laboratories and identifying opportunities for improvement in them to enhance performance efficiency that will be reflected on the quality of test results, ultimately leading to the availability of safe and effective medication for Egyptian patients.

2. Scope

Quality control laboratories in Pharmaceutical factories of companies in Egypt that included in annual inspection plan for the quality control laboratories of pharmaceutical companies.

3. Abbreviations:

EGAC: The Egyptian accreditation counsel

4. Definitions:

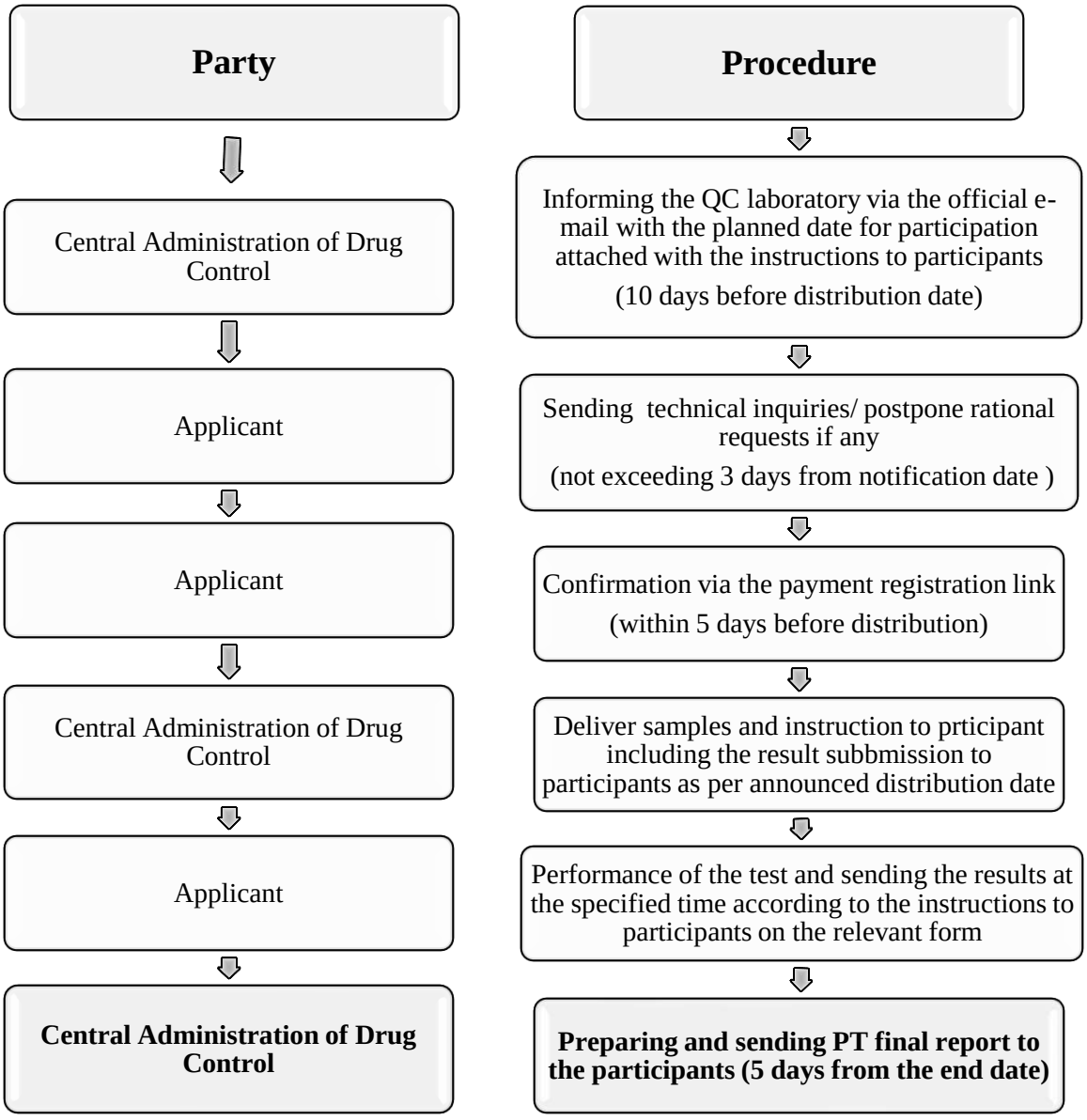
None

5. Main Topic

5.1.Program privileges

- The participant laboratory in proficiency testing rounds organized by the Egyptian Drug Authority receives a detailed report explaining the technical performance of the laboratory in the test.
- The participants may receive an accredited certificate (if desired by the participant) in case of participation in proficiency tests under the announced accredited scope by EGAC
- Fulfilling basic requirement for the evaluation of good laboratory practice.
- Evaluate the performance of the analysts by comparing their results with participants from other laboratories, as well as helping in identifying their training needs.
- Finding opportunities of improvement via test results analysis.
- Instilling the confidence in the analysis results issued by the laboratory.

5.2. Mechanism of participation in the program's rounds



5.3. Calculation of scores

- The scores are calculated based on the proficiency testing score taking into consideration the number of times of applying to get satisfactory results.
- In case of unsatisfactory results, the score will be zero
- In the event of lagging to participate, the score will be zero according to the general terms and conditions.

5.4. Timetable for interim implementation

- The implementation of the program will proceed as indicated in the following table:

Phase	Time frame	Scope	Annual participation frequency
First phase Initial implementation	From the start date up to a period not exceeding one periodic inspection round for the QC laboratories of the pharmaceutical companies	All companies	Once
Second phase Periodic evaluation	After passing the initial implementation	Factories have withdrawal plan 100%	4 times
		Factories have withdrawal plan each 4 months	3 times
		Factories have withdrawal plan each 6/ or 8 months	2 times
		Factories have withdrawal plan each 12 month	Once

5.5. Service fees

As the following table

S.N.	Service	Fee (L.E)
1	Deliver the PT sample for Good laboratory practice evaluation	2500
2	Analysis of the participant results	2500
3	Issuance of a PT certificate – accredited	1000

5.6. General Terms and Conditions:

- The applicant must adhere to the regulatory rules and technical controls issued by the Egyptian Drug Authority.
- If the applicant does not adhere to the specified time frames for receiving the samples, the score will be zero and the actions to be taken as a consequence of that will be taken.
- The company has the right to submit a rational request directed to head of central administration of drug control to postpone for a limited time in not exceeding 3 days after notification and receiving the instruction to participants where the request will be studied and responded with acceptance or rejection
- In case of not passing the test, the participant has the right to submit a request directed to the head of central administration of drug control for another participation in Proficiency test.
- Number of all repetitions of the test in case of not passing is considered as one participation.
- The head of central administration of drug control has the right to instruct by participation of a company in unplanned PT rounds if necessary (as in case of NCs)
- The results of PT schemes organized upon request from EDA-Pharma lab program are considered in the number of PT tests required by the decree 273 for year 273 that predetermined annually according to withdrawal plan

5.7. Official communication channels

- PT program official E-mail
  dc.edapt@edaegypt.gov.eg
- Application Form:
  https://forms.office.com/r/1Xk1eQyAYj
- Registration& fees:
  https://forms.office.com/r/tNAzVDBUVG
- Technical inquiries:
  https://forms.office.com/r/d0VdUTuXqN
- Customer feedback:
  https://forms.office.com/r/sAv83nfdY9

6. References

- ISO/IEC 17043:2023
- ISO 13528:2022
- Official Method of Analysis of AOAC international 22nd, Edition (22)
- ICH Topic Q2 (R1) Validation of Analytical Procedures: Text and Methodology

7. Annexes/ Attachments

7.1. Attachments: None

7.2. Annexes:

Annex 1: Documents to be delivered as hard copies

Annex 1: Documents to be delivered as hard copies

- An original application form signed by the authorized person.
- Delegation letter to the person who receives and delivers the PT items and PT round relevant documents.
- Original copy of the receipt for payment of the service fees