

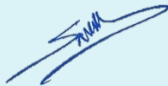




BIOGENIX

POLICY PROCEDURE FOR PERSONNEL MANAGEMENT

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2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
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4. POLICY STATEMENT

The procedure define broad outlines applied for the appointment of staff and their deployment and/or promotions to higher posts based on competence and needs of the Laboratory. This procedure ensures that competent human resources are available to perform the work in the best possible way.

5. PURPOSE

The purpose of this procedure is to ensure that the personnel performing specific operations related to testing are competent enough to carry out the operations. This procedure gives direction about the personnel right from the recruitment till performance appraisal. This procedure is as per clause no. 5.1. of ISO15189:2012 requirements for quality and competence and DOH Abu Dhabi requirement.

6. SCOPE

- 6.1. Requirement, Training and performance evaluation of staff at all levels.
- 6.2. **Target Audience:** BIOGENIX laboratory staff

7. DEFINITIONS

- 7.1. CME: Continuous Medical Education refers to a specific form of continuing education (CE) that helps those in the medical field maintain competence and learn about new and developing areas of their field.

8. ACRONYMS

- 8.1. PQR: Personnel Qualification Requirement
- 8.2. DOH: Department of Health Abu Dhabi

9. RESPONSIBILITIES

- 9.1. **Primary Responsibility** : HR manager/Lab Director
- 9.2. **Secondary responsibility:** Quality Manager





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10. PROCEDURE

10.1. PROCEDURE FOR HIRING NEW STAFF:

- 10.1.1. After checking the workload Laboratory Director decides if there is need to hire a new staff.
- 10.1.2. The Laboratory Director is responsible for staffing the laboratory adequately with qualified personnel. Human Resource Management service coordinates actual hiring.
- 10.1.3. The Laboratory Director establishes the selection guidelines for each category of staff: Pathologist, Technologists, Technicians and office staff. Actual selection responsibility and authority has been delegated to the Laboratory Director. Once selection is done by the Laboratory Director, it is reviewed and approved by the Chief medical officer and finally by the CEO.
- 10.1.4. All the technical staff are being hired as per HAAD PQR.
- 10.1.5. After hiring process complete laboratory director gives job description to the new staff.
- 10.1.6. After the approval of the laboratory director, the required details are passed on to the HR department to complete the recruitment process for the accepted person(s).
- 10.1.7. The appointed candidates report to Laboratory director on the joining

10.2. Job Description:

- 10.2.1. Job analysis is done by Laboratory director and the job description is prepared for all the work affecting quality.
 - 10.2.2. The job description of Laboratory Director is given by CMO;
 - 10.2.3. The job description contains the following details:
 - i. Job Summary
 - ii. Main Responsibilities
 - iii. Codes of Conduct
 - iv. Education
 - v. Qualification
 - vi. Experience
 - vii. License / Registration
 - viii. Skills/Competencies Required
 - 10.2.4. Recruitment to various levels in the organization is done on the basis of the job description.
 - 10.2.5. When the laboratory utilizes personnel who are employed by, or additional technical and key support personnel are used, the Laboratory Director ensures that the personnel are supervised and competent in accordance to the laboratory Quality System.
- ### 10.3. Personnel introduction to the organizational environment





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10.3.1. Upon commencement of work by the new staff member, the employee undergoes orientation on the following:

- 10.3.1.1. Laboratory orientation
- 10.3.1.2. Intra-department orientation
- 10.3.1.3. Safety orientation/training

10.3.2. Each of these are documented and signed by the employee. The records are kept in the employee file.

10.3.3. An Orientation is conducted for new staff by Quality Manager and Safety Officer.

10.4. Training

10.4.1. BIOGENIX has formulated the goals with respect to the education, training and skills of the laboratory personnel to meet the requirements.

10.4.2. The Laboratory director is responsible for identifying and organizing required training to ensure that all staff members are competent enough to perform assigned duties.

10.4.3. The necessary training and skill required for a particular position is considered at the time of recruitment or in specific cases.

10.4.4. Laboratory Director determines the training requirement of new recruits as well as the existing employees in the department annually based on their capability and performance

10.4.5. Laboratory Director guides the technical staff in technical aspects relating to test, Laboratory services and interpretation of data.

10.4.6. Wherever there is a need for deputing the staff for external training, Laboratory Director takes decision and relieve the Employee for training.

10.4.7. Laboratory Director / Deputy Director/Quality Manager also identify the need for In-house training program of Management, technical and general nature for their staff.

10.4.8. Training to the employees is provided based on

- 10.4.8.1. Training needs identification Record.
- 10.4.8.2. Repeated non-conformances in a particular area.
- 10.4.8.3. Induction of new equipment within the organization.
- 10.4.8.4. New recruitments in the organization.
- 10.4.8.5. Periodic assessment.
- 10.4.8.6. New technology/ test methods.
- 10.4.8.7. Training feedback.
- 10.4.8.8. Client's feedback or complaints.
- 10.4.8.9. Material wastage
- 10.4.8.10. Promotion to new levels.
- 10.4.8.11. Feedback from higher authority.





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10.4.9. Specific on the job training is also given to staff on complaint handling, Customer Response and guiding the customer on use of Laboratory services.

10.4.10. All employees are trained in the following methods and skills required to perform their work

- i. Proper handling of materials and equipment.
- ii. Reading and understanding the documentation provided.
- iii. Process control, data collection and analysis, problem identification, corrective action and improvement, team working and communication methods.
- iv. Relevant knowledge of technology used for testing.
- v. Defects / degradation which may occur during testing.
- vi. Understanding the significance of deviations found with regard to the normal use of items, materials, products concerned.
- vii. Knowledge of the general requirement expressed in the legislation and standards.

10.4.11. Effectiveness of training is determined from the feedback taken from trainees for external training and in-house training from the Laboratory Director / Quality Manager. Pre Test and post tests are being conducted with the trainings or Observation/ demonstration of procedure by staff to laboratory director.

10.4.12. The Laboratory director assesses the effectiveness of training.

10.4.13. The Laboratory Director ensures that all its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives by conducting regular trainings and briefing in Management review meetings.

10.5. **Employee assessment for competency**

10.5.1. All the employees are assessed in their core working areas as well as in other related areas to ensure that they are continually suitable and competent enough to their work requirements.

10.5.2. New employees are checked for competency twice during their first year of employment in the laboratory. The first competency check should be completed before any patient results are reported by the new employee and followed by 6 months after initial competency.

10.5.3. Assessment for all employees is done once a year and is based on their knowledge; past performance, skills, present job responsibilities and requirements and the details are entered in the personnel file;

10.5.4. Assessment approach

- 10.5.4.1. Direct observation of routine work process, procedures including all applicable safety practices
- 10.5.4.2. Direct observation of equipment maintenance and function checks.





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- 10.5.4.3. Monitoring the recording and reporting of examination results
- 10.5.4.4. Assessment of problem-solving skills
- 10.5.4.5. Examination of specially provided samples such as previously examined sample, inter laboratory comparison materials or split samples
- 10.5.5. Personnel performing work-affecting quality are evaluated by Laboratory director/ Quality Manager for required competency with respect to the requirements.
- 10.5.6. For the assessment of Lab Technical Staff, Lab. Director decide on the assessment criteria, acceptance limits & frequency based on the criticality of the person concerned in the process.
- 10.5.7. All the details of assessment and actions taken are maintained in the personnel file.

10.6. TYPES OF CME PROGRAMME IN OUR LAB:

10.6.1. INTERNAL CME PROGRAMME:

- 10.6.1.1. These activities may take place as live events, online programs or lectures;
- 10.6.1.2. Content for these programs is developed, reviewed, and delivered by lab director/ Laboratory Staff;
- 10.6.1.3. The staff is encouraged to do lectures by themselves & select the topic as well
- 10.6.1.4. 3 topics to be covered in a month and is repeated every week to cover all the shift staff
- 10.6.1.5. CME's are conducted as per the plan.
- 10.6.1.6. The CME session extends for a minimum of half an hour to maximum of 1 hour.
- 10.6.1.7. All laboratory staffs are encouraged to attend CMEs conducted in the BIOGENIX laboratory every week.
- 10.6.1.8. Records of the topic presented and attendance are kept.

10.6.2. EXTERNAL CME HOURS:

- 10.6.2.1. The staff gains it by attending:
 - 10.6.2.1.1. Live lectures;
 - 10.6.2.1.2. Workshop: Workshops offer the trainee, the opportunity to achieve a high degree of competency in a short period of time;
 - 10.6.2.1.3. Online lectures.
- 10.6.2.2. In case of attending live lectures or workshop for CME outside the BIOGENIX laboratory, the staff has to take permission from Laboratory Director before attending.
- 10.6.2.3. All documents are documented in the lab staff personnel file.

10.7. EMPLOYEE FILE CONTENT & MAINTENANCE





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10.7.1. A folder for each employee is created titled Personnel Files, used for storing the following personnel information:

- i. Applicant interview result and up to date Job applicant curriculum vitae (CV);
- ii. Credential;
- iii. Copy of data flow result;
- iv. HAAD license copy;
- v. Employee Job description;
- vi. Signed confidentiality statement;
- vii. Detailed employee orientation-record;
- viii. Current malpractice insurance;
- ix. Continuous on-going training /proficiency/competency –record;
- x. Continuous medical education(CME) record;
- xi. Employee annual appraisals;
- xii. Achievements;
- xiii. Updated corrective action;
- xiv. Hepatitis vaccination status-record;
- xv. Color discrimination test result;
- xvi. Basic life support certificate (BLS);
- xvii. Infection control;
- xviii. Leave records.

10.7.2. above mentioned records are kept in a logical fashion in a file. Some records may not be present (such as the competency assessment reports and possible accident reports). These are added later in the process of implementing the quality management system.

10.7.3. After completion, HR personnel store the Personnel Files folder in a locked cabinet that is only accessible to the laboratory director and HR personnel (as the files contain privacy sensitive data such as the health record the files should be prevented from unauthorized access after they have been finalized; only the laboratory director is allowed to access the personnel files and the staff members are allowed to access their own personnel file).

10.7.4. Every year the HR personnel/lab director review & update their staff's personnel files.

10.7.5. The lab director can delegate the authority to review and update the department staff's files;

10.7.6. Each staff member is responsible for updating his/her personnel data when needed from him/her.





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11. CROSS REFERENCE

- 11.1. HAAD standards for clinical laboratories
- 11.2. ISO: 15189:2012 Medical Laboratories requirements for Quality and competence

12. RELEVANT DOCUMENTS & RECORDS

- 12.1 BG/REC/GEN/013 Training Plan
- 12.2 BG/REC/GEN/012 New Staff Orientation Checklist
- 12.3. BG/REC/GEN/063 New Staff Training Checklist
- 12.4. BG/REC/GEN/009 Competency Assessment Form
- 12.5 BG/REC/GEN/065 Staff Summary Monitoring List
- 12.6 BG/REC/GEN/014 Trainee Assessment Sheet
- 12.7 BG/REC/GEN/015 Trainer Assessment
- 12.8 BG/REC/GEN/066 Competency Of Quality Manager

