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An Overview of Personnel Requirement in Pharmaceutical Industry As Per Various Regulatory Guidelines

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Chagi Venkatesh[1] and S.B.Puranik[2]

[1]Research scholar Prist University, Thanjavur, Tamilnadu, India.

[2]Research Guide Prist University, Thanjavur, Tamilnadu, India.

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ABSTRACT

Personnel is the key element of any industry and is responsible for the organizational growth and outcomes. Personnel engaged in the pharmaceutical industry shall have the minimum qualification, practical experience and adequate training to handle the different tasks carried out during manufacturing, testing, warehousing and distribution of the pharmaceutical goods. The establishment and maintenance of a satisfactory system of QA and the correct manufacture and control of pharmaceutical products and active ingredients rely upon people. For this reason, there must be sufficient qualified personnel to carry out all the tasks for which the manufacturer is responsible. Individual responsibilities should be clearly defined and understood by the persons concerned and recorded as written descriptions.

INTRODUCTION

Current study is aimed at requirements of personnel as per the different regulatory guidelines viz., WHO, Schedule M of D and C Act, USFDA, MHRA, TGA. Since the ICH Quality guideline is not dealt with respect to personnel the same shall be omitted in the study.

Each of the selected guidelines describes the requirement of personnel under the different chapters as below.

WHO: WHO describes about the personnel requirement in Annex 3 **WHO good manufacturing practices for pharmaceutical products: main principles**

Schedule M: Schedule M describes about the personnel requirement in PART 1 **Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.**

USFDA: USFDA describes about the personnel requirement in **PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals Subpart B—Organization and Personnel.**

MHRA: MHRA describes about the personnel requirement in **Chapter II Guidance on Good Manufacturing Practice (GMP) 2 Personnel.**

TGA/PICS: TGA/PICS describes about the personnel requirement in **CHAPTER 2 Personnel.**

Detailed comparison of the selected guidelines with respect to personnel requirement in pharmaceutical industry is given in Table 1.

Table 1: Comparison of regulatory guidelines for personnel requirement in pharmaceutical industry.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
WHO describes about the personnel requirement in **Annex 3** **WHO good manufacturing practices for pharmaceutical products: main principles**	**Schedule M** describes about the personnel requirement in PART **1 Good Manufacturing Practices For Premises And Materials of Good Manufacturing Practices And Requirements Of Premises, Plant And Equipment For Pharmaceutical Products.**	**USFDA** describes about the personnel requirement in **PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals.** **Subpart B—Organization and Personnel.**	**MHRA** describes about the personnel requirement in **Chapter II Guidance On Good Manufacturing Practice (GMP)** **Chapter 2 – Personnel.**	**TGA/PICS** describes about the personnel requirement in **CHAPTER 2** **Personnel.**
9.2 The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibilities placed on any one individual should not be so extensive so as to present	6.1 The manufacturer shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience in the relevant dosage form and / or active pharmaceutical	§211.22 Responsibilities of quality control unit. (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to	**General** 2.1 The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibilities placed on any one individual should not be	**General** 2.1. The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibilities placed on any one individual should not be

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
any risk to quality.	products.	assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.	so extensive as to present any risk to quality.	so extensive as to present any risk to quality.
9.3 Responsible staff should have its specific duties recorded in written descriptions and adequate authority to carry out its responsibilities. Its duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with	6.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.	(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.	2.2 The manufacturer must have an organization chart. People in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the	2.2. The manufacturer must have an organization chart. People in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
the application of GMP. The manufacturer should have an organization chart.			responsibilities of those personnel concerned with the application of Good Manufacturing Practice.	responsibilities of those personnel concerned with the application of Good Manufacturing Practice.
9.4 All personnel should be aware of the principles of GMP that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs. All personnel should be motivated to support the establishment and maintenance of high quality standards.	6.3 Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.	(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.	**Key Personnel** 2.3 Key Personnel include the head of Production, the head of Quality Control, and if at least one of these persons is not responsible for the duties described in Article 51 of Directive 2001/83/EC, 1 the Qualified Person(s) designated for the purpose. Normally key posts should be occupied by full-time personnel. The heads of Production and Quality	**Key Personnel** 2.3. Key Personnel includes the head of Production, the head of Quality Control, and if at least one of these persons is not responsible for the release of products the authorized person(s) designated for the purpose. Normally key posts should be occupied by full-time personnel. The heads of Production and Quality Control must be independent

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
			Control must be independent from each other. In large organizations, it may be necessary to delegate some of the functions listed in 2.5, 2.6 and 2.7.	from each other. In large organizations, it may be necessary to delegate some of the functions listed in 2.5., 2.6. and 2.7.
9.5 Steps should be taken to prevent unauthorized people from entering production, storage and QC areas. Personnel who do not work in these areas should not use them as a passageway.	6.4 Written duties of technical and Quality Control personnel shall be laid and followed strictly.	(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.	2.4 The duties of the Qualified Person(s) are fully described in Article 51 of Directive 2001/83/EC, and can be summarized as follows: (a) For medicinal products manufactured within the European Community, a Qualified Person must ensure that each batch has been produced and tested/checked in accordance with the	2.5. The head of the Production Department generally has the following responsibilities: i. To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality. ii. To approve the instructions relating to production operations and to ensure their strict

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
			directives and the marketing authorization.	implementation. iii. To ensure that the production records are evaluated and signed by an authorized person before they are sent to the Quality Control Department. iv. To check the maintenance of his department, premises and equipment. v. To ensure that the appropriate validations are done. vi. To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.
9.6 Key personnel	6.5 Number of personnel		(b) for medicinal	2.6. The head of the Quality

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
Key personnel include the heads of production, the head(s) of quality unit(s) and the authorized person. The quality unit(s) typically comprises the quality assurance and quality control functions. In some cases, these could be combined in one department. The authorized person may also be responsible for one or more of these quality unit(s). Normally, key posts should be occupied by full-time personnel. The heads of production and quality unit(s) should be independent of each other. In large organizations, it may be	employed shall be adequate and in direct proportion to the workload.		products manufactured outside the European Community, a Qualified Person must ensure that each imported batch has undergone, in the importing country, the testing specified in paragraph1 (b) of Article 51.	Control Department generally has the following responsibilities: i. To approve or reject, as he sees fit, starting materials, packaging materials, and intermediate, bulk and finished products. ii. To evaluate batch records. iii. To ensure that all necessary testing is carried out. iv. To approve specifications, sampling instructions, test methods and other Quality Control procedures. v. To approve and monitor any contract analysts. vi. To check the

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
necessary to delegate some of the functions; however, the responsibility cannot be delegated.				maintenance of his department, premises and equipment. vii. To ensure that the appropriate validations are done. viii. To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.
9.7 Key personnel responsible for supervising the production and quality unit(s) for pharmaceutical products should possess the qualifications of a scientific education and practical experience required by national legislation.	6.6 The licensee shall ensure in accordance with a written instruction that all personnel in production area or into Quality Control. Laboratories shall receive training appropriate to the duties and responsibility assigned to them. They	§211.25 Personnel qualifications. (a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing	(c) A Qualified Person must certify in a register or equivalent document, as operations are carried out and before any release, that each production batch satisfies the provisions of Article 51.The persons responsible for	2.7. The heads of Production and Quality Control generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, subject to any national regulations: • The authorization of written procedures

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
Their education should include the study of an appropriate combination of: (a) Chemistry (analytical or organic) or biochemistry; (b) Chemical engineering; (c) Microbiology; (d) Pharmaceutical sciences and technology; (e) Pharmacology and toxicology; (f) Physiology; and (g) Other related sciences. They should also have adequate practical experience in the manufacture and QA of pharmaceutical products. In order to gain such	shall be provided with regular in-service training.	practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.	these duties must meet the qualification requirements laid down in Article 493 of the same Directive, they shall be permanently and continuously at the disposal of the holder of the Manufacturing Authorization to carry out their responsibilities. Their responsibilities may be delegated, but only to other Qualified Person(s).	and other documents, including amendments. • The monitoring and control of the manufacturing environment. • Plant hygiene. • Process validation; • Training. • The approval and monitoring of suppliers of materials. • The approval and monitoring of contract manufacturers. • The designation and monitoring of storage conditions for materials and products. • The retention of records. • The monitoring of

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgment, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and QC of pharmaceutical products.				compliance with the requirements of GMP. • The inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality.
9.8 The heads of the production and the quality unit(s) generally have some shared,	**Health, clothing and sanitation of workers:** 7.1 The personnel	(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the	2.5 The head of the Production Department generally has the following responsibilitie	**Training** 2.8. The manufacturer should provide training for all the personnel

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
or jointly exercised, responsibilities relating to quality. These may include, depending on national regulations: (a) Authorization of written procedures and other documents, including amendments. (b)Monitoring and control of the manufacturing environment. (c) Plant hygiene. (d) Process validation and calibration of analytical apparatus. (e) Training, including the application and principles of QA. (f) Approval and monitoring of suppliers of materials. (g) Approval	handling Beta-lactum antibiotics shall be tested for Penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects. These personnel should be moved out of these sections (except in dedicated facilities), by rotation, as a health safeguard.	education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.	s: (i) To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality. (ii) To approve the instructions relating to production operations and to ensure their strict implementation. (iii) To ensure that the production records are evaluated and signed by an authorised person before they are sent to the Quality Control Department. (iv) To check the maintenance of his department, premises and	whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
and monitoring of contract manufacturers. (h) Designation and monitoring of storage conditions for materials and products. (i) Performance and evaluation of in-process controls. (j) Retention of records. (k) Monitoring of compliance with GMP requirements; and (l) Inspection, investigation and taking of samples in order to monitor factors that may affect product quality.			equipment. (v) To ensure that the appropriate validations are done; (vi) To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.	
9.9 The head of the production generally has the following responsibilities	7.2 Prior to employment, all personnel, shall undergo medical examination including eye	(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug	2.6 The head of the Quality Control Department generally has the following responsibilitie	2.9. Besides the basic training on the theory and practice of Good Manufacturing

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
: (a) To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality. (b) To approve the instructions relating to production operations, including the in-process controls, and to ensure their strict implementation. (c) To ensure that the production records are evaluated and signed by a designated person. (d) To check the maintenance of the department, premises and equipment. (e) To ensure	examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof. The licensee shall provide the services of a qualified physician for assessing the health status of personnel involved in different activities.	product.	s: (i) To approve or reject, as he sees fit, starting materials, packaging materials, and intermediate, bulk and finished products. (ii) To evaluate batch records; (iii) To ensure that all necessary testing is carried out. (iv) To approve specifications, sampling instructions, test methods and other Quality Control procedures. (v) To approve and monitor any contract analysts. (vi) To check the maintenance of his department,	Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available. (f) To ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.			premises and equipment. (vii) To ensure that the appropriate validations are done. (viii) To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.	
9.10 The head(s) of the quality unit(s) generally have the following responsibilities : (a) To approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in	7.3 All persons prior to and during employment shall be trained in practices which ensure personnel hygiene. A high level of personal hygiene shall be observed by all those engaged in the manufacturing processes.	§211.28 Personnel responsibilities. (a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.	2.7 The heads of Production and Quality Control generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, subject to any national regulations: • The authorization	2.10. Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
relation with their specifications. (b) To evaluate batch records. (c)To ensure that all necessary testing is carried out. (d) To approve sampling instructions, specifications, test methods and other QC procedures. (e) To approve and monitor analyses carried out under contract. (f) To check the maintenance of the department, premises and equipment. (g) To ensure that the appropriate validations, including those of analytical procedures, and calibrations of control	Instructions to this effect shall be displayed in change- rooms and other strategic locations.		of written procedures and other documents, including amendments. • The monitoring and control of the manufacturing environment. • Plant hygiene. • Process validation. • Training. • The approval and monitoring of suppliers of materials. • The approval and monitoring of contract manufacturers. • The designation and monitoring of storage conditions for materials and products. • The retention of records.	

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
equipment are carried out. (h) To ensure that the required initial and continuing training of quality unit personnel is carried out and adapted according to need. (i) Establishment, implementation and maintenance of the quality system. (j) Supervision of the regular internal audits or self-inspections. (k) Participation in external audit (vendor audit). (l) Participation in validation programmes.			• The monitoring of compliance with the requirements of Good Manufacturing Practice. • The inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality.	
9.11 The authorized person is responsible for compliance with technical	7.4 No person showing, at any time, apparent illness or open lesions which	(b) Personnel shall practice good sanitation and health habits.	Training 2.8 The manufacturer should provide training for all the personnel	2.11. Visitors or untrained personnel should, preferably, not be taken into

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale or supply.	may adversely affect the quality of products, shall be allowed to handle starting materials, packaging materials, in-process materials, and drug products until his condition is no longer judged to be a risk.		whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.	the Production and Quality Control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.
9.12 Assessment of finished products should embrace all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification	7.5 All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.	(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.	2.9 Besides the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its	2.12. The concept of Quality Assurance and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
for the finished product, and an examination of the finished pack.			practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept.	
9.13 No batch of product is to be released for sale or supply prior to certification by the authorized person(s). In certain countries, by law, the batch release is a task of the authorized person from production together with the authorized person from QC.	7.6 Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.	(d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical	2.10 Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.	**Personal Hygiene** 2.13. Detailed hygiene programmes should be established and adapted to the different needs within the factory. They should include procedures relating to the health, hygiene practices and clothing of personnel.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
		personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.		These procedures should be understood and followed in a very strict way by every person whose duties take him into the production and control areas. Hygiene programmes should be promoted by management and widely discussed during training sessions.
9.14 The authorized person responsible for approving a batch for release should always ensure that the following requirements have been met: (a) The marketing authorization and the manufacturing authorization	7.7 All personnel shall wear clean body coverings appropriate to their duties. Before entry into the manufacturing area, there shall be change rooms separate for each sex with adequate facilities for personal cleanliness such as wash	§211.34 Consultants. Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they	2.11 Visitors or untrained personnel should, preferably, not be taken into the Production and Quality Control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and	2.14. All personnel should receive medical examination upon recruitment. It must be the manufacturer's responsibility that there are instructions ensuring that health conditions that can be of relevance to the quality of

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
requirements for the product have been met for the batch concerned. (b) The principles and guidelines of GMP, as laid down in the guidelines published by WHO, have been followed. (c) The principal manufacturing and testing processes have been validated, if different. (d) All the necessary checks and tests have been performed and account taken of the production conditions and manufacturing records. (e) Any planned changes or deviations in manufacturing or quality control have been notified	basin with running water,[clean towels or hand dryers], soaps, disinfectants, etc. The change rooms shall be provided with cabinets for the storage of personal belongings of the personnel. 7.8 Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicines shall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.	provide.	the prescribed protective clothing. They should be closely supervised.	products come to the manufacturer's knowledge. After the first medical examination, examinations should be carried out when necessary for the work and personal health.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
in accordance with a well-defined reporting system before any product is released. Such changes may need notification to, and approval by, the medicines regulatory authority. (f) Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover planned changes and deviations. (g) All necessary production and QC documentation has been completed and endorsed by supervisors trained in appropriate disciplines.				

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
(h) Appropriate audits, self-inspections and spot-checks are carried out by experienced and trained staff. (i) Approval has been given by the head of QC; and (j) All relevant factors have been considered, including any not specifically associated with the output batch directly under review (e.g. subdivision of output batches from a common input, factors associated with continuous production runs).				
9.15 The function of the approval of the release of a finished batch or a product			2.12 The concept of Quality Assurance and all the measures	2.15. Steps should be taken to ensure as far as is practicable

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
can be delegated to a designated person with appropriate qualifications and experience who will release the product in accordance with an approved procedure. This is normally done by QA by means of batch review.			capable of improving its understanding and implementation should be fully discussed during the training sessions.	that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of medicinal products.
Training 10.1 The manufacturer should provide training in accordance with a written programme for all personnel whose duties take them into manufacturing areas or into control laboratories (including the technical, maintenance and cleaning personnel) and for other			Personnel Hygiene 2.13 Detailed hygiene programmes should be established and adapted to the different needs within the factory. They should include procedures relating to the health, hygiene practices and clothing of personnel. These	2.16. Every person entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
personnel as required.			procedures should be understood and followed in a very strict way by every person whose duties take him into the production and control areas. Hygiene programmes should be promoted by management and widely discussed during training sessions.	
10.2 Besides basic training on the theory and practice of GMP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness periodically assessed.			2.14 All personnel should receive medical examination upon recruitment. It must be the manufacturer' s responsibility that there are instructions ensuring that health conditions that can be of relevance to the quality of products come to the	2.17. Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or personal medication in the production and storage areas should be prohibited. In general, any unhygienic practice within the manufacturing areas or in any other area

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
Approved training programmes should be available. Training records should be kept.			manufacturer's knowledge. After the first medical examination, examinations should be carried out when necessary for the work and personal health.	where the product might be adversely affected should be forbidden.
10.3 Personnel working in areas where contamination is a hazard e.g. Clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled should be given specific training.			2.15 Steps should be taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of medicinal products.	2.18. Direct contact should be avoided between the operator's hands and the exposed product as well as with any part of the equipment that comes into contact with the products.
10.4 The concept of QA and all the measures which aid its understanding and implementatio			2.16 Every person entering the manufacturing areas should wear protective garments	2.19. Personnel should be instructed to use the hand-washing facilities.

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
n should be fully discussed during the training sessions.			appropriate to the operations to be carried out.	
10.5 Visitors or untrained personnel should preferably not be taken into the production and QC areas. If this is unavoidable, they should be given relevant information in advance (particularly about personal hygiene) and the prescribed protective clothing. They should be closely supervised.			2.17 Eating, drinking, chewing or smoking, or the storage of food, drink or personal medication in the production and storage areas should be prohibited. In general, any unhygienic practice within the manufacturing areas or in any other area where the product might be adversely affected should be forbidden.	2.20. Any specific requirements for the manufacture of special groups of products, e.g. sterile preparations, are covered in the Supplementary Guidelines.
10.6 Consultant and contract staff should be qualified for the services they provide. Evidence of this should be included in the			2.18 Direct contact should be avoided between the operator's hands and the exposed product as well as with any part of the	

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
training records.			equipment that comes into contact with the products.	
Personal Hygiene 11.1 All personnel, prior to and during employment, as appropriate, should undergo health examinations. Personnel conducting visual inspections should also undergo periodic eye examinations.			2.19 Personnel should be instructed to use the hand-washing facilities.	
11.2 All personnel should be trained in the practices of personal hygiene. A high level of personal hygiene should be observed by all those concerned with manufacturing processes. In particular, personnel			2.20 Any specific requirements for the manufacture of special groups of products, for example sterile preparations.	

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
should be instructed to wash their hands before entering production areas. Signs to this effect should be posted and instructions observed.				
11.3 Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle starting materials, packaging materials, in-process materials or medicines products until the condition is no longer judged to be a risk.				
11.4 All employees should be				

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
instructed and encouraged to report to their immediate supervisor any conditions (relating to plant, equipment or personnel) that they consider may adversely affect the products.				
11.5 Direct contact should be avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk product.				
11.6 To ensure protection of the product from contamination, personnel should wear clean body coverings appropriate to the duties they perform, including				

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
appropriate hair covering. Used clothes, if reusable, should be stored in separate closed containers until properly laundered and, if necessary, disinfected or sterilized.				
11.7 Smoking, eating, drinking, chewing, and keeping plants, food, drink, smoking material and personal medicines should not be permitted in production, laboratory and storage areas, or in any other areas where they might adversely influence product quality.				
11.8 Personal hygiene procedures including the use of				

WHO[1]	Schedule M[2]	USFDA[3]	MHRA[4]	TGA[5]/PICS[6]
protective clothing should apply to all persons entering production areas, whether they are temporary or full-time employees or nonemployees, e.g. contractors, employees, visitors, senior managers and inspectors.				

DISCUSSION

Based on the above comparative study of personnel requirement in the pharmaceutical industry as per WHO, Schedule M of D and C act, USFDA, MHRA and TGA/PICS Good Manufacturing Practice Guidelines below are the discussion outcomes. Discussion is carried out under different heading for better understanding purpose.

Guidelines Chapters

WHO describes about the personnel requirement in **Annex 3 WHO good manufacturing practices for pharmaceutical products: main principles**

Schedule M: Schedule M describes about the personnel requirement in **PART 1 Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.**

USFDA: USFDA describes about the personnel requirement in **PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals Subpart B—Organization and Personnel.**

MHRA: MHRA describes about the personnel requirement in **Chapter II Guidance on Good Manufacturing Practice (GMP) 2 Personnel.**

TGA/PICS: TGA/PICS describes about the personnel requirement in **CHAPTER 2 Personnel.**

General:

The training and personnel health and hygiene is detailed under the chapter personnel in MHRA, TGA/PICS, USFDA whereas WHO and Schedule M details in different chapters however these topics are also selected along with the personnel requirement in the present study.

Qualification and Practical Experience:

Requirement of Qualification and Practical Experience for the personnel engaged in the pharmaceutical industry is detailed under different points in each guideline as below:

WHO: Point no. 9.2, 9.7 and 9.15

Schedule M: Point no. 6.1 and 6.3

USFDA: 211.25

MHRA: 2.1

TGA: 2.1

Duties:

The details of duties and organization chart are given under point no. 9.3 of WHO guide, 6.4 of Schedule M, 211.28 of USFDA, 2.2 of MHRA and 2.2 of TGA/PICS guidelines. Schedule M and USFDA does not detail about the organization chart under personnel.

GMP Training:

Training on GMP and specific duties carried out by the personnel is very important to perform the duties to assure the identity, quality, safety and efficacy of the pharmaceutical products. Also, the training records shall be maintained for all the training conducted in the organization. The requirement of training is detailed in Point no. 9.4 of WHO, 6.6 of Schedule M, 211.25 (a) of USFDA, 2.8 and 2.9 of MHRA, 2.8, 2.9 of TGA/PICS.

Health and Hygiene:

Requirements of health and hygiene is given under different sections of WHO and Schedule M whereas the same is given under Personnel in USFDA, MHRA and TGA/PICS guidelines. Health and Hygiene practices are given in point 11.1 to 11.8 of WHO, 7.1 to 7.8 of Schedule M, 211.28 (b) and (d) of USFDA, 2.13 to 2.20 of TGA/PICS, 2.13 to 2.20 of MHRA.

Accessibility of Production and testing area:

211.28 (c) of USFDA, Point 9.5 of WHO describes that only authorized personnel or personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

The Schedule M, MHRA and TGA guidelines are not detailed the above point however these guidelines quoted that personnel viz., visitor should receive training before entering into manufacturing and testing areas and those personnel should be accompanied by another authorized personnel with close monitoring.

Key personnel:

Point 2.3 of MHRA, 2.3 of TGA/PICS, 9.6 of WHO details about the requirement of key personnel in the pharmaceutical industry. The USFDA and Schedule M does not give the separate section for Key personnel however the requirement of qualification and experience for the personnel authorized to perform technical, quality control and quality assurance is given in 211.25 of USFDA under personnel qualifications and 211.22 under responsibilities of quality control unit and point 6.2 and 6.3 of Schedule M.

Visitor:

10.5 of WHO, 2.11 of TGA/PICS, 2.11 of MHRA details the requirement of visitor to enter the production and quality control areas. According to these guidelines, visitors or untrained personnel should, preferably, not be taken into the Production and Quality Control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised. Schedule M and USFDA does not detail specifically about visitors however visitor shall be closely monitored and trained.

Consultants:

211.34 of USFDA and 1.6 of WHO details about the requirements of consultants and contract staff under personnel requirements, other selected guidelines is not detailed these requirements under personnel,

Qualified person(s)

Only MHRA guidelines detail about the requirements of qualified person. Based on the above study it is understood that the duties of key personnel described under other guidelines is equivalent to the duties of qualified person described in MHRA guide. However qualified person is appointed by the authority to perform specific duties as follows,

For medicinal products manufactured within the European Community, a Qualified Person must ensure that each batch has been produced and tested/checked in accordance with the directives and the marketing authorization.

For medicinal products manufactured outside the European Community, a Qualified Person must ensure that each imported batch has undergone, in the importing country, the testing specified in paragraph 1 (b) of Article 51.

A Qualified Person must certify in a register or equivalent document, as operations are carried out and before any release, that each production batch satisfies the provisions of Article 51. The persons responsible for these duties must meet the qualification requirements laid down in Article 493 of the same directive, they shall be permanently and continuously at the disposal of the holder of the Manufacturing Authorization to carry out their responsibilities. Their responsibilities may be delegated, but only to other Qualified Person(s).

CONCLUSION

Development Of Theory For Personnel Requirement In Pharmaceutical Industry

Based on the above comparative analysis and discussion on personnel requirement in pharmaceutical industry as per the different regulatory guidelines below is the theory developed which is common for all the regulatory requirement. Following of the below common theory shall suffice the requirements of all the regulatory guidelines with respect to personnel.

Qualification and Practical Experience:

According to all the guidelines, personnel responsible for supervision of manufacturing and testing of pharmaceutical products should possess minimum qualification accordingly below is the minimum requirement of qualification to suffice the regulatory requirements.

The personnel's education should include the study of an appropriate combination of: (a) chemistry (analytical or organic) or biochemistry; (b) chemical engineering; (c) microbiology; (d) pharmaceutical sciences and technology; (e) pharmacology and toxicology; (f) physiology; and (g) other related sciences. They should also have adequate practical experience in the manufacture and QA of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgment, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and QC of pharmaceutical products. They should be able to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

The personnel responsible for performing the functions of designated personnel during his absence should also possess the equivalent qualification and practical experience.

Duties:

The personnel responsible for supervision of manufacturing, testing and release activities shall be whole time employees of the organization. The manufacturer must have an organization chart. People in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of Good Manufacturing Practice.

Number of personnel employed shall be adequate and in direct proportion to the workload.

GMP Training:

The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and

cleaning personnel), and for other personnel whose activities could affect the quality of the product. Besides the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept.

Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

Health and Hygiene:

Detailed hygiene programmes should be established and adapted to the different needs within the factory. They should include procedures relating to the health, hygiene practices and clothing of personnel. These procedures should be understood and followed in a very strict way by every person whose duties take him into the production and control areas. Hygiene programmes should be promoted by management and widely discussed during training sessions.

All personnel should receive medical examination upon recruitment. It must be the manufacturer's responsibility that there are instructions ensuring that health conditions that can be of relevance to the quality of products come to the manufacturer's knowledge. After the first medical examination, examinations should be carried out when necessary for the work and personal health.

Steps should be taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of medicinal products.

Every person entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.

Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or personal medication in the production and storage areas should be prohibited. In general, any unhygienic practice within the manufacturing areas or in any other area where the product might be adversely affected should be forbidden.

Direct contact should be avoided between the operator's hands and the exposed product as well as with any part of the equipment that comes into contact with the products.

Personnel should be instructed to use the hand-washing facilities.

Any specific requirements for the manufacture of special groups of products, for example sterile preparations, should be complied with.

Accessibility of Production and testing area:

Only authorized personnel or personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

Visitor should receive training before entering into manufacturing and testing areas and those personnel should be accompanied by another authorized personnel with close monitoring.

Key personnel:

Key personnel includes the heads of production, the head(s) of quality unit(s) and the authorized person. The quality unit(s) typically comprises the quality assurance and quality control functions. In some cases, these could be combined in one department. The authorized person may also be responsible for one or more of these quality unit(s). Normally, key posts should be occupied by full-time personnel. The heads of Production and Quality unit(s) should be independent of each other. In large organizations, it may be necessary to delegate some of the functions; however, the responsibility cannot be delegated.

Key personnel responsible for supervising the production and quality unit(s) for pharmaceutical products should possess the qualifications of a scientific education and practical experience required by national legislation. Their education should include the study of an appropriate combination of (a) chemistry (analytical or organic) or biochemistry; (b) chemical engineering; (c) microbiology; (d) pharmaceutical sciences and technology; (e) pharmacology and toxicology; (f) physiology; and (g) other related sciences. They should also have adequate practical experience in the manufacture and QA of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgment, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and QC of pharmaceutical products.

The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.

The heads of the production and the quality unit(s) generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, depending on national regulations:

(a) Authorization of written procedures and other documents, including amendments.

(b) Monitoring and control of the manufacturing environment.

(c) Plant hygiene.

(d) Process validation and calibration of analytical apparatus.

(e) Training, including the application and principles of QA.

(f) Approval and monitoring of suppliers of materials.

(g) Approval and monitoring of contract manufacturers.

(h) Designation and monitoring of storage conditions for materials and products.

(i) Performance and evaluation of in-process controls.

(j) Retention of records.

(k) Monitoring of compliance with GMP requirements; and

(l) Inspection, investigation and taking of samples in order to monitor factors that may affect product quality.

The head of the production generally has the following responsibilities:

(a) To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality.

(b) To approve the instructions relating to production operations, including the in-process controls, and to ensure their strict implementation.

(c) To ensure that the production records are evaluated and signed by a designated person.

(d) To check the maintenance of the department, premises and equipment.

(e) To ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available.

(f) To ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.

The head(s) of the quality unit(s) generally have the following responsibilities:

(a) To approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in relation with their specifications.

(b) To evaluate batch records.

(c) To ensure that all necessary testing is carried out.

(d) To approve sampling instructions, specifications, test methods and other QC procedures.

(e) To approve and monitor analyses carried out under contract.

(f) To check the maintenance of the department, premises and equipment.

(g) To ensure that the appropriate validations, including those of analytical procedures, and calibrations of control equipment are carried out.

(h) To ensure that the required initial and continuing training of quality unit personnel is carried out and adapted according to need.

(i) Establishment, implementation and maintenance of the quality system.

(j) Supervision of the regular internal audits or self-inspections.

(k) Participation in external audit (vendor audit).

(l) Participation in validation programmes.

The authorized person is responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale or supply. Assessment of finished products should embrace all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack.

No batch of product is to be released for sale or supply prior to certification by the authorized person(s). In certain countries, by law, the batch release is a task of the authorized person from production together with the authorized person from QC.

The authorized person responsible for approving a batch for release should always ensure that the following requirements have been met:

(a) The marketing authorization and the manufacturing authorization requirements for the product have been met for the batch concerned.

(b) The principles and guidelines of GMP, as laid down in the guidelines published by WHO, have been followed.

(c) The principal manufacturing and testing processes have been validated, if different.

(d) All the necessary checks and tests have been performed and account taken of the production conditions and manufacturing records.

(e) Any planned changes or deviations in manufacturing or quality control have been notified in accordance with a well-defined reporting system before any product is released. Such changes may need notification to and approval by, the medicines regulatory authority.

(f) Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover planned changes and deviations.

(g) All necessary Production and QC documentation has been completed and endorsed by supervisors trained in appropriate disciplines.

(h) Appropriate audits, self-inspections and spot-checks are carried out by experienced and trained staff.

(i) Approval has been given by the head of QC; and Quality Assurance department.

(j) All relevant factors have been considered, including any not specifically associated with the output batch directly under review (e.g. subdivision of output batches from a common input, factors associated with continuous production runs).

The function of the approval of the release of a finished batch or a product can be delegated to a designated person with appropriate qualifications and experience who will release the product in accordance with an approved procedure. This is normally done by QA by means of batch review.

Visitor:

Visitors or untrained personnel should, preferably, not be taken into the production and Quality Control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.

Consultants:

Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

Qualified person(s)

Pharmaceutical industry should appoint a qualified person to authorize the products manufactured are as per the requirements of marketing authorization. The qualified person shall be independent from the pharmaceutical industry and shall be registered as qualified person in regulatory authority.

REFERENCES

1. World Health organization describes about the personnel requirement in **Annex 3 WHO good manufacturing practices for pharmaceutical products.**

2. **Schedule M** describes about the personnel requirement in PART **1Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.**

3. USFDA describes about the personnel requirement in **PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals**

Subpart B—Organization and Personnel

4. Medicines and Healthcare products regulatory Agency (MHRA): describes about the personnel requirement in **Chapter II Guidance On Good Manufacturing Practice (GMP) - Personnel**

5. TGA describes about the personnel requirement in **CHAPTER 2Personnel**

6. PICS describes about the personnel requirement in **CHAPTER 2Personnel**

USFDA GUIDANCE reference

http://www.ecfr.gov/cgi-bin/text-idx?SID=600eecf12667dca16f77f5f22d05a56d&mc=true&node=pt21.4.211&rgn=div5#sp21.4.211.b