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Quality Assurance in Pharmaceutical and Biotech Industries as Per Regulatory Guidelines

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ABSTRACT

Quality Assurance is the key element of any industry and is responsible for the organizational growth and outcomes. QA is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical Products are of the quality required for their intended use. QA, therefore, Incorporates GMP and other factors, including those outside the scope of this guide such as product design and development. Current study is aimed at requirements of quality assurance 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 detailed with respect to Quality Assurance the same shall be omitted in the study.

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INTRODUCTION

WHO describes the Quality Assurance in **Annex 3 WHO good manufacturing practices for pharmaceutical products: main principles; Quality Assurance**

Schedule M: Schedule M describes the Quality Assurance in **PART 1 Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products; 14. Quality Assurance.**

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

MHRA: MHRA describes the Quality Assurance in **Chapter II-2EU Guidance on Good Manufacturing Practice (GMP) - Quality Assurance**

TGA/PICS: TGA/PICS describes the Quality Assurance in **CHAPTER 1Quality Management-Quality Assurance.**

Table 1: Comparison of regulatory guidelines for Quality Assurance in pharmaceutical industry

WHO	Schedule M	USFDA	MHRA	TGA/PICS
WHO describes the Quality assurance in **WHO good manufacturing practices for pharmaceutical products: main principles**[1]	**Schedule M** describes the Quality assurance in **PART 1** **Good Manufacturing Practices For Premises And Materials of Good Manufacturing Practices And Requirements Of Premises, Plant And Equipment For Pharmaceutical Products**[2]	USFDA describes the Quality Assurance in PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals **e-CFR data is current as of January 12, 2016** **Title 21 → Chapter I → Subchapter C → Part 211 → Subpart B** [3]	**MHRA** describes the Quality Assurance in **Section II – 2EU Guidance On Good Manufacturing Practice (GMP)** - **Quality Assurance**[11]	**TGA/PICS** describes about the Quality Assurance in **CHAPTER 1** **Quality Management** - **Quality Assurance**[12]
Quality assurance 1.1Principle.QA is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the	**14.0Quality Assurance:** This is a wide-ranging concept concerning all matters that individually or	**211.22**Responsibilities of quality control unit[4]. (a) There shall be a quality control unit that shall have the responsibility and	**QUALITY ASSURANCE** **1.2** Quality Assurance is a wide-ranging concept which covers all matters which Individually or	**QUALITY ASSURANCE** **1.1**Quality Assurance is a wide-ranging concept, which

WHO	Schedule M	USFDA	MHRA	TGA/PICS
totality of the arrangements made with the object of ensuring that pharmaceutical Products are of the quality required for their intended use. QA, therefore, Incorporates GMP and other factors, including those outside the scope of this guide such as product design and development. **1.2** The system of QA appropriate to the manufacture of pharmaceutical products should ensure that: (a) pharmaceutical products are designed and developed in a way that takes account of the requirements of GMP and other associated codes such as those of good laboratory practice and good clinical practice (b) production and control operations are clearly specified in a written form and GMP requirements are adopted; (c) managerial responsibilities are clearly specified in job descriptions; (d) arrangements are made for the manufacture, supply and use of the correct starting and packaging materials; (e) all necessary controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations, and validations are carried out; (f) the finished product is	collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that products are of the quality required for their intended use. **14.1** The system of quality assurance appropriate to the manufacture of pharmaceutical products shall ensure that: – (a) the pharmaceutical products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practices (hereinafter referred as GMP) and other associated codes such as those of Good Laboratory Practices (hereinafter referred as GLP) and Good Clinical Practices (hereinafter referred as GCP); (b) Adequate arrangements are made for manufacture, supply and use of the correct starting and packaging materials. (c) Adequate controls on starting materials, intermediate products and bulk products and other in-process controls, calibrations, and validations are carried out. (d) the finished product is correctly processed	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 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. (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. (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. (d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed. **211.100** written	collectively influence the quality of a product. It is the total sum of the organized arrangements made with the object of ensuring that Medicinal products are of the quality required for their intended use. Quality Assurance, therefore, incorporates Good Manufacturing Practice plus Other factors outside the scope of this Guide. The system of Quality Assurance appropriate for the manufacture of medicinal products should ensure that: **(i)** Medicinal products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice and Good Laboratory Practice; **(ii)** Production and control operations are clearly specified and Good Manufacturing Practice adopted; **(iii)** Managerial responsibilities are clearly specified; **(iv)** Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials; **(v)** All necessary controls on intermediate products, and any other in process controls and validations are carried out; **(vi)** The finished product is correctly processed and checked, according to the	covers all matters, which individually or collectively influence the quality of a product. It is the sum total of the organized arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use. Quality Assurance, therefore, incorporates Good Manufacturing Practice plus other factors outside the scope of this Guide. The system of Quality Assurance appropriate for the manufacture of medicinal products should ensure that: i. medicinal products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice; ii. production and control

WHO	Schedule M	USFDA	MHRA	TGA/PICS
correctly processed and checked, according to the defined procedures; (g) pharmaceutical products are not sold or supplied before the authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of pharmaceutical products; (h) satisfactory arrangements exist to ensure, as far as possible, that the pharmaceutical products are stored by the manufacturer, distributed, and subsequently handled so that quality is maintained throughout their shelf-life; (i) There is a procedure for self-inspection and/or quality audit that regularly appraises the effectiveness and applicability of the QA system; (j) deviations are reported, investigated and recorded; (k) there is a system for approving changes that may have an impact on product quality; (l) regular evaluations of the quality of pharmaceutical products should be conducted with the objective of verifying the consistency of the process and ensuring its continuous improvement; and (m) There is a system for QRM.	and checked in accordance with established procedures; (e) The pharmaceutical products are not released for sale or supplied before authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the label claim and any other provisions relevant to production, control and release of pharmaceutical products.	procedures; deviations[5]. (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. (b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified. **211.180**General requirements [6]. Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§211.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations	defined procedures; **(vii)** Medicinal products are not sold or supplied before a Qualified Person has certified that each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of medicinal products; **(viii)** Satisfactory arrangements exist to ensure, as far as possible, that the medicinal products are stored, distributed and subsequently handled so that quality is maintained throughout their shelf life; **(ix)** There is a procedure for Self-Inspection and/or quality audit which regularly appraises the effectiveness and applicability of the Quality Assurance system. **Good Manufacturing Practice for Medicinal Products (GMP)** **1.3** Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation or product specification. Good Manufacturing Practice is concerned with both production and Quality	operations are clearly specified and Good Manufacturing Practice adopted; iii. managerial responsibilities are clearly specified; iv. arrangements are made for the manufacture, supply and use of the correct starting and packaging materials; v. all necessary controls on intermediate products and any other in-process controls and validations are carried out; vi. the finished product is correctly processed and checked, according to the defined procedures; vii. medicinal products are not sold or supplied before an authorized person has certified that each production batch has been produced and controlled in accordance with

WHO	Schedule M	USFDA	MHRA	TGA/PICS
1.3 The manufacturer must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the marketing authorization and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment of staff in many different departments and at all levels within the company, the company's suppliers, and the distributors. To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of QA incorporating GMP and QC. It should be fully documented and its effectiveness monitored. All parts of the QA system should be adequately staffed with competent personnel, and should have suitable and sufficient premises, equipment and facilities. 1.4 QRM is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively. 1.5 QRM should ensure that: — the evaluation of the risk to quality is based on		issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration. (a) All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph. **211.204** Returned drug products[7]. Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed	control. The basic requirements of GMP are that: **(i)** All manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications; **(ii)** Critical steps of manufacturing processes and significant changes to the process are validated; **(iii)** All necessary facilities for GMP are provided including: **(iv)** Appropriately qualified and trained personnel; **(v)** Adequate premises and space; **(vi)** Suitable equipment and services; **(vii)** Correct materials, containers and labels; **(viii)** **A**pproved procedures and instructions; **(ix)** Suitable storage and transport; **(x)** Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided; **(xi)** Operators are trained to carry out procedures correctly;	the requirements of the marketing authorisation and any other regulations relevant to the production, control and release of medicinal products; viii. satisfactory arrangements exist to ensure, as far as possible, that the medicinal products are stored, distributed and subsequently handled so that quality is maintained throughout their shelf life; ix. There is a procedure for self-inspection and/or quality audit, which regularly appraises the effectiveness and applicability of the quality assurance system. **Good Manufacturing Practice For Medicinal Products (GMP)** **1.2** Good Manufacturing

WHO	Schedule M	USFDA	MHRA	TGA/PICS
scientific knowledge, experience with the process and ultimately links to the protection of the patient; and — the level of effort, formality and documentation of the QRM process is commensurate with the level of risk. **Product quality review** 1.6 Regular, periodic or rolling quality reviews of all medicinal products, including export-only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product to highlight any trends and to Accepted by Venkat identify product and process improvements. Such reviews should normally be conducted and documented annually, taking into account previous reviews, and should include at least: (i) a review of starting materials and packaging materials used for the product, especially those from new sources; (ii) a review of critical in-process controls and finished product results; (iii) a review of all batches that failed to meet established specification(s)and their investigation; (iv) a review of all		unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of §211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed. **211.208** Drug product salvaging [8.] Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall	**(xii)** Records are made, manually and/or by recording instruments, during Manufacture which demonstrates that all the steps required by the defined procedures and instructions were in fact taken and that the Quantity and quality of the product were as expected. Any significant deviations are fully recorded and investigated; **(xiii)** Records of manufacture including distribution which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form; **(xiv)** The distribution (wholesaling) of the products minimizes any risk to their quality; **(xv)** a system is available to recall any batch of product, from sale or supply; **(xvi)** Complaints about marketed products are examined, the causes of Quality defects investigated and appropriate measures were taken in respect of the defective products and to prevent reoccurrence.	Practice is that part of Quality Assurance which ensures that Medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that: i. all manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications; ii. critical steps of

WHO	Schedule M	USFDA	MHRA	TGA/PICS
significant deviations or non-conformances, the related investigations and the effectiveness of resultant corrective and preventive actions taken; (v) a review of all changes made to the processes or analytical methods; (vi) a review of dossier variations submitted, granted or refused; (vii) a review of the results of the stability monitoring program and any adverse trends; (viii) a review of all quality-related returns, complaints and recalls and the investigations performed at the time; (ix) a review of adequacy of any other previous corrective actions on product process or equipment;(x) for new dossiers and variations to the dossiers, a review of postmarketing commitments; (xi) the qualification status of relevant equipment and utilities, e.g. heating, ventilation and air-conditioning (HVAC), water, or compressed gasses; and (xii) a review of technical agreements to ensure that they are up to date. The manufacturer and marketing authorization holder, where different, should evaluate the results of this review and an assessment should be made whether corrective and preventive action or any		not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is (a) evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and (b) evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products subject to this section. **211.198** Complaint files [9]. (a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for		manufacturing processes and significant changes to the process are validated; iii. all necessary facilities for GMP are provided including: a. appropriately qualified and trained personnel; b. adequate premises and space; c. suitable equipment and services; d. correct materials, containers and labels; e. approved procedures and instructions; f. suitable storage and transport; iv. instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided; v. operators are trained to carry out procedures

WHO	Schedule M	USFDA	MHRA	TGA/PICS
revalidation should be undertaken. Reasons for such corrective actions should be documented. Agreed corrective and preventive actions should be completed in a timely and effective manner. There should be management procedures for the ongoing management and review of these actions and the effectiveness of these procedures should be verified during self-inspection. Quality reviews may be grouped by product type, e.g. solid dosage forms, liquid dosage forms, or sterile products, where scientifically justified. Where the marketing authorization holder is not the manufacturer, there should be a technical agreement in place between the various parties that defines their respective responsibilities in producing the quality review. The authorized person responsible for final batch certification, together with the marketing authorization holder, should ensure that the quality review is performed in a timely manner and is accurate.		review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with §211.192. (b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, such written records shall be maintained for 3 years after distribution of the drug product. (1) The written record		correctly; vi. Records are made, manually and/or by recording instruments, during manufacture which demonstrates that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product were as expected. Any significant deviations are fully recorded and investigated; vii. records of manufacture including distribution which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form; viii. the distribution (wholesaling) of the products minimizes any risk to their quality; ix. a system is

WHO	Schedule M	USFDA	MHRA	TGA/PICS
		shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant. (2) Where an investigation under §211.192 is conducted, the written record shall include the findings of the investigation and follow-up. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with §211.180(c). (3) Where an investigation under §211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination. **211.192** Production record review [10.] All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.		available to recall any batch of product, from sale or supply; x. complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures were taken in respect of the defective products and to prevent re-occurrence

WHO	Schedule M	USFDA	MHRA	TGA/PICS
		Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.		

DISCUSSION:

Based on the above comparative study of Quality Assurance 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 components in the form of table for better understanding purpose.

Guidelines Chapters

WHO describes the Quality Assurance in **Annex 3 WHO good manufacturing practices for pharmaceutical products: main principles; Quality Assurance**

Schedule M: Schedule M describes the Quality Assurance in **PART 1 Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products; 14. Quality Assurance.**

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

MHRA: MHRA describes the Quality Assurance in **Chapter II Guidance on Good Manufacturing Practice (GMP) - Quality Assurance**

TGA/PICS: TGA/PICS describes the Quality Assurance in **CHAPTER 1Quality Management-Quality Assurance**

Component of QA	**WHO**	**Schedule M**	**USFDA**	**MHRA**	**TGA/PICs**
Principle of QA	Specified	Specified	Not specified	Specified	Specified
Responsibilities of QA	Specified	Specified	Specified as responsibilities of Quality Control Unit	Specified	Specified
Responsibilities – Verification of compliance to GMP, GCP, GLP	Specified	Specified	Specified	Specified	Specified
Responsibilities – Verification of written procedures for production, monitoring of environmental conditions, HVAC systems	Specified	Specified	Specified	Specified	Specified
Responsibilities – Verification of managerial responsibilities	Specified	Not specified	Specified	Specified	Specified
Responsibilities – Verification of correct starting and packing materials	Specified	Specified	Specified	Specified	Specified
Responsibilities – Verification of in-process controls, calibrations and validations	Specified	Specified	Specified	Specified	Specified
Responsibilities – Verification of Finished product as per procedure	Specified	Specified	Specified	Specified	Specified
Responsibilities – Verification of requirements of marketing authorization and batch release by authorized personnel	Specified	Specified	Specified	Specified	Specified
Responsibilities – Verification of storage and transportation	Specified	Not specified under Responsibilities	Specified	specified	Specified

as per the product requirement		of QA, however, this is specified under Section 1 requirements of building and facilities and section 2 warehousing area of Schedule M			
Responsibilities – Self-inspection	Specified	Not specified under Responsibilities of QA, however, this is specified under Section 15 of Schedule M	Not specified in this section.	Specified	Specified
Responsibilities – deviation handling Change control handling Market complaint handling Product recalls	Specified	Not specified under Responsibilities of QA, however, this is specified under Section 28 of Schedule M for complaint handling, 12.5 for change management, 27 for product recalls	Specified	Specified	Specified
Quality risk management	Specified	Not specified	Not specified under Quality control Unit, however, cross reference is given to ICH Q9	Not specified	Not specified
Annual Product Quality Review	Specified	Not specified	Specified	Specified	Specified

RESULTS

Development of Theory for Quality Assurance requirement in pharmaceutical industry

Based on the above comparative analysis and discussion on Quality Assurance 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 Quality Assurance.

Responsibilities of QA:

As per the above comparative evaluation of different regulatory guidelines with respect to Responsibilities of Quality Assurance, below are the duties to be carried out by QA and are to be specifically documented in job description to suffice the requirement of all selected regulatory guidelines.

(a) Pharmaceutical products are designed and developed in a way that takes account of the requirements of GMP and other associated codes such as those of good laboratory practice and good clinical practice

(b) Production and control operations are clearly specified in a written form and GMP requirements are adopted;

(c) Managerial responsibilities are clearly specified in job descriptions;

(d) Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials;

(e) All necessary controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations, and validations are carried out;

(f) The finished product is correctly processed and checked, according to the defined procedures;

(g) Pharmaceutical products are not sold or supplied before the authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of pharmaceutical products;

(h) SATISFACTORY arrangements exist to ensure, as far as possible, that the pharmaceutical products are stored by the manufacturer, distributed, and subsequently handled so that quality is maintained throughout their shelf-life;

(i) There is a procedure for self-inspection and/or quality audit that regularly appraises the effectiveness and applicability of the QA system;

(j) Deviations are reported, investigated and recorded;

(k) There is a system for approving changes that may have an impact on product quality;

(l) Regular evaluations of the quality of pharmaceutical products should be conducted with the objective of verifying the consistency of the process and ensuring its continuous improvement; and

(m) There is a system for QRM.

Quality risk management:

As per the above comparative evaluation of different regulatory guidelines with respect to Quality Risk Management, It is found that Quality Risk Management is not covered in all the selected guidelines, WHO GMP guide is having the information on QRM procedure and other selected guidelines is not having the information on QRM procedure, however it is cross referenced to ICH Q9 in USFDA guideline. However implementing the QRM procedure in the pharmaceutical industry will suffice the requirement of all the guidelines.

Annual Product Quality Review:

Annual Product Quality Review is mentioned in WHO GMP guide, USFDA Guide, MHRA Guide, TGA/ PICs guide but it is not specified in Schedule M of Drugs and Cosmetics Act. Conducting and recording Annual Product Quality Review in pharmaceutical industry will suffice the requirements of all the regulatory guidelines.

REFERENCES

1) WHO describes the Quality Assurance in Annex 3 WHO good manufacturing practices for pharmaceutical products: main principles; Quality Assurance.
2) Schedule M: Schedule M describes the Quality Assurance in PART 1 Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products; 14. Quality Assurance.
3) USFDA: USFDA describes the Quality Assurance in PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals Subpart B—Organization and Personnel.
4) USFDA: USFDA describes the Quality Assurance in PART —211.22 Responsibilities of quality control
5) USFDA describes the Quality Assurance in PART —211.100 Written Procedures and deviation.

6) USFDA describes the Quality Assurance in PART —211.180 General requirements.
7) USFDA describes the Quality Assurance in PART —211.204 Retained drug products.
8) USFDA describes the Quality Assurance in PART —211.208Drug product salvaging.
9) USFDA describes the Quality Assurance in PART —211.198. Complaint files
10)USFDA describes the Quality Assurance in PART —211.192 Product record review.
11)Section II and chapter 2-EU guidance on Good Manufacturing Practice (GMP) Part I –Basic requirements of Medicinal prducts.
12)TGA/PICS: TGA/PICS describes the Quality Assurance in CHAPTER 1Quality Management-Quality Assurance.