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Quality Assurance in Pharmaceutical and Biotech Industries as **Per Regulatory Guidelines**



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Keywords: WHO, Schedule M of D and C Act, USFDA, MHRA, TGA.

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.

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 describes the Quality assurance in WHO good manufacturing practices for pharmaceutical products: main principles¹ 	Schedule M describesthe Quality assurance inPART 1Good ManufacturingPractices ForPremises AndMaterials of GoodManufacturingPractices AndRequirements OfPremises, Plant AndEquipment ForPharmaceuticalProducts 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 \rightarrow Chapter I \rightarrow Subchapter C \rightarrow Part 211 \rightarrow 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	14.0Quality Assurance: This is a wide-ranging concept concerning all matters that	 211.22Responsibilities of quality control unit⁴. (a) There shall be a quality control unit that shall have the 	QUALITY ASSURANCE 1.2 Quality Assurance is a wide-ranging concept which covers all matters	QUALITY ASSURANCE 1.1Quality Assurance is a wide-ranging

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WHO	Schedule M	USFDA MHRA		USFDA MHRA		TGA/PICS
totality of the arrangements	collectively influence	authority to approve or	collectively influence the	covers all		
made with the object of	the quality of a product.	reject all components,	quality of a product. It is	matters, which		
ensuring that	It is the totality of the	drug product containers,	the total sum of the	individually or		
pharmaceutical Products are	arrangements made	closures, in-process	organized arrangements	collectively		
of the quality required for	with the object of	materials, packaging	made with the object of	influence the		
their intended use. QA,	ensuring that products	material, labeling, and	ensuring that Medicinal	quality of a		
therefore, Incorporates	are of the quality	drug products, and the	products are of the quality	product. It is		
GMP and other factors,	required for their	authority to review	required for their intended	the sum total of		
including those outside the	intended use.	production records to	use. Quality Assurance,	the organized		
scope of this guide such as	14.1 The system of	assure that no errors have	therefore, incorporates	arrangements		
product design and	quality assurance	occurred or, if errors have	Good Manufacturing	made with the		
development.	appropriate to the	occurred, that they have	Practice plus Other	objective of		
1.2 The system of OA	manufacture of	been fully investigated.	factors outside the scope	ensuring that		
appropriate to the	nharmaceutical	The quality control unit	of this Guide. The system	medicinal		
manufacture of	products shall ensure	shall be responsible for	of Quality Assurance	products are of		
pharmaceutical products	that -	approving or rejecting	appropriate for the	the quality		
should ensure that:	that.	drug products	manufacture of medicinal	required for		
should ensure that.	(a) the pharmaceutical	manufactured, processed,	products should ensure	their intended		
(a) pharmaceutical products	products are designed	packed, or held under	that:	use. Quality		
are designed and developed	and developed in a way	contract by another	(i) Medicinal products are	Assurance,		
in a way that takes account	that takes account of the	company.	designed and developed	therefore,		
of the requirements of GMP	requirements of Good	(b) Adequate laboratory	in a way that takes	incorporates		
and other associated codes	Manufacturing	facilities for the testing	account of the	Good		
such as those of good	Practices (hereinafter	and approval (or	requirements of Good	Manufacturing		
laboratory practice and good	referred as GMP) and	rejection) of components,	Manufacturing Practice	Practice plus		
clinical practice	other associated codes	drug product containers,	and Good Laboratory	other factors		
(b) production and control	such as those of Good	closures, packaging	Practice;	outside the		
operations are clearly	Laboratory Practices	materials, in-process	(!!) Due due tien and	scope of this		
specified in a written form	(hereinalter referred as	materials, and drug	(II) Production and	Guide.		
and GMP requirements are	Clinical Practices	products shall be	control operations are	The system of		
adopted;	(horainaftar referred as	available to the quality	Good Manufacturing	Quality		
(c) managerial	GCP).	control unit.	Practice adopted:	Assurance		
responsibilities are clearly	0Cl),	(c) The quality control	Tractice adopted,	appropriate for		
specified in job	(b) Adequate	unit shall have the	(iii) Managerial	the manufacture		
descriptions:	arrangements are made	responsibility for	responsibilities are clearly	of medicinal		
cesenperene,	for manufacture, supply	approving or rejecting all	specified;	products should		
(d) arrangements are made	and use of the correct	procedures or	(iv) Arrangements are	ensure that:		
for the manufacture, supply	starting and packaging	specifications impacting	made for the manufacture,	i. medicinal		
and use of the correct	materials.	on the identity, strength.	supply and use of the	products are		
starting and packaging	(c) Adequate controls	quality, and purity of the	correct starting and	designed and		
materials;	on starting materials,	drug product.	packaging materials;	developed in a		
(e) all necessary controls on	intermediate products			way that takes		
starting materials,	and bulk products and	(d) The responsibilities	(v) All necessary controls	account of the		
intermediate products, and	other in-process	and procedures applicable	on intermediate products,	requirements of		
bulk products and other in-	controls, calibrations,	to the quality control unit	and any other in process	Good		
process controls,	and validations are	snall be in writing; such	controls and validations	Manufacturing		
calibrations, and validations	carried out.	written procedures shall	are carried out;	Practice;		
are carried out;	(d) the finished product	de followed.	(vi) The finished product			
(f) the finished product is	is correctly processed	211.100 written	is correctly processed and	ii. production		
(1) the minister product is	is contectly processed		checked, according to the	anu control		

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

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

who	Schedule M	USFDA	USFDA MHRA	
scientific knowledge,		unless examination,		Practice is that
appariance with the process		testing, or other	(vii) Pacarda ara mada	part of Quality
and ultimately links to the		investigations prove the	(MI) Records are made,	Assurance
protection of the patient:		drug product meets	recording instruments	which ensures
and		appropriate standards of	during Manufacture	that Medicinal
und		safety, identity, strength,	which demonstrates that	products are
— the level of effort,		quality, or purity. A drug	all the steps required by	consistently
formality and		product may be	the defined procedures	produced and
documentation of the QRM		reprocessed provided the	and instructions were in	controlled to
process is commensurate		subsequent drug product	fact taken and that the	the quality
with the level of risk.		meets appropriate	Quantity and quality of	standards
Product quality review		standards, specifications,	the product were as	appropriate to
1.6 Regular, periodic or		Records of returned drug	expected. Any significant	use and as
rolling quality reviews of all		products shall be	deviations are fully	required by the
medicinal products,		maintained and shall	recorded and investigated;	marketing
including export-only		include the name and	(xiii) Records of	authorisation or
products, should be		label potency of the drug	manufacture including	product
conducted with the		product dosage form, lot	distribution which enable	specification.
objective of verifying the		number (or control	the complete history of a	Card
consistency of the existing		number or batch number),	batch to be traced, are	Good Monufo atumin a
process, the appropriateness		reason for the return,	retained in a	Practico is
of current specifications for		quantity returned, date of	comprehensible	concerned with
both starting materials and		disposition, and ultimate	and accessible form.	both production
finished product to highlight		disposition of the returned		and quality
any trends and to Accepted		drug product. If the	(xiv) The distribution	control The
by Venkat identify product		reason for a drug product	(wholesaling) of the	basic
and process improvements.		being returned implicates	products minimizes any	requirements of
Such reviews should		associated batches, an	risk to their quality;	GMP are that:
normally be conducted and		appropriate investigation	(xv) a system is available	
taking into account provious		shall be conducted in	to recall any batch of	1. all
ravious and should include		accordance with the	product, from sale or	manufacturing
at least:		requirements of §211.192.	supply;	processes are
at least.		Procedures for the	(xvi) Complaints about	clearly defined,
(i) a review of starting		nolding, testing, and	marketed products are	systematically
materials and packaging		drug products shall be in	examined, the causes of	light of
materials used for the		writing and shall be	Quality defects	experience and
product, especially those		followed	investigated and	shown to be
from new sources;		lonowed.	appropriate measures	capable of
		211.208 Drug product	were taken in respect of	consistently
(ii) a review of critical in-		salvaging ^{8.} Drug products	the defective products and	manufacturing
finished product results:		that have been subjected	to prevent reoccurrence.	medicinal
		to improper storage		products of the
(111) a review of all batches		extremes in temporature		required quality
that failed to meet		humidity smoke fumes		and complying
established		nerssure are or radiation		with their
specification(s) and their		due to natural disasters		specifications;
investigation;		fires. accidents. or		ii. critical steps
(iv) a review of all		equipment failures shall		of

WHO	Schedule M	USFDA	MHRA	TGA/PICS
significant deviations or		not be salvaged and		manufacturing
non-conformances, the		returned to the		processes and
related investigations and		marketplace. Whenever		significant
the effectiveness of resultant		there is a question		changes to the
corrective and preventive		whether drug products		process are
actions taken;		have been subjected to		validated;
(v) a review of all changes		such conditions, salvaging		iii. all necessary
made to the processes or		operations may be		facilities for
analytical methods:		conducted only if there is		GMP are
		(a) evidence from		provided
(vi) a review of dossier		laboratory tests and		including:
variations submitted,		assays (including animal		e de g
granted or refused;		feeding studies where		a. appropriately
(vii) a review of the results		applicable) that the drug		qualified and
of the stability monitoring		products meet all		trained
program and any adverse		applicable standards of		personnel;
trends:		identity, strength, quality,		b. adequate
		and purity and (b)		premises and
(viii) a review of all quality-		evidence from inspection		space:
related returns, complaints		of the premises that the		-F,
and recalls and the		drug products and their		c. suitable
investigations performed at		associated packaging		equipment and
the time;		were not subjected to		services;
(ix) a review of adequacy of		improper storage		d. correct
any other previous		conditions as a result of		materials,
corrective actions on		the disaster or accident.		containers and
product process or		Organoleptic		labels;
equipment;(x) for new		examinations shall be		
dossiers and variations to		acceptable only as		e. approved
the dossiers, a review of		supplemental evidence		procedures and
postmarketing		that the drug products		instructions;
commitments;		meet appropriate		f. suitable
		standards of identity,		storage and
(x1) the qualification status		strength, quality, and		transport;
of relevant equipment and		purity. Records including		• • • •
utilities, e.g. heating,		name, lot number, and		iv. instructions
ventilation and air-		disposition shall be		and procedures
conditioning (HVAC),		maintained for drug		are written in an
water, or compressed		products subject to this		instructional
gasses; and		section.		form in clear
(xii) a review of technical		211.198 Complaint files ^{9.}		unambiguous
agreements to ensure that				language.
they are up to date. The		(a) written procedures		specifically
manufacturer and marketing		describing the handling of		applicable to
authorization holder, where		all written and oral		the facilities
different, should evaluate		complaints regarding a		provided.
the results of this review		drug product shall be		Provideu,
and an assessment should be		established and followed.		v. operators are
made whether corrective		Such procedures shall		trained to carry
and preventive action or any		include provisions for		out procedures

WHO	Schedule M	USFDA	MHRA	TGA/PICS
revalidation should be		review by the quality		correctly;
undertaken. Reasons for		control unit, of any		-
such corrective actions		complaint involving the		
should be documented.		possible failure of a drug		vi. Records are
Agreed corrective and		product to meet any of its		made, manually
preventive actions should be		specifications and, for		and/or by
completed in a timely and		such drug products, a		recording
effective manner. There		determination as to the		instruments,
should be management		need for an investigation		during
procedures for the ongoing		in accordance with		manufacture
management and review of		\$211.192.		which
these actions and the		0		demonstrates
effectiveness of these		(b) A written record of		that all the steps
procedures should be		each complaint shall be		required by the
verified during self-		maintained in a file		defined
inspection		designated for drug		procedures and
inspection.		product complaints. The		instructions
Quality reviews may be		file regarding such drug		were in fact
grouped by product type,		product complaints shall		taken and that
e.g. solid dosage forms,		be maintained at the		the quantity and
liquid dosage forms, or		establishment where the		quality of the
sterile products, where		drug product involved		product were as
scientifically justified.		was manufactured,		avposted Any
Where the marketing		processed, or packed, or		significant
authorization holder is not		such file may be		deviations
the manufacturer, there		maintained at another		fully recorded
should be a technical		facility if the written		runy recorded
agreement in place between		records in such files are		and
the various parties that		readily available for		investigated;
defines their respective		inspection at that other		vii. records of
responsibilities in producing		facility. Written records		manufacture
the quality review. The		involving a drug product		including
authorized person		shall be maintained until		distribution
responsible for final batch		at least 1 year after the		which enable
certification. together with		expiration date of the drug		the complete
the marketing authorization		product, or 1 year after		history of a
holder, should ensure that		the date that the complaint		batch to be
the quality review is		was received, whichever		traced, are
performed in a timely		is longer. In the case of		retained in a
manner and is accurate		certain OTC drug		comprehensible
		products lacking		and accessible
		expiration dating because		form:
		they meet the criteria for		,
		exemption under		viii. the
		8211 137 such written		distribution
		records shall be		(wholesaling)
		maintained for 2 years		of the products
		after distribution of the		minimizes any
		drug product		risk to their
		(1) The written record		quality;
		(1) The written record		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		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
		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.		

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.		

HUMAN

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			
		Specifical under			
		Section 1			
		requirements of			
		building and			
		facilities and			
		section 2			
		warehousing			
		area of			
		Schedule M			
		Belledule M			
Responsibilities – Self-	Specified	Not specified	Not specified in this section.	Specified	Specified
inspection		under	I	I	
mopoulon		Responsibilities			
		of OA			
		oi QA,			
		however, this is			
		specified under			
		Section 15 of			
		Schedule M			
Responsibilities – deviation	Specified	Not specified	Specified	Specified	Specified
handling		under			
		Responsibilities			
Change control handling		of QA,			
		however, this is	V TY		
Market complaint handling		specified under	La Co		
Product recells		Section 28 of			
1 Ioduct recails		Schedule M for	AN		
		complaint			
		complaint			
		handling 125			
		handling, 12.5			
		handling, 12.5 for change			
		handling, 12.5 for change management,			
		handling, 12.5 for change management, 27 for product			
		handling, 12.5 for change management, 27 for product recalls			
		handling, 12.5 for change management, 27 for product recalls			
Quality risk management	Specified	handling, 12.5 for change management, 27 for product recalls Not specified	Not specified under Quality	Not specified	Not
Quality risk management	Specified	handling, 12.5 for change management, 27 for product recalls Not specified	Not specified under Quality control Unit, however, cross	Not specified	Not specified
Quality risk management	Specified	handling, 12.5 for change management, 27 for product recalls Not specified	Not specified under Quality control Unit, however, cross reference is given to ICH Q9	Not specified	Not specified
Quality risk management	Specified	handling, 12.5 for change management, 27 for product recalls Not specified	Not specified under Quality control Unit, however, cross reference is given to ICH Q9	Not specified	Not
Quality risk management Annual Product Quality	Specified	handling, 12.5 for change management, 27 for product recalls Not specified	Not specified under Quality control Unit, however, cross reference is given to ICH Q9 Specified	Not specified	Not specified Specified
Quality risk management Annual Product Quality Review	Specified	handling, 12.5 for change management, 27 for product recalls Not specified Not specified	Not specified under Quality control Unit, however, cross reference is given to ICH Q9 Specified	Not specified Specified	Not 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;

(1) 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.

