12 September, 2013

Dr Sabine Kopp
Manager, Medicines Quality Assurance Programme
Quality Assurance and Safety: Medicines
World Health Organization
1211 Geneva 27
Switzerland

Subject: Submission of comments for WHO Working Document QAS/13.517/Rev.1, Proposed Updated Text for Who Good Manufacturing Practices for Pharmaceutical Products: Main Principles

Dear Dr. Kopp,

ISPE welcomes the opportunity to comment on the text referenced above. ISPE supports the proposed changes to the document and proposes the specific comments listed in the accompanying form.

The International Society for Pharmaceutical Engineering (ISPE) is an individual membership Society of more than 20,000 professionals involved in the manufacture of pharmaceuticals and related products. All scientific and technical areas of the pharmaceutical manufacturing industry are represented among the ISPE Membership. ISPE is committed to creating a forum for uniting the world's pharmaceutical manufacturing community and regulators.

Thank you again for the opportunity to provide feedback on this draft text. Please feel free to contact me if you have any questions.

Yours sincerely,

President/CEO, ISPE

cc: Ms. Marie Gaspard

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Comments on WHO Working Document QAS/13.517/Rev.1
Title of the document: Proposed Updated Text for Who Good Manufacturing Practices for Pharmaceutical Products: Main Principles

Comments submitted by : ISPE – International Society for Pharmaceutical Engineering
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Template for comments

*Kindly complete the table **without modifying the format** of the document - thank you.*

General comment(s) if any :	**Originator of the comments**
ISPE supports the proposed changes to the document and would make the following specific comments:	

# section	**Line no.**	**Comment / Rationale**	**Proposed change / suggested text**	**Classification** **L**= low **M**= medium **H**= high	**Originator of the comments**
1.3		Manufacture of product has to take place in adequately designed facilities and equipment which has undergone a thorough qualification/verification process according to ASTM E2500 or similar.	(a) product realization is achieved by designing, planning, implementing, **qualifying**, maintaining and continuously improving a system that allows the consistent delivery of products with appropriate quality attributes;	M	
1.3		With a risk assessment the critical process parameters and critical process attributes need to be determined and those parameters are the minimum to be monitored.	(m) product and processes **(critical process parameters and critical process attributes)** are monitored and the results taken into account in batch release…	M	
1.10		The review should include not only in-process controls and results but also review of critical process parameters and critical process attributes.	(ii) a review of critical in-process controls, **critical process parameters and critical process attributes** and finished product results	M	

# section	Line no.	Comment / Rationale	Proposed change / suggested text	Classification **L**= low **M**= medium **H**= high	Originator of the comments
2.1 (a)		Add:**for associated risks in the light of scientific knowledge and experience**	Under GMP: (a) all manufacturing processes are clearly defined, systematically reviewed **for associated risks in the light of scientific knowledge and experience**, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications;	H	
17.3 (a)		Add: **,and Other Media e.g Purified Water , Water For injection, Pure Steam etc.**	(a) adequate facilities, trained personnel and approved procedures must be available for sampling, inspecting, and testing starting materials, packaging materials, and intermediate, bulk and finished products **and any other media e.g purified water , water for injection, pure steam etc. having direct impact on the product quality** and where	H	
17.3 (b)		Add: ,**Other Critical Media**	samples of starting materials, **other critical media,** packaging materials, intermediate products, bulk products and finished products must be taken by methods and personnel approved of by the QC department;	H	
17.4		Add: **Participating in Quality Risk Management (QRM)**	**(g) Participation in Quality Risk Management (QRM) Programs**	H	
		Please add rows as necessary (with "copy and paste" empty rows)			