TABLE FOR COMMENTS

COMMENTS ON WHO WORKING DOCUMENT: QAS/20.869/Rev1

TITLE OF THE DOCUMENT: WHO GUIDELINES ON THE TRANSFER OF TECHNOLOGY IN PHARMACEUTICAL MANUFACTURING

Name:	**International Society for Pharmaceutical Engineering (ISPE)**
Employer (company/lab/etc.)**:**	n/a
Position Title:	n/a
City, Country:	**North Bethesda, USA**

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

General comment(s) if any :	**Originator of the comments**
Some of the bulleted lists in the original (2011) guide were useful; these seem to have been reduced. It is suggested that it should be mentioned somewhere that the regulatory status of the receiving unit (RU) – depending on the nature of the TT product – should be considered. For example, an extension of his manufacturing license may be required.	**ISPE**

Section	**Line**	**Comment/rationale**	**Proposed change/suggested text**	**Classification** L= low, M= medium, H= high	**Originator of the comments** (for WHO use)
1 and 3	95, 314	The definition of "Technology Transfer" does not include the concept of "Knowledge Transfer". In this guide, technology transfer is defined as "A logical procedure that controls the transfer of any process, together with its documentation and professional expertise. Technology transfers may involve development, manufacture and/or testing sites." Knowledge is a broader term that can include procedures, methodologies, expertise, undocumented knowledge, practices, automated	Suggest adapting the definition to include the concept of knowledge, for example: "A logical procedure that controls the transfer of product and process knowledge, together with its documentation and professional expertise. Technology transfers may involve development, manufacture and/or testing sites.	M	ISPE

Section	Line	Comment/rationale	Proposed change/suggested text	Classification L= low, M= medium, H= high	Originator of the comments (for WHO use)
		system metadata, etc.).			
1.10	146	A new section 1.10 and 1.11 should be added that moves the words currently in 12.14 and 12.15 to this place). These sections seem more appropriately located in the Introduction due to their importance.	New 1.10 (Was 12.14.) Product, process and procedure knowledge should be an essential part of the transfer process from SU to RU. New 1.11 (Was 12.15.) The critical quality attributes, critical process parameters, material attributes, control strategy and any other impacting elements on the quality of the product should be available. (See also ICH guidelines.)	M	ISPE
4.5	355/6	This seems too wide ranging. The purpose of TT is about ensuring the quality & technical aspects of the product at the receiving unit are achieved adequately i.e., delivering a control strategy. Sure, business matters support this (including cost, supply chain, legal etc) but I suggest these should be out of scope for this Guideline.	The assessment to determine feasibility for technology transfer should concentrate on ensuring technical and quality aspects are achieved, for example to enable an effective, practical control strategy to be put in place at the receiving unit.	M	
5.11	397	Suggest adding 'product/process knowledge and'	Consideration should be given to the technical expertise, site technology and site capabilities for the RU. Any product/process knowledge and robustness issues should be identified upfront by the SU so that plans may be put in place at the RU. .	L	
6.5	445	Suggest adding some wording to ensure the risk process is output focussed i.e., ensuring appropriate risks have been considered to enable successful outcome at the RU	6.5. Quality risk management should be implemented as a systematic process for the assessment, control, communication and review of risks. The risk process should concentrate ensuring a successful outcome at the RU		

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5.12	401	The SU should also confirm that appropriate RU personnel are identified to receive the knowledge to be transferred.	Suggest expanding the sentence to include qualified or appropriate personnel as part of the "degree of preparedness of the RU before transfer".	M	
5.13	407	This sentence should not be limited to IQ/OQ of equipment. Should include all qualification scope as identified in a GAP assessment. This includes IQ, OQ, analytical equipment, Cleaning Validation information for transferred product, product transport qualification, etc.	The paragraph should either be expanded to include other IQ/OQ activities or simplified to say something like: "The SU and the RU should jointly verify that appropriate facilities, production and analytical equipment, computing equipment have completed IQ and OQ and cleaning procedures are validated.	L	
5.17	424	This section should be expanded. For some projects, it is equally or more important to also send RU personnel to the SU sites or locations to gather the knowledge needed and review how the process is executed at the SU. Additionally, experience from TTs of vaccine processing during the Covid pandemic indicate that virtual/remote interaction has proved successful	Expand the sentence to establish that SU and RU sites should plan for sending personnel to each other to gather all the critical tech transfer information and knowledge, or that use of modern virtual interactive technology should be considered.	M	
6	431	This section is missing the mention of Change Management during the technology transfer. Change management should track all changes to process, methods, and systems for future reference and to determine if additional studies are needed to justify and approve process	Please add reference to Change Management in Section 6.	H	

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		adaptations.			
12.2	595	It is suggested Sections 12.2. and 12.3 should be combined and the wording simplified. Section 12.3 should be deleted – level of "interest" is part of the rationale. The highlighted sentence is considered a useful addition.	12.2. During the initiation phase of the project, a unit should normally identify the ~~need~~ rationale for the technology transfer. ~~This may be because of lack of capacity, transfer from development to commercial site or transfer from one company to another~~. The success criteria for the transfer project should be agreed at this time.	M	
12.10	621	See proposed additions highlighted in yellow, particularly regarding control strategy, "Raw materials" is not defined in the Glossary and perhaps should be. Suggest deleting "in QC". Analytical procedures could be applied on line and/or in production as well as in QC.	12.10. The team should develop a control strategy (see definition in this document) which includes, for example: • Risks to the control strategy (e.g. arising from analysis & understanding of product and processes at both SU & RU) • raw, starting and packaging material attributes; • analytical procedures ~~in QC~~; • critical quality attributes (CQAs), critical process parameters (CPPs), and in-process controls; and • acceptance criteria and limits	H	
12.14 & 12. 15	638 - 643	12.14. Product, process and procedure knowledge, should be an essential part of the transfer process from SU to RU 12.15. The critical quality attributes, critical process	These are important paragraphs and should be moved into Section 1 (see above)	H	

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		parameters, material attributes, control strategy and any other impacting elements on the quality of the product should be available. (See also ICH guidelines.)			
12.22	693	The line "product ion (example: finished pharmaceutical product) seems to stand alone and could be waiting for an example.	Deletion or addition of text or an example should be considered	L	
12.41	814	Therapeutic doses of active ingredients are no longer used to set cleaning limits, and therefore should not be included in this section. Refer to reference [14] for cleaning limits.	Eliminate the reference bullet of "minimum therapeutic doses of active ingredients". Consideration should be given to including reference to Health Based Exposure Limits and/or Permitted daily exposure	H	
12.45	838	The progress and success of the transfer of technology should be monitored and reviewed during and after completion of the project. It is recommended that the highlighted phrase is added as an important addition.	The progress and success of the transfer of technology should be monitored and reviewed during and after completion of the Project, and compared to success factors set out at the commencement of the transfer project	M	
12.49	853	It is suggested the sentence is simplified. It is assumed that the intent is that an authorised person (or persons) signs the report	The report, which should include an assessment of the data and information and a conclusion, should be authorized by the appropriate responsible person (s) ~~responsible in doing so~~.	L	
		Please add rows as necessary			