EU GUIDELINES FOR GOOD MANUFACTURING PRACTICE
FOR MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE
ANNEX 15: QUALIFICATION AND VALIDATION

Comments from GE Healthcare Life Sciences – May 2014

No.	Ref	Comment
1	1.3 Validation personnel	*"Validation personnel should report as defined in the pharmaceutical quality system although this may not necessarily be to a quality management or a quality assurance function, however there should be appropriate oversight over the whole validation life cycle"* Comment: As the QA function should make an independent judgment on the validations performed, this may be hindered if the Validation personnel reports into QA (example QA may accept a lower than acceptable report due to resource issues)
2	2.5 Third Party protocols	*"Where validation protocols are supplied by a third party, the manufacturer should confirm suitability and compliance with company procedures before approval."* Comment: This implies that the Supplier is working to the Customer's procedures. Suggested wording: "Where validation protocols are supplied by a third party, the manufacturer should confirm suitability and compliance with *the documentation requirements* before approval."
3	4.14 Concurrent validation	*"In exceptional circumstances where there is a strong risk – benefit to the patient,.."* Comment: This falsely implies that the patient is being treated on a Risk versus Benefit basis, (i.e. we can do something risky to the patient, if there may be a chance of a good outcome). Suggested wording: "In exceptional circumstances where there is strong evidence of a potential benefit to the patient, ……."
4	4.20 b) and c)	CQA's should be CQAs CPP's should be CPPs
5	4.20 e) and f)	*" ... monitoring/recording equipment) together with the calibration status."* Should be part of the previous sentence, ie. items e) and f) are one
6	5.2 Validation of transportation	*"It is recognised that validation of transportation may be challenging due to the variable factors involved however transportation routes should be clearly defined. For transport across continents seasonal variations should also be considered."* Comment 1: To include seasonal variations may make the transport validation a very lengthy process if it would be required to determine the influence of the seasons on the transport Comment 2: It seems odd that the transport "across continents" would only be influenced by the seasonal variation. All transport is influenced by the seasons
7	6.1 Variation in equipment processing parameters	*"Variation in equipment processing parameters during primary packaging may have a significant impact of the integrity and correct functioning of the pack (e.g. blister strips, sachets and sterile components) therefore primary packaging processes should undergo validation."* Comment: This should be part of the process validation as the packaging in the primary container is part of the overall production process that leads to the final drug product