Comments on the revised Guidelines on Good Distribution Practice of Medicinal Products for Human Use

Chapter	Sub section	Query
Chap. 1 Quality Management	Principle: (i) Wholesale distributors must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities (ii) The quality system should incorporate quality risk management principles. – ALSO referenced in Quality System (Sec. 1.7 and 1.8)	Any specific guidance to be referenced for risk management techniques / principles other than inter alia in the EU Guidelines to Good Manufacturing Practice?
Chap. 5 Operations	Qualification of Suppliers, sec. 5.4 states that 'the supply chain of medicinal products should be known and documented'.	How is it possible to know where the supplier purchased the medicinal products prior to procurement by ourselves?
	Qualification of Customers, sec. 5.9 states that 'Checks and periodic re-checks may include (but are not limited to): requesting copies of customer's authorisations according to national law, verifying status on an authority website'	Is there a list or link to how one could search or indeed find authority websites other than the IMB?
	Delivery , sec. 5.32 states that 'Records should be kept so that the actual physical journey undertaken by the product can be tracked'	Does this mean temperature records??
Chap. 7 Contract Operations	Contract Giver, Sec. 7.2 states that 'An audit of the Contract Acceptor should be performed before the beginning of the outsourced activities and afterwards audits should be done periodically'.	Could you carry out an audit of a transportation provider and / or Pest Control company remotely? What is the desired frequency of re audit?
Chap. 8 Self Inspections	Self – Inspections, sec. 8.1 states that 'A self-inspection programme should be implemented to cover all aspects of GDP'	'All aspects'..does this mean each chapter of EU GDP(e.g.) is it acceptable to self inspect all chapters over a 2 year period??
Chap. 9 Transportation	Temperature Control during Transport, Sec. 0.19 states 'Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) should be used to ensure correct transport conditions are maintained between the distributor and customer'	Does this mean that Containers used to transport 'temperature controlled' (i.e) 8 to 30 deg C, medicinal product need to be validated?