EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07-Oct-11

Submission of comments on '**Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use**>' (EMA/…/…)

Comments from:

Jennifer Benner, Executive Director of Quality Assurance, PACE Bio Solutions

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

2. Specific comments on text

Line number(s) of the relevant text ***(e.g. Lines 20-23)***	**Stakeholder number** ***(To be completed by the Agency)***	**Comment and rationale; proposed changes** ***(If changes to the wording are suggested, they should be highlighted using 'track changes')***	**Outcome** ***(To be completed by the Agency)***
Section 2.3 regarding "Responsible Person"		Comment: It is not feasible that logistics companies would have a pharmacist on staff to act as the "Responsible Person", especially since their interaction with the product is limited in scope and time and the logistics company would not make any decisions regarding which lots would be sent to the final destination. Proposed change (if any): Requirements for "Responsible Person" at logistics companies who transport and hold the product on a temporary basis should be a member of quality assurance or the local terminal manager with no requirements to be a registered pharmacist.	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.