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European Medicines Agency (EMEA)
Inspections Sector
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European Commission
Pharmaceuticals Unit
Brussels
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Ref: Concept Paper on the Implementation of ICH Q10;
doc EMEA/INS/GMP/34212/2009; 11 March 2009
Deadline for comments: 30 June 2009

To: Responsible Person: European Commission, Pharm. Unit
Responsible Person: EMEA Inspections Sector

PDA is pleased to provide comments on the concept paper for implementation of ICH Q10 in the EU GMP guide. As ICH Q10 is not a standalone document, special focus should be given to enabling principles of Quality Risk Management (see ICH Q9) and Knowledge Management. For this reason we recommend the following changes in Section 4 of the concept paper (added text in *italics*):

Section 4. Recommendation:

2) Clearer guidance on the handling and investigations of deviations, Corrective and Preventive action and change control *taking into account the principles of quality risk management and knowledge management.*

3) Emphasising the role of senior management in ensuring that there is an effective Quality Management System *that is knowledge-based and enables risk-based decision making* to support GMP**.**

Thank you for the opportunity to support appropriate and useful guidance. Please contact me, or James Lyda of my staff (lyda@pda.org), if you have any questions.

With very best regards,

Georg Roessling, Ph.D.
Senior VP, PDA Europe
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cc: S. Rönninger, S. Mendvil, J. Lyda, R. Levy, R. Dana,