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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,

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cc: S. Rönninger, S. Mendvil, J. Lyda, R. Levy, R. Dana,