PDA
Parenteral Drug Association

Connecting People, Science and Regulation®

Bethesda Towers
4350 East West Highway, Ste. 600
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin
Germany

15 May 2018

European Medicines Agency,
30 Churchill Place
Canary Wharf, London E14 5EU, United Kingdom
ADM-GMDP@ema.europa.eu

Reference: EU Template for GMP Non-Compliance Statement

Dear Sir/Madam:

PDA appreciates the opportunity to respond to this draft template and has the following suggested modification.

On page 4 of the document, PDA recommends modifying item number 3 as follows:
A thorough ~~risk-benefit evaluation~~ risk assessment has been performed for the control and/or acceptance of risk and a report prepared that takes full account of the nature of the non-compliance…

PDA believes that a risk-benefit analysis is not the appropriate evaluation for a MAH to perform; this is more within the NCAs scope as they would determine what the optimal balance between risks and benefits is after taking into account the product criticality and the risk control measures proposed by the MAH for their GMP non-compliance gaps.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. PDA has a public ID number in the EU Transparency Register of 894106921549-04. Our comments are based on a member survey and prepared by a committee of experts in regulatory affairs including members of the PDA Board of Directors and the Regulatory Affairs and Quality Advisory Board.

If there are any questions, please do not hesitate to contact me via email at klar@pda.org .

Sincerely,

Falk Klar
General Manager, PDA Europe

Cc: Richard Johnson, PDA, Denyse Baker, PDA