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From: Valencia, Iliana
Sent: Tuesday, April 25, 2017 12:43 AM
To: Wolfgang Pieken (WPieken@oxfordimmunotec.com)
Subject: STN 125588 NAT and 125589 AFIA: FDA follow up comments to the teleconference held on Thursday, April 20, 2017, regarding software

On behalf of Dr. Lisa Simone

Dear Dr. Pieken,

I am following up on information we discussed during our call on Thursday. I mentioned free training related to risk management. FDA's DICE (Division of Industry and Consumer Information) is hosting a free conference in Atlanta this May 9th and 10th that will also be broadcasted live online. Several topic sessions might be of interest, including "Risk in the Quality System Regulation" where Joseph Tartal will discuss specific analysis tools and also touch on risk management and ANSI/AAMI/ISO 14971. The agenda can be found at: https://events-na12.adobeconnect.com/content/connect/c1/1315899612/en/events/event/shared/1665587312/speaker_info.html?sco-id=1665597997

In addition, we encourage you to continue your alignment goals with ISO 14971. Note that your processes do not need to align exactly with the standard; we have only brought to your attention instances where your processes appear to be in conflict with the standard, and where you may not be leveraging the full benefit of the standard.

If you have questions, please feel free to reach out.

Sincerely,

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