



Connecting People, Science and Regulation®

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9 March 2017

Mr. Yi Cao

Mr. Yan Zhou

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RE: CFDA Drug Data Management Guidance Draft for Comments

Dear Sirs:

PDA recognizes that data integrity and data management are critical issues in the pharmaceutical industry today necessitating action from both manufacturers and regulators. PDA applauds the CFDA for publishing this draft guidance in order to standardize the management of data generated in drug lifecycles and to ensure drug product quality and patient safety and appreciates the opportunity to provide comments.

PDA fully supports the principle that data management should be implemented throughout the whole data lifecycle under the principles of attributable, legible, contemporaneous, original and accurate [ALCOA], so as to ensure data integrity and commends CFDA for taking this approach in alignment with other global health authorities.

PDA welcomes any opportunity to partner with CFDA to meet your goals in the area of Data Integrity. In the past PDA has offered a series of workshops and training. PDA will continue to play an active role through 2017 in developing solutions to address and improve Data Integrity concerns for both industry and health authorities. This includes an *Elements of a Code of Conduct for Data Integrity in the Pharmaceutical Industry*, available for free download from the PDA website. www.pda.org/codeofconduct PDA is also developing technical reports on Data Integrity and we would welcome CFDA review of the draft documents.

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. Our response was prepared by the PDA Data Integrity Task Force, on behalf of the Regulatory and Quality Advisory Board and Board of Directors.

If there are any questions, please do not hesitate to contact me. (Johnson@pda.org)





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Sincerely,

A handwritten signature in black ink that reads "Richard M. Johnson". The signature is written in a cursive style with a large, prominent "R" and "J".

Richard Johnson
President and CEO, PDA

CC: Rich Levy, PDA; Denyse Baker, PDA