



December 18, 2018

From: Pharma & Biopharma Outsourcing Association  
10 Alta Vista Dr.  
Ringwood, NJ 07456  
Tel: 201-788-7994

To: Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Comments from Pharma & Biopharma Outsourcing Association (PBOA) on Docket No. FDA-2018-D-3984 for “Data Integrity and Compliance with Drug cGMP Questions and Answers Guidance for Industry”.**

Dear Sir or Madam,

On behalf of the Pharma & Biopharma Outsourcing Association (“PBOA”), a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations (“CDMOs”), I am pleased to offer feedback on the recent draft guidance, “Data Integrity and Compliance with Drug cGMP Questions and Answers Guidance for Industry”. Our Quality Technical Group, composed of quality and operation leads from more than a dozen of our member companies, has discussed this draft guidance and completely supports FDA in this guidance. We feel this document very clearly outlines the requirements according to 21 CFR parts 210, 211, and 212.

PBOA appreciates the opportunity to review and provide comments pertaining to the draft guidance. We look forward to working with FDA on its continued efforts to ensure public access to high quality pharmaceutical products.

Thank you for considering our views.

Respectfully,

Chris Verbicky, Ph.D., M.B.A.  
Director, Scientific and Regulatory Affairs  
PBOA



## **PBOA Member Companies**

3M Drug Delivery Systems  
Ajinomoto Bio•Pharma Services  
Alcami  
Avid Bioservices  
Avista Pharma Solutions  
Afton Scientific  
Baxter BioPharma Solutions  
Cambrex  
Catalent Pharma Solutions  
CMIC CMO USA, Inc.  
Coating Place, Inc.  
CPC - Contract Pharmacal Corp.  
DPT, a Mylan Co.  
Grand River Aseptic Manufacturing  
Groupe PARIMA  
iBio Inc.  
IDT Biologika  
Jubilant HollisterStier  
Lyophilization Services of New England (LSNE)  
Metrics Contract Services  
Mission Pharmacal/ProSolus Pharma  
Particle Sciences, a Lubrizol Co.  
Patheon Inc., part of Thermo Fisher Scientific  
PCI Pharma Services  
Pfizer CentreOne  
Piramal Pharma Solutions  
Pharma Packaging Solutions  
Renaissance Lakewood  
Tapemark Inc.  
TEDOR Pharma  
Therapure Biomanufacturing