

PDA Global Headquarters

Bethesda Towers,
Suite 600
4350 East West Highway
Bethesda, MD 20814 USA
TEL: +1 (301) 656-5900
FAX: +1 (301) 986-0296

PDA Europe gGmbH

Am Borsigturm 60
13507 Berlin
Germany

OFFICERS*Chair*

Rebecca Devine, PhD
Regulatory Consultant

Chair-Elect

Jette Christensen
Novo Nordisk A/S

Secretary

Steven Lynn
Consultant

Treasurer

Michael Sadowski
Baxter Healthcare

Immediate Past Chair

Martin VanTrieste

President & CEO

Richard M. Johnson

DIRECTORS**Masahiro Akimoto**

Otsuka Pharmaceutical
Factory, Inc.

Barbara Allen, PhD

Eli Lilly and Company

Michael Blackton, MBA

Adaptimmune, LLC

Joyce Bloomfield**Bettine Boltres, PhD**

West Pharmaceutical
Services

Véronique Davoust

Pfizer, Inc.

Ghada Haddad

Merck & Co./Merck
Sharp & Dohme

Stephan O. Krause, PhD

AstraZeneca Diagnostics

Mary Oates, PhD

Lachman Consultant
Services, Inc.

Emma Ramnarine

Roche Pharma

Anil Sawant, PhD

Merck & Co./Merck
Sharp & Dohme

Melissa Seymour

Biogen

October 10, 2019

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Submission of Quality Metrics Data; Revised Draft Guidance for Industry (Docket No. FDA-2015-D-2537)

Dear Madam or Sir:

PDA appreciates the involvement FDA has had with industry stakeholders on the development of the agency's quality metrics reporting program over the last five years. PDA would like to provide five key additional comments on FDA's quality metrics reporting program considering our learning on quality culture and our work with the University of St. Gallen.

1. PDA reiterates our comments of March 27, 2017, regarding the revised draft guidance on metrics and supports the piloting of the key performance indicators (KPIs) lot acceptance rate (LAR), invalidated out of specification (OOS) results, and complaints, with modification as suggested in that letter. As we noted in that letter, PDA feels strongly that metric trending is more valuable than direct metric comparison between sites. Tracking and reporting trends would eliminate many of the issues with different interpretations of metric definitions and other factors. The University of St. Gallen's FDA Quality Metrics Research: 2nd Year Report showed LAR as a meaningful indicator for external inspection outcome and Invalidated OOS inversely correlated with Quality Control Lab Robustness high performers.¹
2. PDA believes that evaluating quality culture is as important as KPI metrics in measuring quality risk and agrees with the St. Gallen 2nd Year Report that, "In particular, the importance of cultural excellence should not be underestimated and is best considered together with any KPI-led performance assessment" and "The foundation of the [Pharmaceutical Production System Model] house is Cultural Excellence which combines employee engagement, quality behavior and quality maturity of a company."²
3. St. Gallen's Enablers replicated the correlation of mature quality attributes with positive quality behaviors that PDA's 2014 Survey demonstrated,³ reinforcing the ability to quantify and benchmark aspects of quality culture. Based on this data driven research, PDA developed a Quality Culture Assessment Tool that incorporates principles from ICH Q10, Q8, Q9, and Q11. Biopharmaceutical firms can use the tool to assess maturity of the mature quality attributes and use the tool as a roadmap for continuous improvement.
4. PDA believes that a quality culture assessment of key specific mature quality attributes related to the pharmaceutical quality system (PQS) is important to complement a specific KPI-led metric program. PDA therefore suggests that FDA include in the metrics program some type of question on quality culture, such as whether a site performs a quality culture

¹ University of St. Gallen, FDA Quality Metrics Research: 2nd Year Report, Nov. 2018, 23 and 9.

² *Id.* at 49 and 18 (internal references omitted).

³ Patel *et al.*, Quality Culture Survey Report, PDA Journal of Pharm. Sci. & Tech., 2015, 631-642.



assessment utilizing a quantitative tool and/or conducts benchmarking to drive continuous improvement of the site's quality culture.

5. PDA believes that assessing attributes such as the St. Gallen Cultural Excellence measures or the PDA Mature Quality Attributes is fundamental to PQS effectiveness, leading to lower quality risk, and that these attributes are better suited to assess site quality risk than KPI metrics alone.

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 comments have been prepared by a committee of experts in pharmaceutical manufacturing and quality on behalf of our Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions or would like to discuss further, please do not hesitate to contact me.

Sincerely,

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

Richard M. Johnson
President & CEO
PDA

Cc: Tina Morris, PDA; Ruth Miller, PDA; Tara Goen Bizjak, FDA