# Form FDA 483 Response Best Practices Announced by the FDA

In Draft Guidance published this week by the U.S. Food and Drug Administration (FDA), **Guidance for Industry – Processes and Practices Applicable to Bioresearch Monitoring Inspections**, the Agency provides some wisdom on best practices for responding to Form FDA 483s, albeit in the context of its Bioresearch Monitoring (BIMO) program inspections, but very much translatable to *any* Form FDA 483 response. FDA notes the following best practices:

> A response should demonstrate the establishment's acknowledgment and understanding of FDA's observations. It should also demonstrate the establishment's commitment to address the observations, including a commitment from senior leadership.
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> Responses should be well-organized and structured to:
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> - Address each observation separately
> - Note whether the establishment agree(s) or disagree(s), and why
> - Provide both corrective and preventive actions and timelines for completion
> - Provide both completed and planned actions and related timelines
> - Provide a method of verifying or monitoring the effectiveness of the actions
> - Submit documentation (e.g., training, Standard Operating Procedures (SOPs), corrective action plans, records, etc.)

Importantly, FDA also states that timely Form FDA 483 responses that include "appropriate corrective and preventive actions could impact FDA's determination of the need for subsequent Agency action." FDA encourages responses within 15 business days after the end of an inspection and, helpfully, notes that any responses received within that window "will be considered before further Agency action or decision." Interested stakeholders may submit comments **here** on FDA's Draft Guidance until August 5, 2024.

*Please contact **Julie Tibbets** or any member of our **Life Sciences Regulatory & Compliance practice** with questions on FDA's Draft Guidance or on responding to Form FDA 483s.*