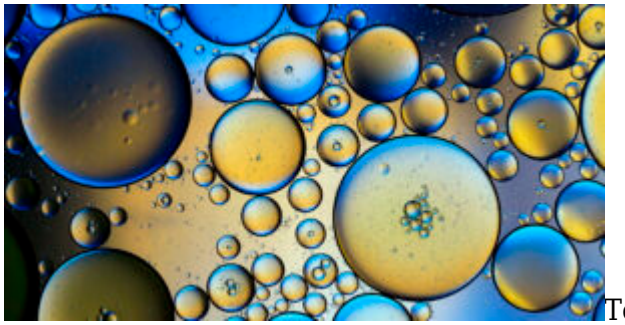
A Look Ahead in Life Sciences: What We Are Tracking in the Second Quarter of 2025 and Beyond

 To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q2 2025 updates **here**.

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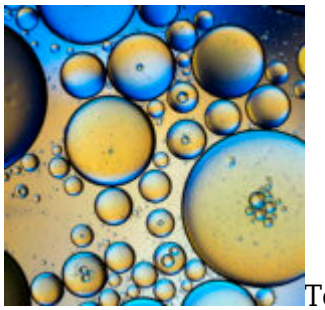
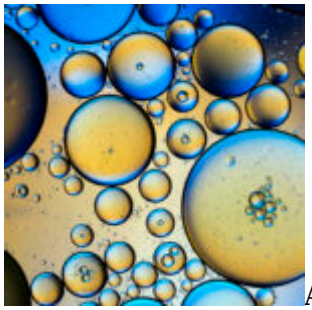
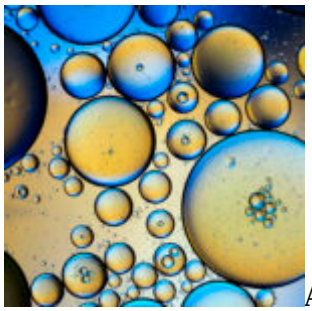
 To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q1 2025 updates **here**.

A Look Ahead in Life Sciences: What We Are Tracking in the Fourth Quarter of 2024 and

Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q4 2024 updates **here**.

A Look Ahead in Life Sciences: What We Are Tracking in the Third Quarter of 2024 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q3 2024 updates **here**.

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:

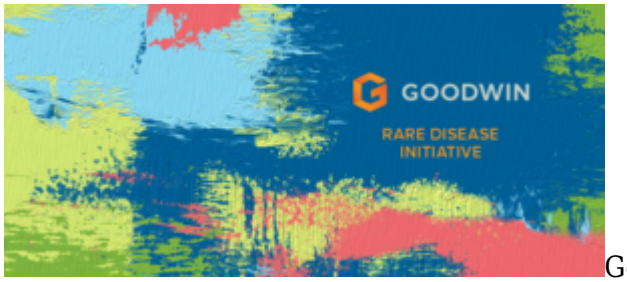
> A response should demonstrate the establishment's acknowledgment and understanding of FDA's observations. It should also demonstrate the establishment's commitment to address the observations, including a commitment from senior leadership.
>
> Responses should be well-organized and structured to:
>
> - 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.*

Recap: Goodwin Rare Disease Symposium

2024



Goodwin's **Rare Disease Initiative** hosted its Annual Rare Disease Symposium in Boston on March 13, 2024. Participants were invited to join for an afternoon of engaging and inspirational conversations led by **Julie Tibbets**, **Matt Wetzel**, and **Danielle Lauzon**, in addition to networking with peers in the rare disease community. The program included speakers covering the patient, advocacy, policy, research, and CEO perspectives.

For more event highlights and key takeaways from our speakers, please visit the **Goodwin Rare Disease Symposium 2024** page.

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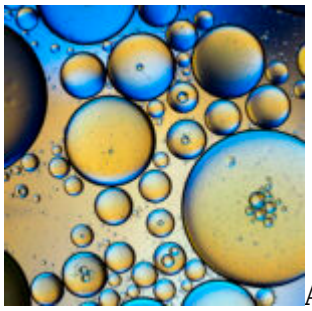
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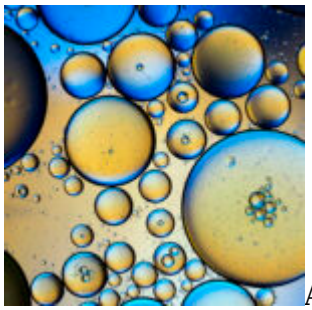
Goodwin's Annual Rare Disease Symposium

Goodwin's Life Sciences team will be hosting an upcoming event in our Boston office on March 13, 2024 to spotlight the critical work being done to address the 7,000+ rare diseases that impact more than 300 million people globally.

Join us **in person** in our Boston office or attend **virtually** for our Annual Rare Disease Symposium on March 13, 2024. Look forward to an afternoon of engaging fireside chats, inspirational presentations, and networking with your peers in the rare disease community. This year's program will include speakers covering the patient, advocacy, policy, research, and CEO's perspectives.

A Look Ahead in Life Sciences: What We Are Tracking in Q1 2024 and Beyond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A Look Ahead in Life Sciences: What We Are Tracking in Q4 2023 and Beyond

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