When Things Go Wrong
Agenda

10:00 a.m. – 10:15 a.m. **Introduction to the Virtual Conference / Regulations Guiding the Manufacture of cGMP Products and/or Services**

- Understanding the importance and criticality of the code of federal regulations (CFR) guiding the various products, industries and processes
- Compliance expectations, requirements and specific roles of manufacturers of products regarding compliance
- Other national and international regulations guiding the manufacture of various products and their relationship and importance

10:15 a.m. – 11:00 a.m. **Session 1**
Types and Levels of FDA's Regulatory Findings and Disciplinary Actions Relating to Various Compliance Issues

- What constitutes Form 483 findings and the sequence of events that trigger their progression into warning letters
- How the slippery slope of 483 to warning letter can lead to the issuance of a consent decree
- Understanding what an FDA's consent decree is and what triggers the initiation of a consent decree
- Detailed understanding of an FDA's Form 483 compliance issue findings
- What triggers an FDA's form 483 compliance issue findings
- What constitutes an adequate response time to an FDA's form 483 compliance issue findings
- What constitutes an effective handling and response to an FDA's form 483 compliance issue findings
- How to resolve an FDA's form 483 compliance issue findings
- What some companies are **Doing Well** in effectively addressing and resolving an FDA's form 483 compliance issue findings
- What some companies are **Not Doing So Well** in effectively addressing and resolving an FDA's form 483 compliance issue findings
- What does a recurring non-compliance of an FDA form 483 compliance issue findings mean
- Impact and next disciplinary actions if the compliance issue findings are not effectively resolved by companies
- How to effectively perform a remediation of an FDA's form 483 compliance issue findings
- Remediation activities associated with FDA's form 483 compliance issue

findings
- Preparing for future FDA visits and audits after a previous FDA's warning letter compliance issue findings

11:00 a.m. – 11:10 a.m. **Break**

11:10 a.m. – 11:55 a.m. **Session 2**
Detailed Understanding of an FDA's Form 483 Findings-Compliance Issues

Attendees will gain an understanding in the following key areas:

- What triggers an FDA's Warning Letter
- What Constitutes an Adequate response time to an FDA's Warning Letter
- What Constitutes an Effective Handling and Response to an FDA's Warning Letter
- How to Resolve an FDA's Warning Letter
- What Some Companies are **Doing Well** in Effectively Addressing and Resolving an FDA's Warning Letter
- What Some Companies are **Not Doing So Well** in Effectively Addressing and Resolving an FDA's Warning Letter
- What Does a Recurring Non-compliance of an FDA Warning Letter Compliance Issues mean
- Impact and Next Disciplinary Actions if FDA's Warning Letter Compliance Issues are not effectively resolved by Companies
- How to Effectively Remediate an FDA's Warning Letter
- Remediation Activities Associated an FDA's Warning Letter Compliance Issue
- Preparing for Future FDA Visits and Audits after a Resolution of a Previous FDA's Warning Letter FDA's Form 483 Compliance Issue

11:55 a.m. – 12:40 p.m. **Lunch**

12:40 p.m. – 1:25 p.m. **Session 3**
Effectively Handling, Resolving and Remediating an FDA Issued Consent Decree

The Attendees will gain an understanding in the following key areas:

- What triggers an FDA's Consent Decree
- Steps that leads to the issuance of an FDA's Consent Decree
- What Constitutes an Effective Handling and Response to an FDA's Consent Decree
- How to Resolve an FDA's Consent Decree Compliance issues
- What Some Companies are **Doing Well** in Effectively Addressing and Resolving an FDA's Consent Decree Compliance issues.
- What Some Companies are **Not Doing So Well** in Effectively Addressing and Resolving an FDA's Consent Decree Compliance issues

- Impact and Next Disciplinary Actions if FDA's Consent Decree Compliance issues are not effectively resolved by Companies
- How to Effectively Remediate an FDA's Consent Decree Compliance issues
    a. Remediation Activities Associated an FDA's Consent Decree Compliance issues.
    b. FDA Consent Decree and Third Party Consulting Companies
        - Role of FDA Approved Third Party
        - Role of the Company's Executives and Employees
        - Outside Consultants and Costs

- Commitments and Timelines Associated with an issued Consent Decree Agreement
    a. What is known as Commitments and understanding the Criticality of Consent Decree Commitments
    b. Timelines Associated with Consent Decree
    c. Fines Associated with Consent Decree Timelines

- Impact of a Consent Decree on a Business
    a. Costs Associated with a Consent Decree
    b. Impact to Personnel Within the Company
    c. Impact to the Company
    d. Impact to all Manufactured and New Products
    e. Possible Facility Closure
    f. Possible Business Bankruptcy
    g. Possible FDA Injunction
    h. Possible Debarment-Who may be affected
    i. Product Recall and Investigations

- Gaining back Reputation after a Consent Decree Compliance Related Issues
- Preparing for Future FDA Visits and Audits after a Previously Issued Consent Decree

1:25 p.m. – 1:35 p.m. **Break**

1:35 p.m. – 2:20 p.m. **Session 4**

Damaging Effects, Associated Impact and Preventative Measures Associated with FDA's Form 483, Warning Letter and Consent Decree Compliance Issues

Attendees will gain an understanding in the following key areas:

- Impact of a Compliance Issues on a Manufactured Product and Business
    a. Costs Associated with Compliance Issues
    b. Impact on Personnel Within the Company
    c. Impact on the Business or Company's Bottom Line

d. Impact to all New and Existing Manufactured Products
e. Possible Facility Closure
f. Possible Business Bankruptcy
g. Possible FDA Injunction
h. Possible Debarment-Who may be affected
i. Product Recall and Investigations

Case Study Category #1 (Companies with Recurring FDA's Form 483 Compliance Issues):

a. Discussion of several Case Studies relating to companies with a recurring FDA's Form
b. 483 compliance findings and triggered Warning Letter issuance
c. What was not done "Right" in addressing the compliance related issues based on the FDA's Form 483 Findings
d. Effective ways and approach to resolution that was not applied. Best practices that these companies would have applied that would have prevented the progressive discipline by the FDA into the issuance of an FDA's Warning Letter
e. Examples will be discussed and an interactive session on this case study will be applied

Case Study Category #2 (Companies with an Issued FDA's Warning Letter)

a. Discussion of several Case Studies relating to companies with an FDA's Warning Letter and what triggered the issuance of the FDA's Warning Letter
b. What was not done "Right" in addressing the compliance related issues based on the FDA's Warning Letter
c. Effective ways and approach to resolution of the Warning Letter that was not applied
d. Best practices that these companies would have applied that would have prevented the progressive discipline by the FDA into a Consent Decree
e. Examples will be discussed and an interactive session on this case study will be applied

Case Study Category #3 (Companies with an Issued Consent Decree)

a. Discussion of several Case Studies relating to companies with FDA's Consent Decree and triggered issuance of the Consent Decree
b. What was not done "Right" in addressing the compliance issues based on the FDA's Findings
c. Effective ways and approach to resolution that were not applied to prevent a Consent Decree
d. Best practices that these companies would have applied that would have prevented the progressive discipline by the FDA

e. Examples will be discussed and an interactive session on this case study will be applied

2:20 p.m. – 2:30 p.m. **Closing Comments and Adjournment**