

Dietary Supplement Current Good Manufacturing Practices (GMP) Seminar Agenda

Day One

Day Two

1. **Introduction**
R. Fish 8:00 AM – 8:15 AM
2. **FDA Authority & Enforcement, and Good Manufacturing Practices (cGMP) Overview**
M. Ullman 8:15 AM – 9:15 AM
3. **Subpart A and P: Definitions and Records**
T. Couch 9:15 AM – 9:30 AM
4. **Subpart B: Personnel**
R. Fish 9:30 AM – 10:00 AM
- Break (15 Minutes)**
5. **Subpart C: Physical Plant and Grounds**
R. Fish 10:15 AM – 11:15 AM
6. **Subpart D: Equipment and Utensils**
R. Fish 11:15 AM – 11:45 AM
7. **Documentation and Change Control**
T. Couch 11:45 AM – 12:15 PM
- Lunch (30 Minutes)**
8. **Subpart E: Specifications and Testing**
T. Couch 12:45 PM – 2:15 PM
9. **Subpart E: Representative and Reserve Samples**
T. Couch 2:15 PM – 2:30 PM
10. **Subpart G: Requirements for Components, Packaging and Labeling**
R. Fish 2:30 PM – 3:00 PM
- Break (15 Minutes)**
11. **Subpart F: Requirements for Quality Control**
T. Couch 3:15 PM – 3:45 PM
12. **Subpart J: Requirements for Laboratory Operations**
T. Couch 3:45 PM – 4:30 PM
- Work Session I** 4:30 PM – 5:00 PM

13. **Investigations, Material Reviews and OOS**
T. Couch 8:00 AM – 9:00 AM
14. **Subparts H and I: Master Manufacturing and Batch Production Records**
R. Fish 9:00 AM – 9:45 AM
15. **Subparts K and L: Requirements for Manufacturing, Packaging and Labeling**
R. Fish 9:45 AM – 10:15 AM
- Break (15 Minutes)**
16. **Own Label Distributor GMPs and Quality Agreements**
M. Ullman 10:30 AM – 11:15 AM
17. **Subparts M: Holding and Distribution**
R. Fish 11:15 AM – 11:45 AM
18. **Dietary Supplement Analytical Test Methods**
T. Couch 11:45 AM – 12:30 PM
- Lunch (30 Minutes)**
19. **Dietary Supplement Stability Programs**
T. Couch 1:00 PM – 1:45 PM
20. **Subpart N: Returns**
R. Fish 1:45 PM – 2:15 PM
21. **Subpart O: Product Complaints**
R. Fish 2:15 PM – 2:45 PM
- Work Session II** 2:45 PM – 3:15 PM
- Break (15 Minutes)**
22. **Managing FDA Inspections**
M. Ullman 3:30 PM – 4:30 PM
- GMP Exam** 4:30 PM – 5:00 PM
- Q & A / Evaluations**