Dietary Supplement Current Good Manufacturing Practices (GMP) Seminar Agenda

April 2-3, 2019

Philadelphia, PA

Day One

1. **Introduction and GMP Overview**
   T. Couch/R. Fish

2. **Introduction to FDA Authority**
   M. Ullman

3. **Subpart B: Personnel**
   R. Fish

4. **Subpart C: Physical Plant and Grounds**
   R. Fish

Break

5. **Subpart E: Specifications and Testing**
   T. Couch

6. **Subpart E: Representative and Reserve Samples**
   T. Couch

Lunch

7. **Subpart G: Requirements for Components, Packaging and Labeling**
   R. Fish

8. **Subpart D: Equipment and Utensils**
   R. Fish

9. **Subpart F: Requirements for Quality Control**
   T. Couch

10. **Documentation and Change Control**
    T. Couch

Break

11. **Quality Agreements**
    M. Ullman

12: **Investigations, Material Reviews and OOS**
T. Couch

13. **Work Session I**
    T. Couch/R. Fish

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Day Two

14. **Subparts H and I: Master Manufacturing and Batch Production Records**
    R. Fish

15. **Subparts K and L: Requirements for Manufacturing, Packaging and Labeling**
    R. Fish

16. **Subpart J: Requirements for Laboratory Operations**
    T. Couch

Break

17. **Dietary Supplement Analytical Test Methods**
    T. Couch

18. **Dietary Supplement Stability Programs**
    T. Couch

19. **Subparts M and N: Holding, Distribution, Returns**
    R. Fish

Lunch

20. **Subpart O: Product Complaints**
    R. Fish

21. **Managing FDA Inspections**
    M. Ullman

Break

22. **Work Session II**
    T. Couch/R. Fish

23. **GMP Exam / Q & A/ Evaluations**
    T. Couch /R. Fish

Additional:

- **Case Studies**
- **Warning Letters**
- **SOP Template**
- **Charts**