

Dietary Supplement GMP Training Agenda

Day	Training Topic	Presenter	Time*
1	<i>Introduction</i>		9:00 AM - 9:15 AM
	FDA Authority and Enforcement, and cGMP Overview	Marc Ullman	9:15 AM - 10:15 AM
	Subparts A & P: Definitions & Records	Tara Couch	10:15 AM - 10:30 AM
	Subpart B: Personnel	Bob Fish	10:30 AM - 11:00 AM
	<i>Break</i>		
	Subpart C: Physical Plant & Grounds	Bob Fish	11:15 AM - 12:00 PM
	Subpart D: Equipment & Utensils	Bob Fish	12:00 PM - 12:30 PM
	Documentation & Change Control	Tara Couch	12:30 PM - 1:00 PM
	<i>Work Session #1</i>		
2	Subpart E: Specifications and Testing	Tara Couch	9:00 AM - 10:30 AM
	Subpart E: Representative & Reserve Samples	Bob Fish	10:30 AM - 10:45 AM
	Subpart G: Components, Packaging & Labeling	Bob Fish	10:45 AM - 11:15 AM
	<i>Break</i>		
	Subpart F: Quality Control	Marc Ullman	11:30 AM - 12:00 PM
	Subpart J: Laboratory Operations	Tara Couch	12:00 PM - 12:45 PM
	<i>Work Session #2</i>		
3	Investigations & Material Reviews	Tara Couch	9:00 AM - 10:00 AM
	Subparts H & I: Master Manufacturing & Batch Production Records	Bob Fish	10:00 AM - 10:45 AM
	Subparts K & L: Manufacturing, Packaging, & Labeling Operations	Bob Fish	10:45 AM - 11:15 AM
	<i>Break</i>		
	Own Label Distributor cGMPs and Quality Agreements	Marc Ullman	11:30 AM - 12:15 PM
	Subpart M: Holding & Distribution Operations	Tara Couch	12:15 PM - 12:45 PM
	<i>Work Session #3</i>		
4	Dietary Supplement Test Methods	Tara Couch	9:00 AM - 9:45 AM
	Dietary Supplement Stability Programs	Tara Couch	9:45 AM - 10:45 AM
	<i>Break</i>		
	Subpart N: Returns	Bob Fish	11:00 AM - 11:30 AM
	Subpart O: Product Complaints	Bob Fish	11:30 AM - 12:00 PM
	Managing FDA Inspections	Marc Ullman	12:00 PM - 1:00 PM
	<i>Work Session #4</i>		
<i>Exam</i>			

* Times are approximate and will be adjusted as needed for Q&A. All times are for U.S. Mountain time zone.