# Food and Drug Administration Council on Pharmaceutical Quality

Janet Woodcock, Chair

Ted Sherwood, PM

Dispute Resolution Manager -Ted Sherwood

## **GMP Regulations**

Mary Malarkey, Co-Chair Fred Blumenschein, Co-Chair Vikki Kinsey, PM

# Integrated Systems Approach to CMC Review and CGMP Inspection

Chris Watts, Chair Chris Watts, PM

#### International Activities

Lois Ann Beaver, Chair Tammie Bell, PM

### **Investigational Clinical Supplies**

Joe Famulare, Co-Chair Chris Joneckis, Co-Chair , PM

## **Manufacturing Science**

Moheb Nasr, Chair Christine Moore, PM

#### Part II

Joe Famulare, Chair Diane Hanner, PM

### **Pharmaceutical Quality Standards**

Helen Winkle, Chair Chris Watts, PM

### **Process Analytical Technology**

Helen Winkle, Chair Chris Watts, PM

#### **Process Validation**

Brian Hasselbalch, Chair vacant, PM

# Quality Systems Guidance Development – Continuous Improvement

Joe Famulare, Co-Chair Robert Sausville, Co-Chair Patrick Guinn, PM

# ORA Pharmaceutical Inspectorate Quality Management Systems

Doug Ellsworth, Chair Eileen Cole, PM

## Quality Systems Implementation-Recalls and Warning Letters

Carl Draper, Co-Chair David Elder, Co-Chair Patricia Maroney-Benassi, PM

## **Risk Management**

David Horowitz, Co-Chair Deborah Autor, Co-Chair Vacant, PM